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(54) **DEPTH OF CONSCIOUSNESS MONITOR**

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(58) **Field of Classification Search**

None

See application file for complete search history.

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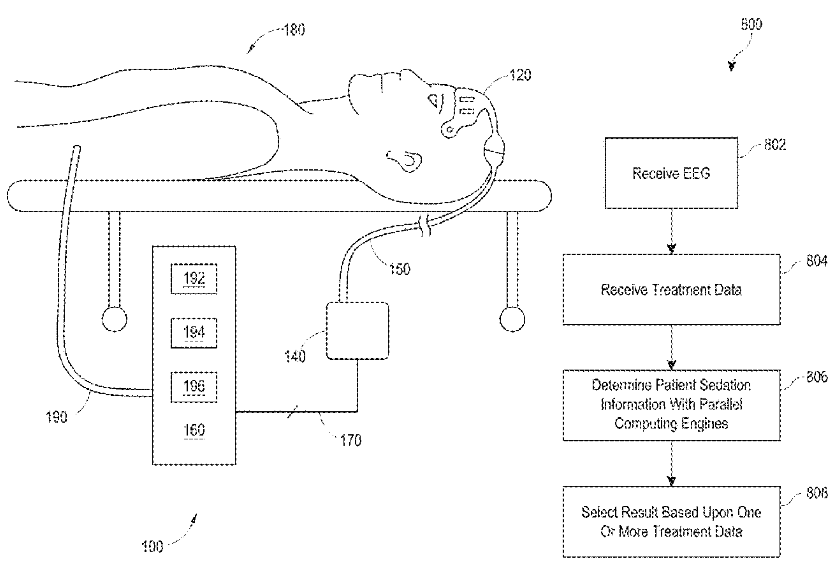
(57) **ABSTRACT**

The present disclosure relates to physiological monitoring to determine the depth of consciousness of a patient under sedation. The monitor includes an EEG sensor and a depth of consciousness monitor. The depth of consciousness monitor can utilize treatment data, such as patient data and/or drug profile information with an EEG signal to determine whether the patient is adequately sedated.

8 Claims, 15 Drawing Sheets



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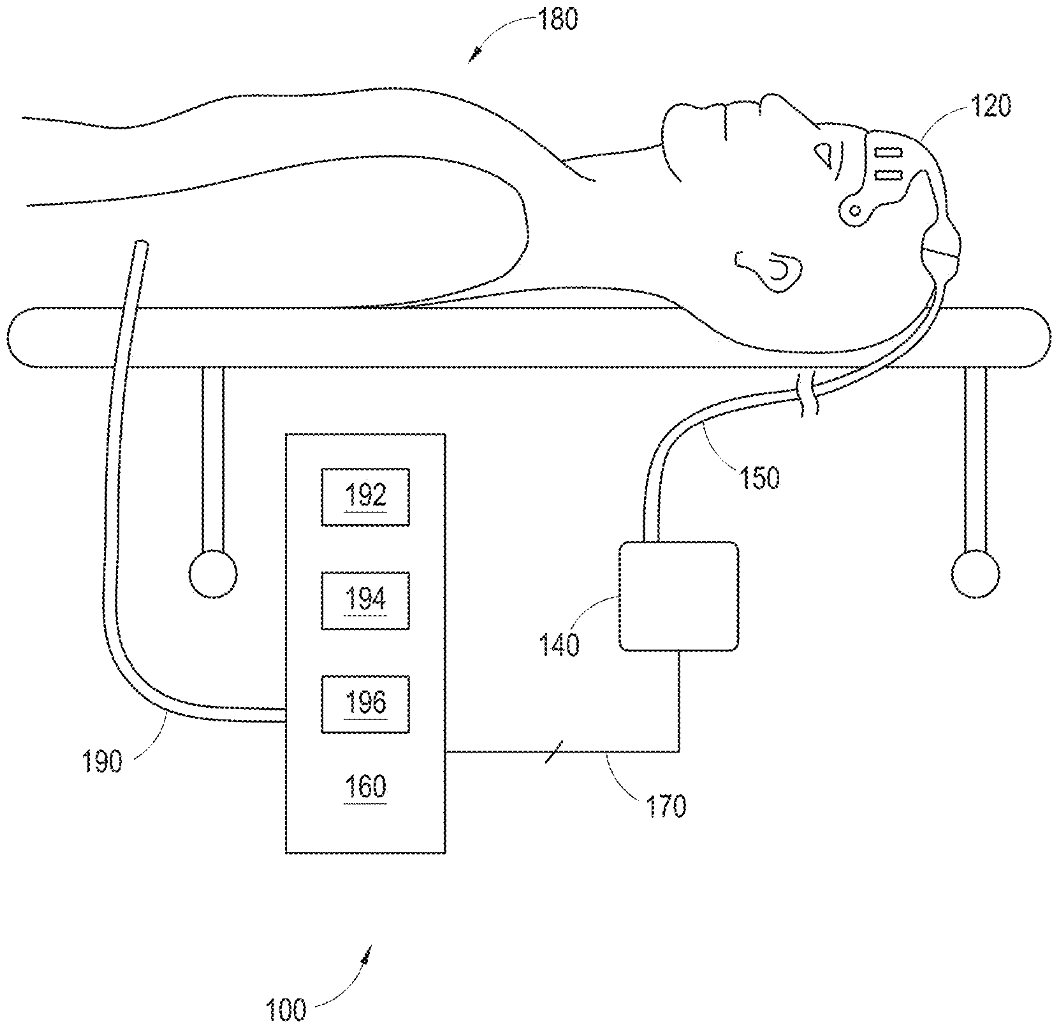

FIG. 1

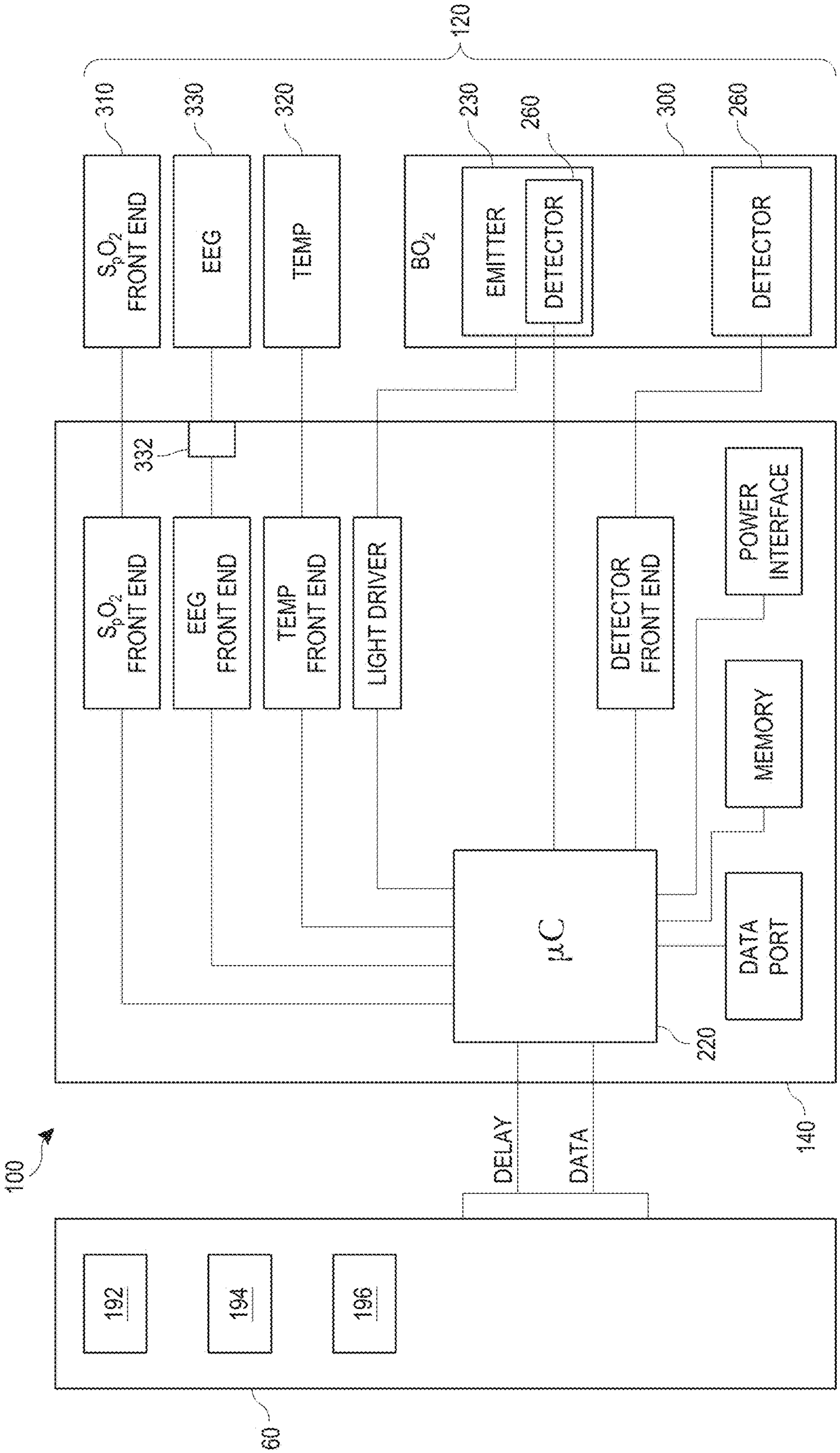
120
310
330
320
230
260
300
260
S_pO_2 FRONT END
EEG
TEMP
BO_2
EMITTER
DETECTOR
DETECTOR
332
S_pO_2 FRONT END
EEG FRONT END
TEMP FRONT END
LIGHT DRIVER
DETECTOR FRONT END
POWER INTERFACE
MEMORY
μC
DATA PORT
220
140
100
DELAY
DATA
192
194
196
160

FIG. 2

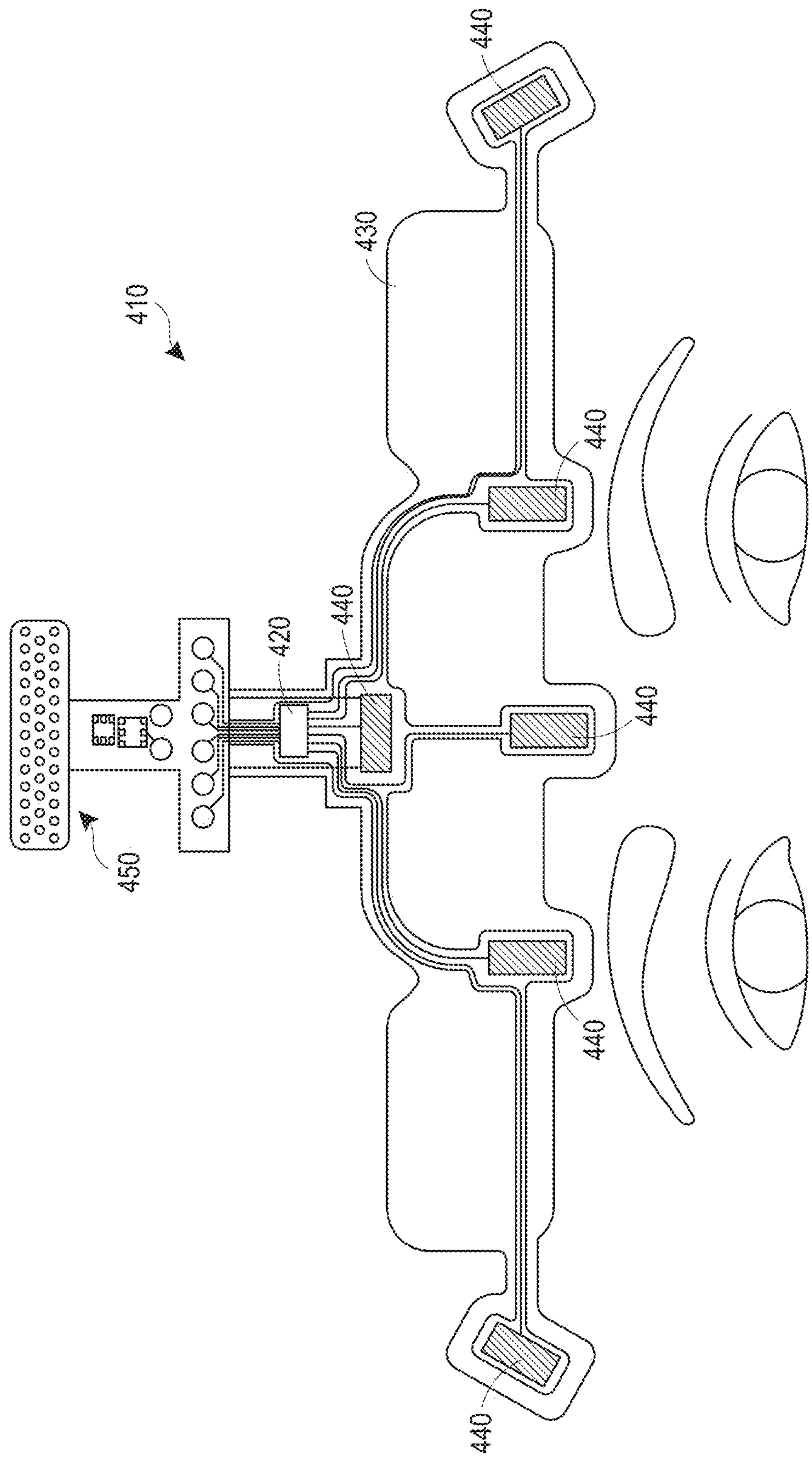

FIG. 3

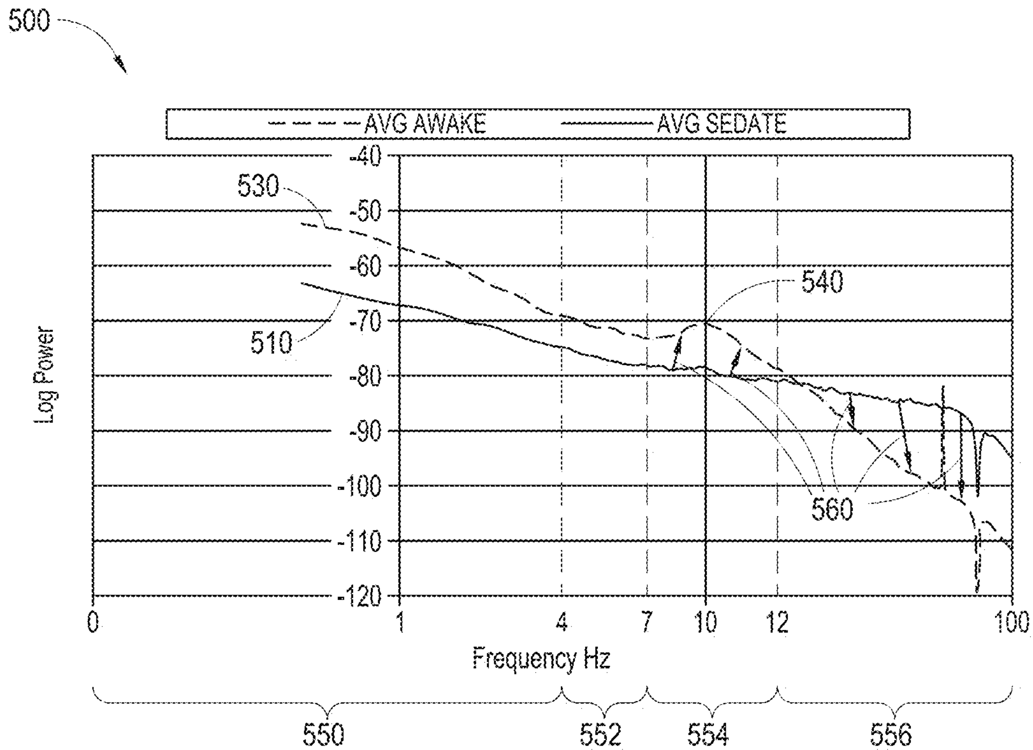
500
AVG AWAKE
AVG SEDATE
530
510
540
560
Log Power
-40
-50
-60
-70
-80
-90
-100
-110
-120
0
1
4
7
10
12
100
Frequency Hz
550
552
554
556

FIG. 4

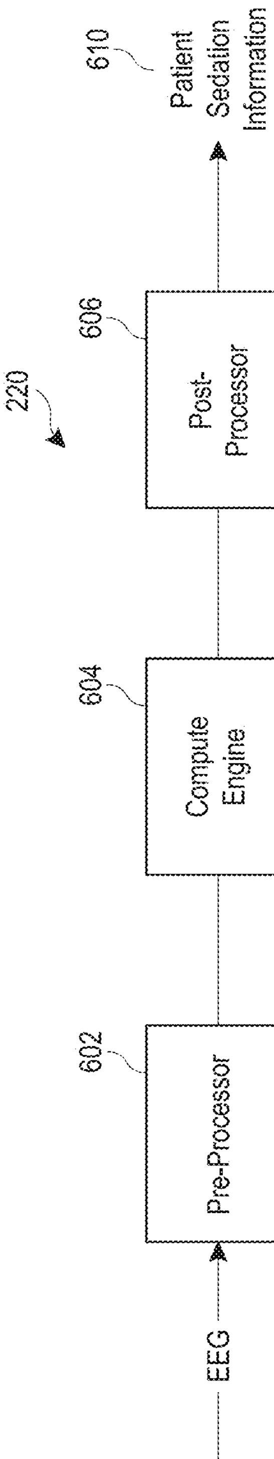
220
EEG
602
Pre-Processor
604
Compute Engine
606
Post-Processor
610
Patient Sedation Information

FIG. 5

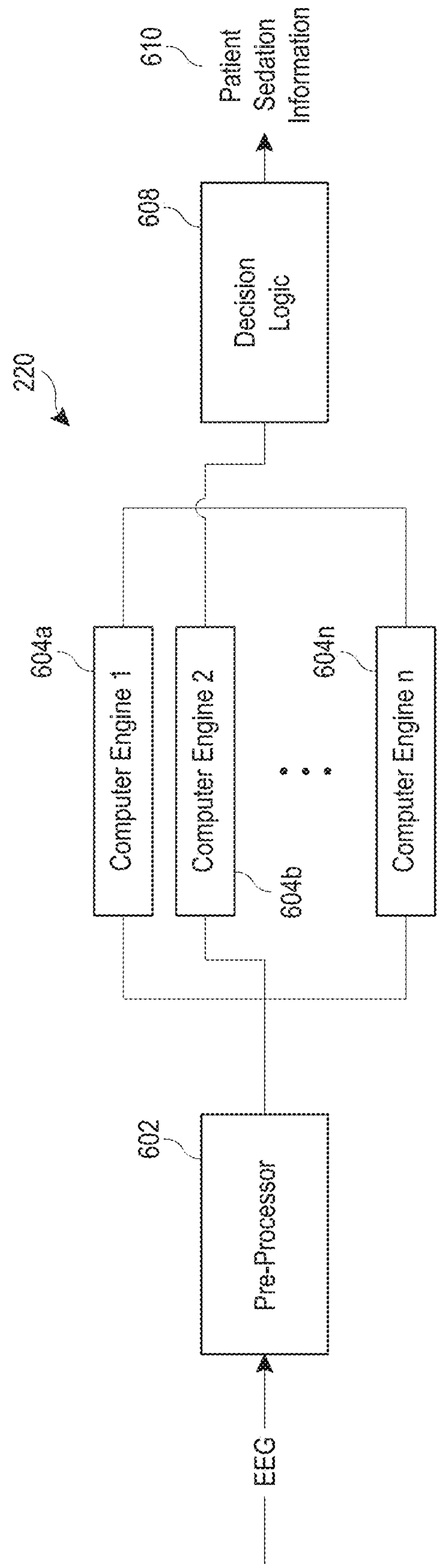
220
EEG
602
Pre-Processor
604a
Computer Engine 1
Computer Engine 2
604b
604n
Computer Engine n
608
Decision Logic
610
Patient Sedation Information

FIG. 6

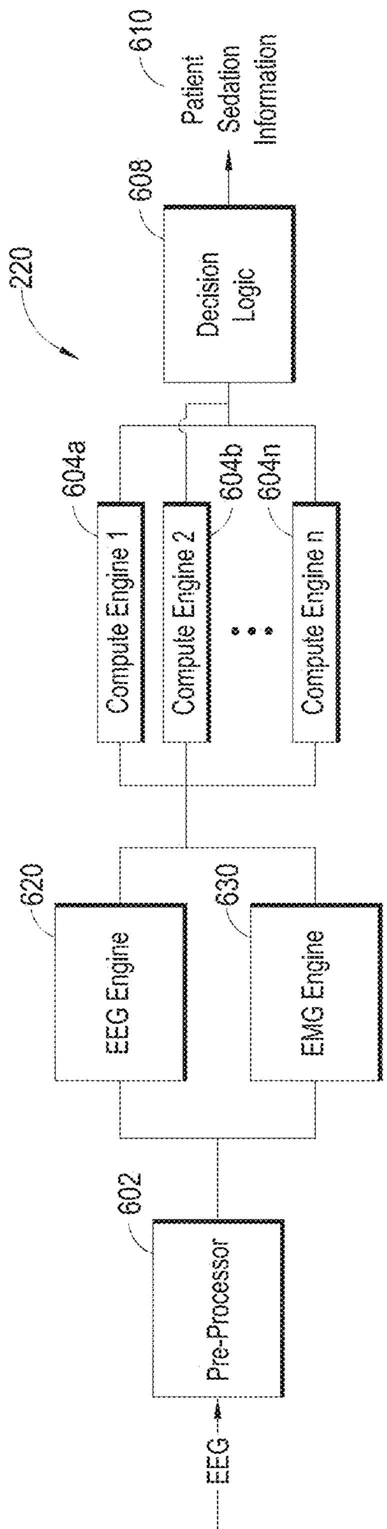
220
EEG
Pre-Processor
602
EEG Engine
620
EMG Engine
630
Compute Engine 1
604a
Compute Engine 2
604b
Compute Engine n
604n
Decision Logic
608
Patient Sedation Information
610

FIG. 7

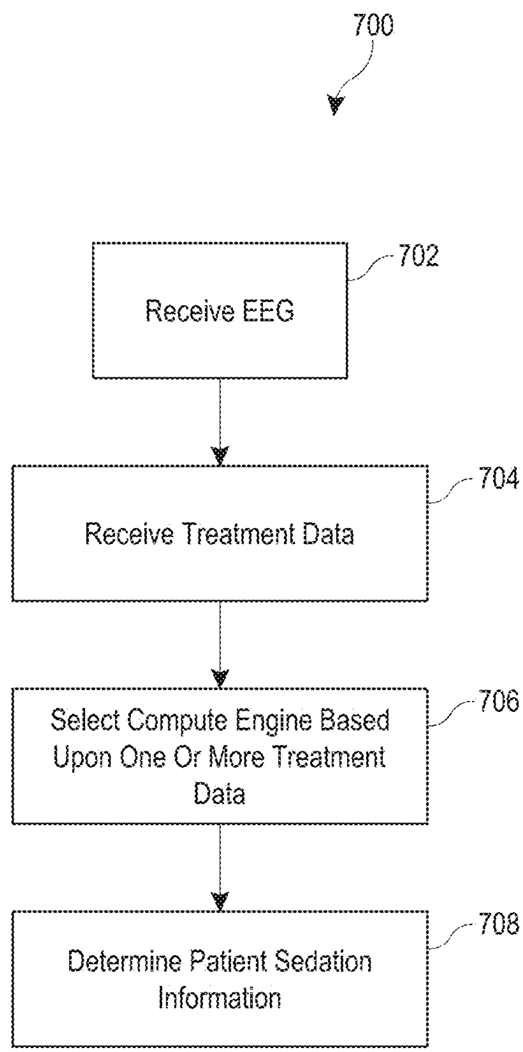
700
Receive EEG
702
Receive Treatment Data
704
Select Compute Engine Based Upon One Or More Treatment Data
706
Determine Patient Sedation Information
708

FIG. 8

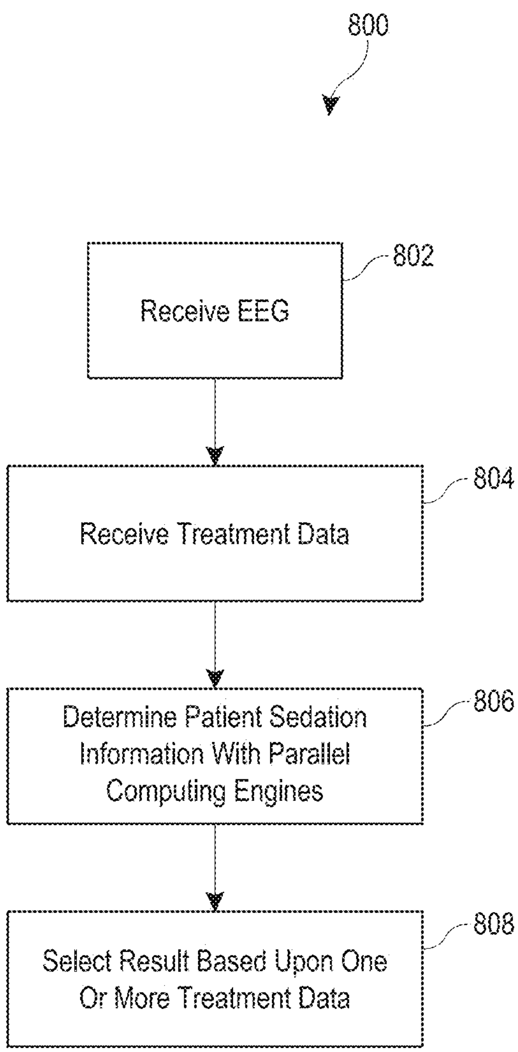
800
Receive EEG
802
Receive Treatment Data
804
Determine Patient Sedation Information With Parallel Computing Engines
806
Select Result Based Upon One Or More Treatment Data
808

FIG. 9

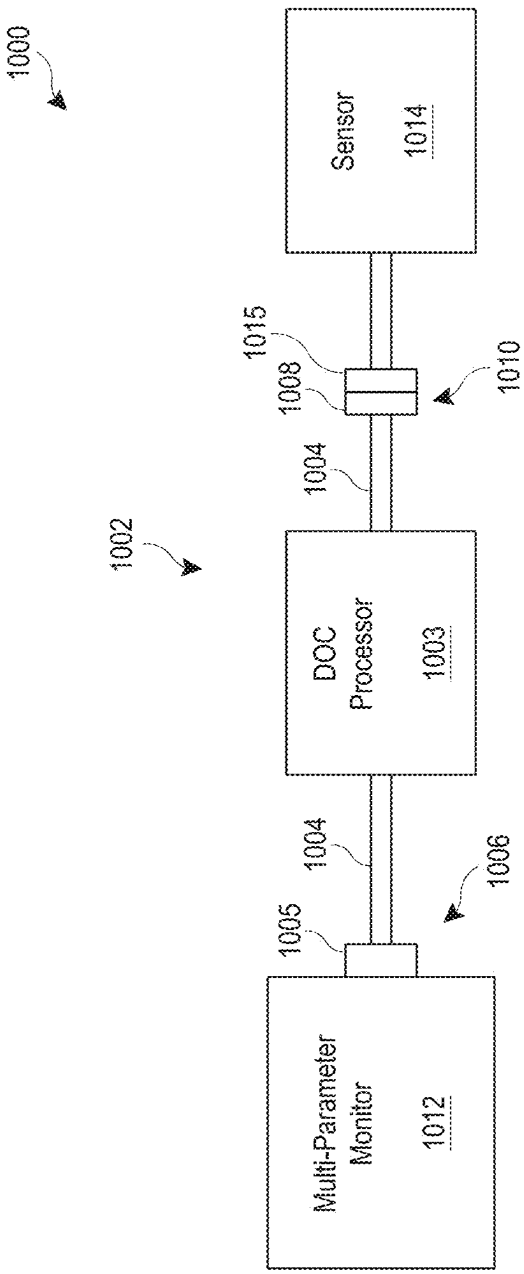
1000
Sensor
1014
1015
1008
1010
1004
1002
DOC
Processor
1003
1004
1006
1005
Multi-Parameter
Monitor
1012

FIG. 10

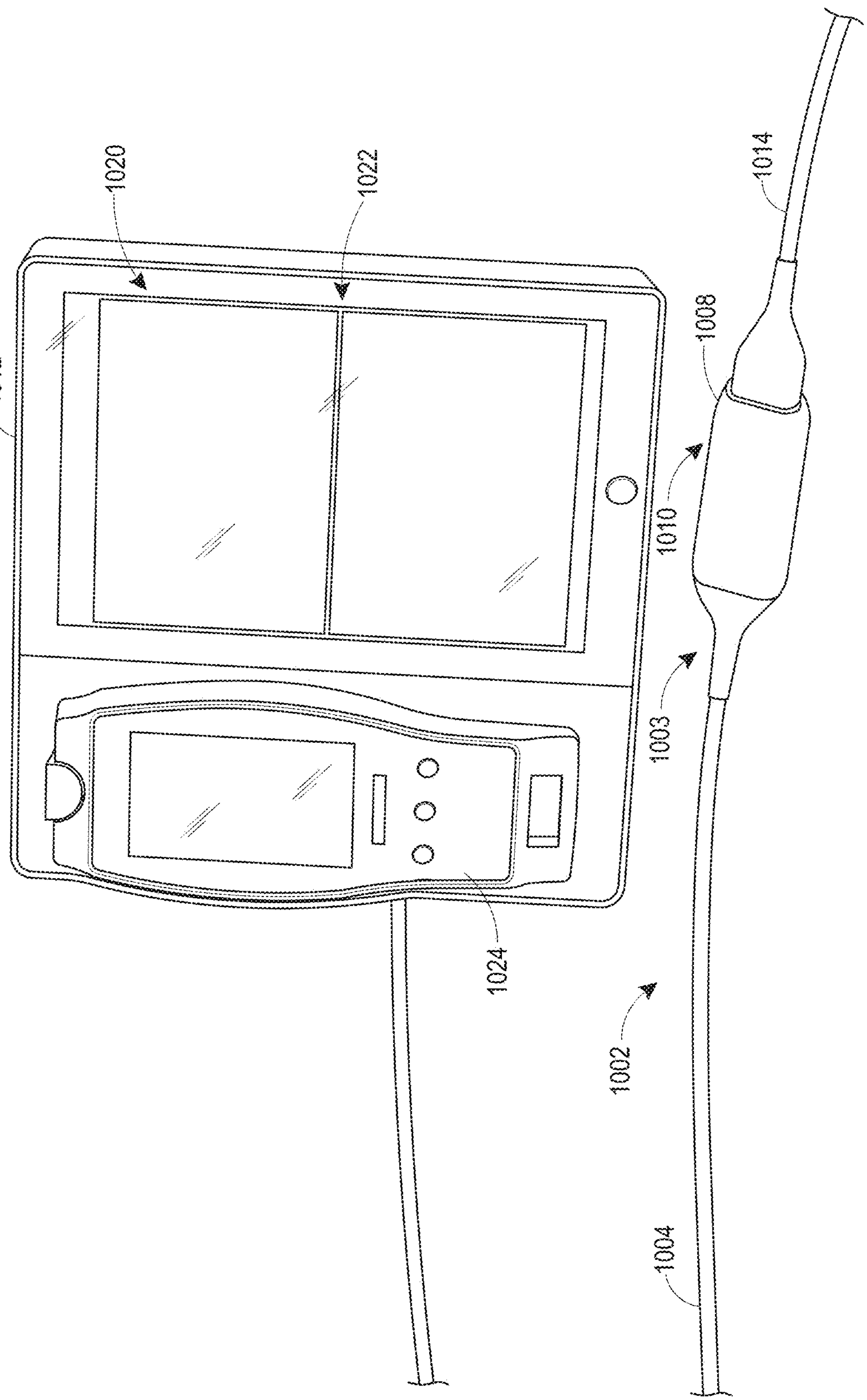

FIG. 11

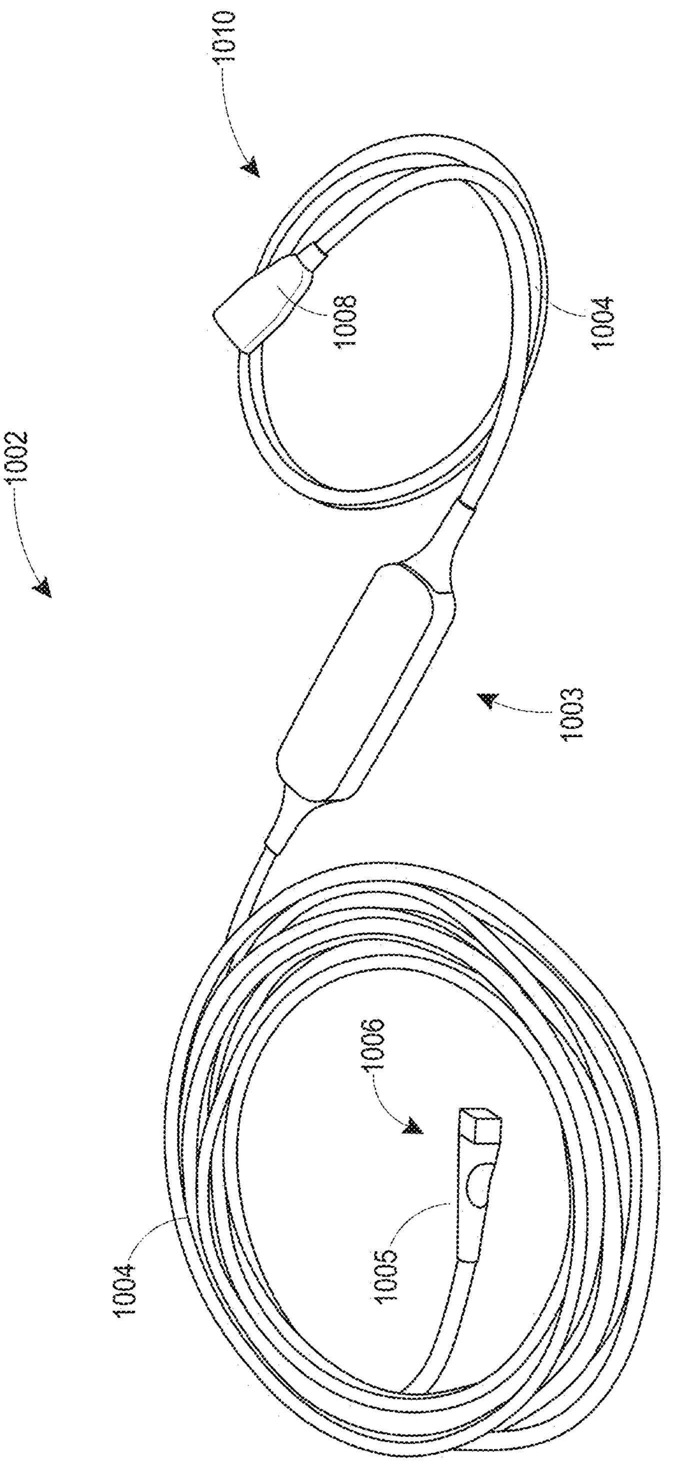

FIG. 12

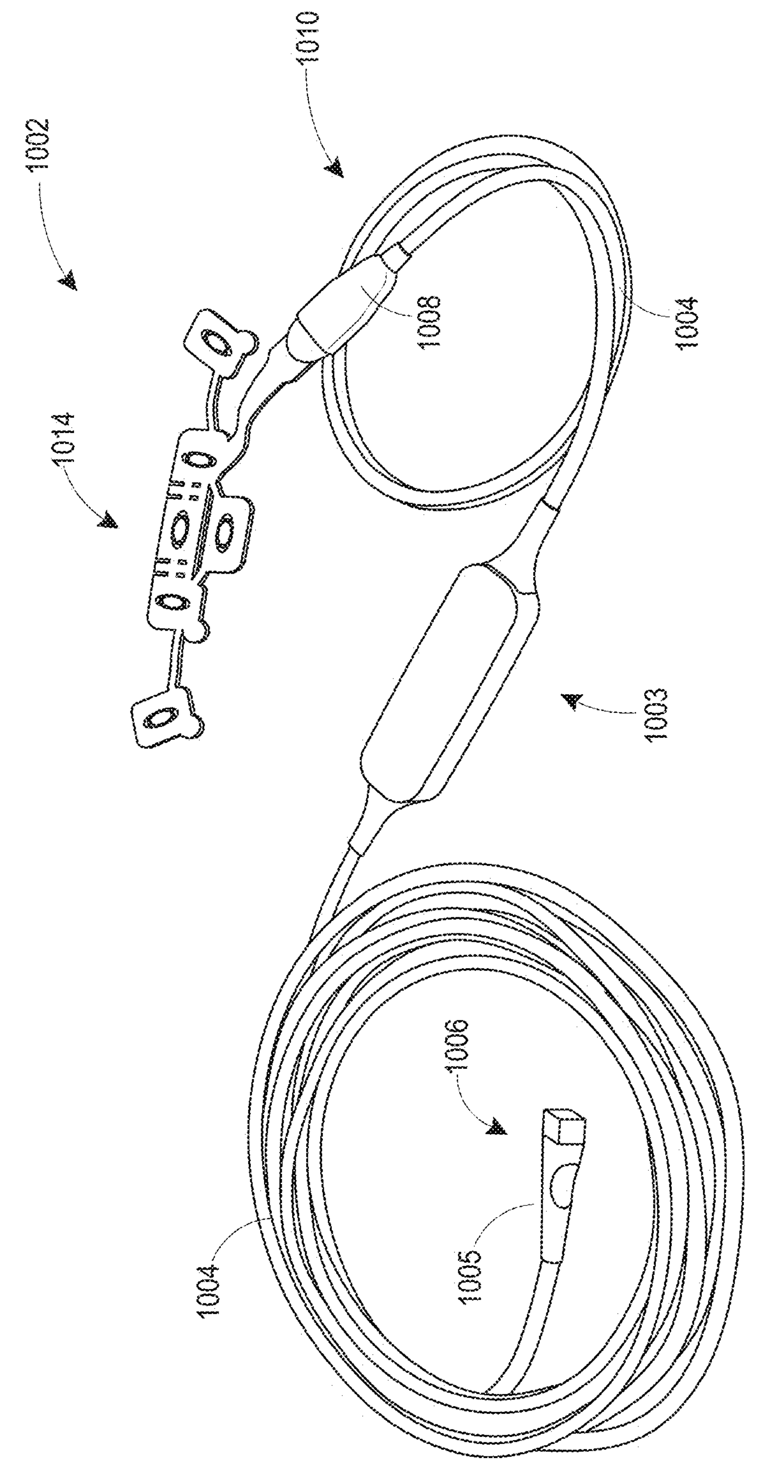

FIG. 13

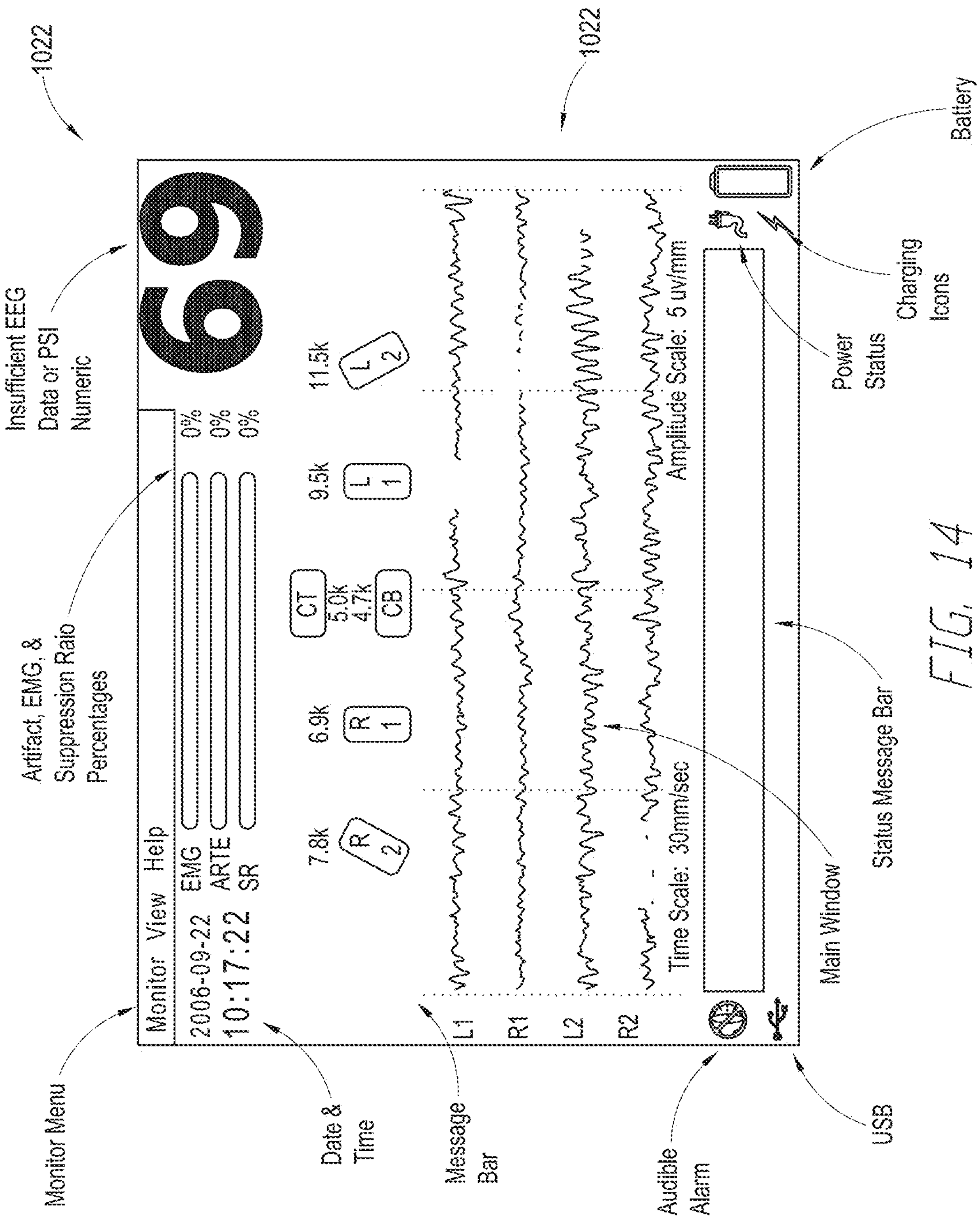
1022
1022
Insufficient EEG Data or PSI Numeric
Artifact, EMG, & Suppression Raio Percentages
Monitor Menu
Date & Time
Message Bar
Audible Alarm
USB
Main Window
Status Message Bar
Power Status
Charging Icons
Battery
Monitor View Help
2006-09-22
10:17:22
EMG
ARTE
SR
0%
0%
0%
69
7.8k
R 2
6.9k
R 1
CT
5.0k
4.7k
CB
9.5k
L 1
11.5k
L 2
L1
R1
L2
R2
Time Scale: 30mm/sec
Amplitude Scale: 5 uv/mm

FIG. 14

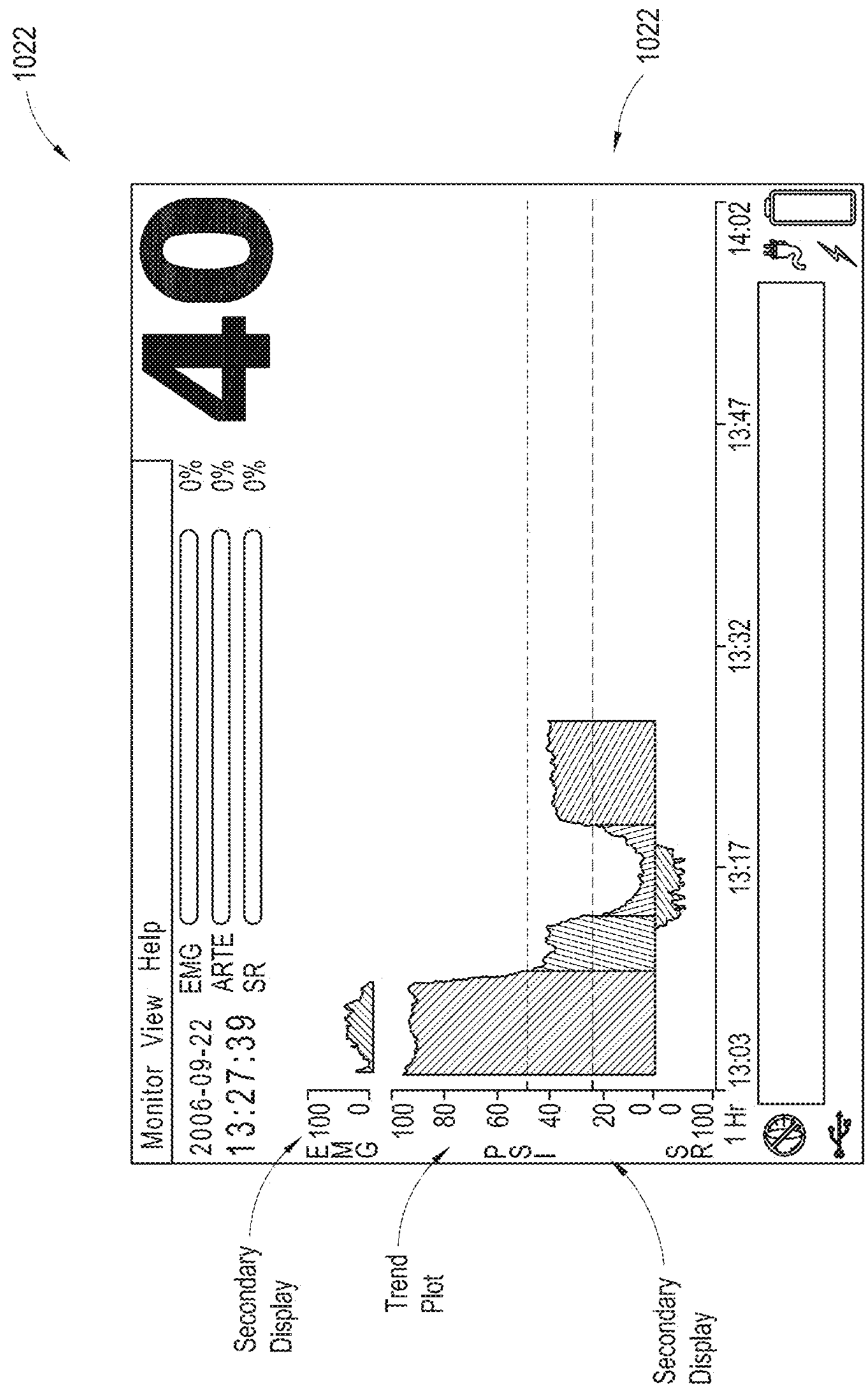
1022
1022
Monitor View Help
2006-09-22
13:27:39
EMG
ARTE
SR
0%
0%
0%
40
EMG
100
0
PSI
100
80
60
40
20
0
SR
0
100
1 Hr
13:03
13:17
13:32
13:47
14:02
Secondary Display
Trend Plot
Secondary Display

FIG. 15

1022

1022

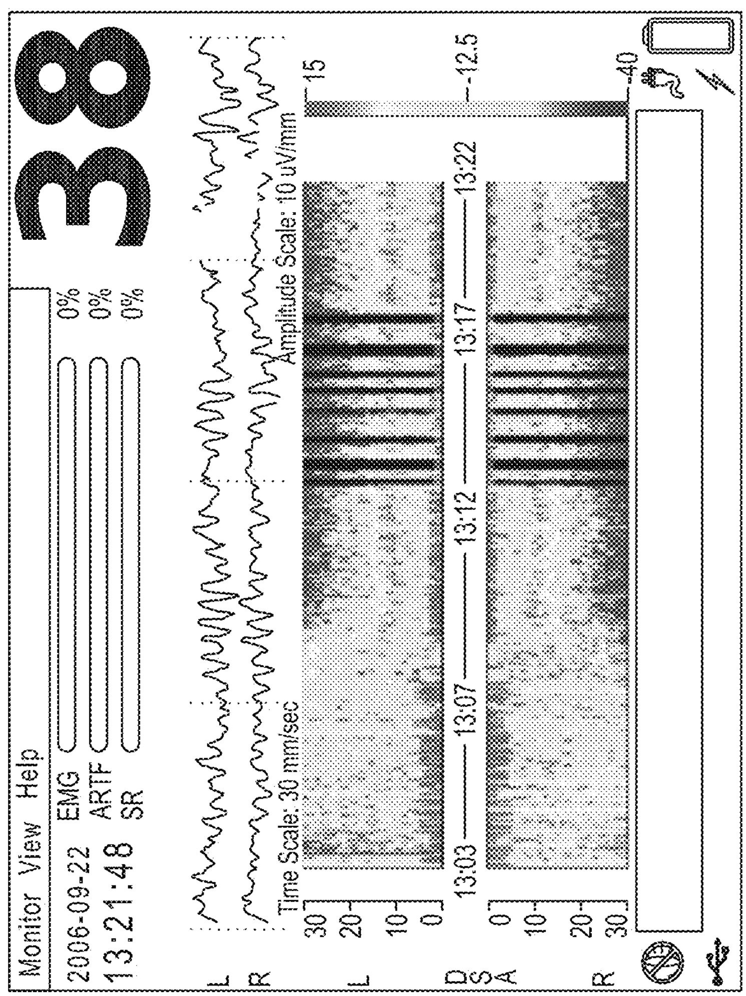

FIG. 16

DEPTH OF CONSCIOUSNESS MONITOR

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 13/911,939, filed Jun. 6, 2013, now U.S. Pat. No. 10,542,903, which claims the benefit of priority from U.S. Provisional No. 61/703,747, filed Sep. 20, 2012, and U.S. Provisional No. 61/656,974, filed Jun. 7, 2012, all of which are incorporated by reference in their entireties.

FIELD OF THE DISCLOSURE

The present disclosure relates to the field of patient monitoring. In some embodiments, the disclosure relates to monitoring the depth of consciousness of a patient under anesthetic sedation.

BACKGROUND

General anesthesia is often used to put patients to sleep and block pain and memory during medical or diagnostic procedures. While extremely useful, general anesthesia is not risk free. Caregivers therefore generally seek to maintain a depth of consciousness consistent with the needs of a particular medical procedure. Caregivers will monitor various physiological parameters of the patient to predict the patient's depth of consciousness. In response to monitored parameters, the caregiver may manually adjust the anesthetic dosage level to avoid over and under dosing. However, as a patient's depth of consciousness may frequently change, caregivers often employ a host of monitoring technologies to attempt to periodically, sporadically, or continually ascertain the wellness and consciousness of a patient. For example, caregivers may desire to monitor one or more of a patient's temperature, electroencephalogram or EEG, brain oxygen saturation, stimulus response, electromyography or EMG, respiration, body oxygen saturation or other blood analytes, pulse, hydration, blood pressure, perfusion, or other parameters or combinations of parameters. For many of the foregoing, monitoring technologies are individually readily available and widely used, such as, for example, pulse oximeters, vital signs monitors, and the like.

In their depth of consciousness monitoring, caregivers may also use recording devices to acquire EEG signals. For example, caregivers place electrodes on the skin of the forehead to detect electrical activity produced by the firing of neurons within the brain. From patterns in the electrical activity, caregivers attempt to determine, among other things, the state of consciousness of the brain. Caregivers may also use a pulse oximeter or cerebral oximetry to determine the percentage of oxygenation of the hemoglobin in the patient's blood. Caregivers may also use an EMG monitor to detect the muscular action and mechanical impulses generated by the musculature around the patient's forehead, among other bodily locations. Caregivers manually monitor such physiological parameters and then manually adjust anesthetic dosage.

However, manual monitoring and dosage adjustment could lead to serious adverse results, including death, if improperly performed. In addition, typical depth of consciousness monitors do not account for variations in responses to sedation therapies that exist between patient demographics. Furthermore, typical depth of consciousness monitors do not account for differences in physiological responses that exists between particular sedation therapies and among different patient populations. Therefore, there remains a need in the art for a depth of consciousness monitor that is configured to automatically communicate with a caregiver and/or an anesthetic dosage device to provide accurate control over patient care by accounting for variations between populations and drug actions.

SUMMARY

Based on at least the foregoing, the present disclosure seeks to overcome some or all of the drawbacks discussed above and provide additional advantages over prior technologies. The present disclosure describes embodiments of noninvasive methods, devices, and systems for monitoring depth of consciousness through brain electrical activity.

In one embodiment, a depth of consciousness monitor is configured to determine the level of sedation of a medical patient. The depth of consciousness monitor includes: an EEG interface configured to receive an EEG signal from an EEG sensor; an EEG front end configured to pre-process the EEG signal; a processor, configured to determine a level of sedation of a medical patient based at least upon the pre-processed EEG signal, wherein the processor is further configured to determine delay information associated with the time the EEG signal is received and the time the level of sedation is determined; and a drug delivery device interface, configured to provide the level of sedation and the delay information to a drug delivery device.

In some embodiments the EEG front end includes an EEG engine and an EMG engine configured to extract EEG information and EMG information from the EEG signal, respectively. In some embodiments, the processor is further configured to time stamp the EEG signal when received from the EEG sensor. In one embodiment, the depth of consciousness monitor also includes an additional sensor front end, such as an SpO2 sensor front end. In some embodiments, the depth of consciousness monitor also includes a data port configured to receive at least one of patient data and drug profile information. The processor may be configured to determine a level of sedation of a medical patient based at least upon the pre-processed EEG signal and the at least one of patient data and drug profile information. In some embodiments, the depth of consciousness monitor also includes the EEG sensor and/or the drug delivery system. In some embodiments, the drug delivery device interface includes a wireless communication device.

In another embodiment, a depth of consciousness monitor is configured to determine the level of sedation of a medical patient. The depth of consciousness monitor includes: an EEG interface configured to receive an EEG signal from an EEG sensor; an EEG front end configured to pre-process the EEG signal; a processor, configured to determine a level of sedation of a medical patient based at least upon the pre-processed EEG signal, and a data port configured to transmit the patient sedation level. The processor can include: two or more computing engines, each configured to compute a possible sedation level according to a different process; and a decision logic module, configured to determine the patient's sedation level based at least upon the possible sedation level computations;

In some embodiments, at least one of the computing engines is configured to implement a motion vector process, a phase coherence process, and/or utilize a brain model to compute one of the possible sedation levels. The EEG front end may include an EEG engine and an EMG engine configured to extract EEG information and EMG informa-

tion from the EEG signal, respectively. In some embodiments, the data port comprises a display and/or a wireless communication device.

In yet another embodiment, a method of determining the level of sedation of a medical patient is provided. The method includes: receiving an EEG signal indicative of a medical patient's EEG; receiving treatment data associated with at least one of the medical patient and a drug to be delivered to the medical patient; and determining a level of sedation based at least upon the EEG signal and the treatment data.

In some embodiments, the treatment data includes at least one of a patient age, age classification, sex, weight, body-mass index, a physiological parameters, a temperature, a blood oxygen concentration, an EMG signal, a drug type, a drug class, a mechanism of delivery, and an active ingredient. In some embodiments, determining a level of sedation comprises determining two or more possible levels of sedation with parallel computing engines and wherein said determining the level of sedation of the medical patient is based upon said possible levels of sedation. In some embodiments, determining the level of sedation comprises averaging two or more possible levels of sedation and/or selecting one of the possible levels of sedation as the level of sedation of the medical patient. In some embodiments, determining the possible levels of sedation is performed with motion vector analysis, phase coherence, and or by utilizing a brain model.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the disclosure have been described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features will be embodied in any particular embodiment of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings and the associated descriptions are provided to illustrate embodiments of the present disclosure and do not limit the scope of the claims.

FIG. **1** illustrates an embodiment of a depth of consciousness monitoring system under closed-loop control.

FIG. **2** illustrates a block diagram of one embodiment of the depth of consciousness monitor of FIG. **1**.

FIG. **3** illustrates one embodiment of the forehead sensor of FIG. **1**.

FIG. **4** illustrates one embodiment of an EEG frequency spectrum of the patient before and during sedation using the depth of consciousness monitor of FIG. **2**.

FIG. **5** illustrates one embodiment of the processor of the depth of consciousness monitor of FIG. **2**.

FIG. **6** illustrates another embodiment of the processor of the depth of consciousness monitor of FIG. **2**.

FIG. **7** illustrates yet another embodiment of the processor of the depth of consciousness monitor of FIG. **2**.

FIG. **8** illustrates one embodiment of a routine to determine patient sedation information that can be performed by any of the processors of FIGS. **5-7**.

FIG. **9** illustrates another embodiment of a routine to determine patient sedation information that can be performed by any of the processors of FIGS. **5-7**.

FIG. **10** illustrates another embodiment of a depth of consciousness monitoring system.

FIG. **11** illustrates one embodiment of the depth of consciousness monitoring system of FIG. **10**.

FIG. **12** illustrates one embodiment of the depth of consciousness monitoring assembly of FIG. **10**.

FIG. **13** illustrates the depth of consciousness monitoring assembly of FIG. **12** attached to a sensor assembly.

FIGS. **14-16** illustrate views of the display of a multi-parameter monitor displaying physiological signals received from the depth of consciousness monitor of FIG. **10**.

DETAILED DESCRIPTION

The present disclosure generally relates to patient monitoring devices. In order to provide a complete and accurate assessment of the state of a patient's various physiological systems, in an embodiment, a sensor may advantageously monitor one, multiple or combinations of EEG, EMG, cerebral oximetry, temperature, pulse oximetry, respiration, and other physiological parameters. In various embodiments, the sensor includes a disposable portion and reusable portion. For example, the disposable portion may advantageously include components near a measurement site surface (the patient's skin), including, for example, an EEG sensor, an EMG sensor, a temperature sensor, tape, adhesive elements, positioning elements, or the like. In addition, or alternatively, the reusable portion may advantageously include other components, circuitry or electronics, which, in some embodiments include time-of-use restrictions for quality control or the like. The reusable portion, can be used multiple times for a single patient, across different patients, or the like, often depending upon the effectiveness of sterilization procedures. The reusable components may include, for example, cerebral oximetry components, pulse oximetry components and other components to measure other various parameters.

In an embodiment, the disposable portion of the sensor may include an inductance connection or other electrical connection to the reusable portion of the sensor. The physiological signals from all sensors can be transmitted through a common cable to a depth of consciousness monitor. In an embodiment, the depth of consciousness monitor may include an analog to digital converter, various electrical filters, and a microcontroller for processing and controlling the various sensor components.

In an embodiment, a depth of consciousness monitor is configured to communicate with the forehead sensor and one or more host display and patient monitoring stations. In an embodiment, the patient monitoring station may be a pulse oximeter. In an embodiment, the pulse oximeter may perform integrated display, data monitoring and processing of patient parameters including a connection for power and data communication. In an embodiment, some or all communication may be through wired, wireless, or other electrical connections. In an embodiment, the depth of consciousness monitor may advantageously be housed in a portable housing. In such embodiments, the unit may advantageously be physically associated with a monitored patient, such as, for example, attached in an arm band, a patient bed pouch, a hood or hat, a pocket of a shirt, gown, or other clothing, or the like. In other embodiments, the unit may be entirely or partially housed in a cable connector. In an embodiment, the signal processing and condition unit and/or the depth of consciousness monitor could also monitor patient parameters through other sensors including, for example, ECG, Sp02 from the earlobe, finger, forehead or other locations, blood pressure, respiration through acoustic or other monitoring technologies, or other clinically relevant physiological parameters.

In an embodiment, the depth of consciousness monitor communicates with a sensor, such as a forehead sensor including one or more light sources configured to emit light at a patient's forehead. In an embodiment, the light source may include one or more emitters or emitter systems, such emitters or emitter systems may be embedded into a substrate. In various embodiments, the emitters could include light emitting diodes ("LEDs"), lasers, superluminescent LEDs or some other light emitting components. These components could be arranged in any pattern on the substrate and could be either a single light emitting source or several light emitting sources. In an embodiment, the emitting components could emit light that deflects off of reflective surfaces associated with a cap of the substrate. The reflective cover could be any number of shapes or sizes and could be constructed to direct light to specific points or a point on the cap or substrate.

In an embodiment, a multi-faceted splitting mirror could reflect light to an opening in the substrate that would allow the light to escape and be emitted to an emission detector in an embodiment also housed in the light source substrate. The emission detector may advantageously sample the light providing feedback usable to create an optical bench or at least optical bench properties of the light source, including, for example, determinations of intensity, wavelength, or the like. In an embodiment, the light source may include a polarized filter for adjusting the emitter light, in some embodiments before exiting an opening in the emitter or being detected by the emission detector.

In an embodiment, a caregiver could analyze physiological information collected from the various sensors including a patient's temperature, EEG, brain oxygen saturation, stimulus response, electromyography or EMG, respiration using acoustic sensor applied to the through, body oxygen saturation, glucose concentration, or other blood analytes, pulse, hydration, blood pressure, perfusion, or other parameters or combinations of parameters to determine relevant information about the state of a patient's well-being. In another embodiment, a caregiver may advantageously analyze information collected from the various sensors to more completely assess the overall depth of a patient's sedation and obtain an assessment superior to an assessment derived from monitoring a single or a few of the parameters mentioned above.

Reference will now be made to the Figures to discuss embodiments of the present disclosure.

FIG. **1** illustrates one example of a depth of consciousness monitoring system **100**. In certain embodiments, the depth of consciousness monitoring system **100** measures one or more physiological parameters including cerebral electrical activity (e.g., via EEG), cerebral muscular activity (e.g., via EMG), temperature, cerebral oxygenation, including venous and arterial oxygenation, arterial oxygenation at various other points on the body, various other blood analytes, including total hemoglobin, glucose, lipids, stimulus response, electromyography or EMG, respiration, pulse, hydration, blood pressure, perfusion, or other parameters or combination of other physiologically relevant patient characteristics. The information from these physiological parameters can be evaluated using trend analysis, absolute and relative measures of certain parameters, combined or alone to evaluate the total wellness and current state of sedation of a patient.

The depth of consciousness monitoring system **100** includes multiple or a single sensor **120** in communication with a depth of consciousness monitor **140** via a communications link **150**. In the illustrated embodiment, the depth of consciousness monitoring system **100** also includes a drug delivery device **160** that receives a control signal from the depth of consciousness monitor **140** via a control link **170**. The drug delivery device **160** provides one or more sedatives (e.g., narcotic, hypnotic, analgesic, opiate, etc.) to a patient **180** via a conduit **190**.

The sensor **120** can include any variety of shapes and sizes, and could be applied to a variety of measurement sites on a patient's skin including any location on the forehead and temples or other location of the head. One example of a sensor **120** configured for placement on a patient's forehead is described below with respect to FIG. **3**. The sensor **120** generally includes one or more electrodes and is configured to measure the electrical activity within the patient's head and generate an EEG signal, as discussed in further detail below.

In some embodiments, the sensor's electrodes are designed to be placed at a measurement site covered with a patient's hair. A caregiver or patient may fasten the sensor **120** to the patient's head with a variety of mechanism including adhesive, straps, caps, combinations of the same, or other devices for fastening sensors to a patient's body or skin known in the art.

In some embodiments, the communication link **150** and/or the control link **170** are wired electrical connections (e.g., an electrical cable, etc.). In other embodiments, the communication link **150** and/or the control link **170** utilize wireless communication to provide portability, and greater flexibility in depth of consciousness monitor placement with respect to the drug delivery device **160**. Wireless communications also help accommodate an ambulatory patient, or other patient in transit. For example, in one embodiment, the depth of consciousness monitor **140** may be attached to an arm band or included in an arm band or other device that is wearable by the patient, including in a cap, a hood, a sling or a pocket of a garment. In such an embodiment, the sensor **120** communicates with the arm band depth of consciousness monitor **140** via a wired or a wireless connection.

In an embodiment, the depth of consciousness monitor **140** communicates wirelessly with the drug delivery device **160** over a wireless control link **170**. This allows the depth of consciousness monitor **140** to be transported between various caregiving facilities, each with their own stationary drug delivery devices **160** without unhooking and reinserting hardwired electrical connections. Instead, the depth of consciousness monitor **140** could establish a wireless communication link with a stationary drug delivery device **160** as the depth of consciousness monitor **140** is brought into proximity with the drug delivery device **160**. In an embodiment, the devices could establish the connection automatically and patient data may be automatically sent from the depth of consciousness monitor **140** to the drug delivery device **160**. In other embodiments, caregiver interaction is required to establish a wireless control link **170** between the depth of consciousness monitor **140** and the drug delivery device **160**. Such configurations advantageously facilitate portability and seamless monitoring of a patient while the patient is transported, for example, from an ambulance to a hospital room or from room to room within a hospital.

In an embodiment, the depth of consciousness monitor **140** also communicates with, or incorporates, a pulse oximeter (not shown). The pulse oximeter may be a multiparameter monitor or other host device capable of monitoring a wide variety of vital signs and blood constituents and other parameters or combinations of parameters such as those monitors commercially available from Masimo Corporation of Irvine, CA, and disclosed herein with reference to U.S. Pat. Nos. 6,584,336, 6,661,161, 6,850,788, and 7,415,297, among others assigned to Masimo Corporation, and U.S. Patent Publication No. 2006/0211924, 2010/

0030040, among others assigned to Masimo Corporation or Masimo Laboratories, Inc. of Irvine CA, all of which are incorporated by reference in their entireties.

The communication link **150** and the control link **170** can include any of a variety of wired or wireless configurations. For example, in some embodiments the links **150**, **170** are implemented according to one or more of an IEEE 801.11x standard (e.g., a/b/g/n, etc.), a BLUETOOTH wireless standard, and a wireless medical information communications standard, etc.

The drug delivery device **160** generally includes at least a drug therapy interface **192**, a drug flow device **194**, and a flow controller **196**. The drug therapy interface **192** receives a drug and provides a flow path to the drug flow device **194**. For example, the drug therapy interface **192** can include a port or receptacle to receive or interface with a drug capsule, intravenous bag, syringe, etc. The drug flow device **194** receives the drug therapy from the drug therapy interface **192** and allows the drug to flow to the patient **180** via the conduit **190**. In some embodiments, the drug flow device **194** includes one or more of a solenoid, a pump, a valve, a peristaltic pump, a variable speed pump, a compression sleeve (e.g., to squeeze an intravenous bag), etc. The action and activation of the drug flow device **194** is controlled by the flow controller **196**. The flow controller **196** includes a microcontroller, a memory, a signal input to receive a control signal from the depth of consciousness monitor **140** via the control link **170** and a signal output to provide control over the functionality of the drug flow device **194**. The signal input can include a wireless radio to facilitate wireless communication over a wireless control link **170**. The signal input allows closed-loop control over the operation of the drug delivery device **160**, as will be described in greater detail below.

In some embodiments, the drug delivery device **160** is manually controlled by a clinician (e.g., an anesthesiologist) and/or includes a manual override to allow the clinician to take control over drug delivery to the patient **180**. Therefore, in some embodiments, the depth of consciousness monitoring system **100** does not include an electronic control link **170** between the depth of consciousness monitor **140** and the drug delivery device. Instead, in such an open-loop configuration, the depth of consciousness monitor **140** displays an indication of the patient's depth of consciousness. The clinician is able to manually adjust drug therapy to the patient in response to the signals displayed by the depth of consciousness monitor **140**.

In some embodiments, the depth of consciousness monitor **140** is configured to generate and/or provide a delay signal (which is a form of delay information) to the drug delivery device **160**. The delay signal may be used by the drug delivery device to control whether the depth of consciousness monitoring system **100** is operating under positive or negative feedback. In some embodiments, the drug delivery device **160** controls or delays the delivery of drugs provided to the patient **180** in response to the delay signal. For example, the drug delivery device **160** may delay drug deliver to make sure that the depth of consciousness monitoring system **100** is operating under negative feedback, and is therefore a stable control system.

The delay signal can be determined by the depth of consciousness monitor **140** in any of a variety of manners. In one embodiment, the depth of consciousness monitor **140** time stamps the data received from the sensor **120** and provides the time stamp information or other related time information to the drug delivery device **160** as the delay signal. For example, in some embodiments, the delay signal includes the time stamp associated with the data received from the sensor **120** as well as a time stamp associated with the time the control signal data packet is sent to the drug delivery device **160**. In other embodiments, the delay signal includes the difference between the two time stamps. In some embodiments, the drug delivery device **160** is configured to calculate or otherwise determine the appropriate control delay based upon the delay signal. For example, the drug delivery device **160** may time stamp the time the control signal is received from the depth of consciousness monitor **140**. The drug delivery device **160** can determine a control delay based upon the difference between the time the control signal is received from the depth of consciousness monitor **140** and the time the depth of consciousness monitor received the signal from the sensor **120** that was used to generate the associated data packet received by the drug delivery device. The signal propagation delay through the depth of consciousness monitoring system **100** may be used to keep the system's feedback negative to avoid oscillation and to achieve stability.

In an embodiment, a caregiver or the patient may attach the depth of consciousness monitor **140** directly to the patient's arm or other part or clothing of the patient through an armband with straps or some other means known in the art to connect a portable monitoring unit to a patient. In an embodiment, a depth of consciousness monitor **140** may be integrated into a hat or other headgear wearable by the patient or some other structure near the patient. In an embodiment, the depth of consciousness monitor **140** can rest on a table or other surface near the patient.

In some embodiments, a depth of consciousness monitor **140** is integrated with the drug delivery device **160**. Alternatively, the depth of consciousness monitor **140** could be a module that is docked or otherwise attached to the drug delivery device **160**. The depth of consciousness monitor **140** can communicate with and/or be integrated with a variety of other device, such as a pulse oximeter, a respiration monitor, and EKG device, a blood pressure measurement device, a respirator, and/or a multi-parameter monitor.

FIG. **2** illustrates a block diagram of one embodiment of the depth of consciousness monitor **140**, sensors **120**, and drug delivery device **160**. In an embodiment, the depth of consciousness monitor **140** includes a processor **220** which may be a micro-controller or other processor, to control and/or process signals received from the sensors **120**. For example, the processor **220** may coordinate, process or condition, or manipulate the signals received from the sensor **120** to generate electronic data, control signals, and/or delay signals that are subsequently displayed and/or communicated to the drug delivery device **160**. In addition, the processor **220** may receive instructions or data control messages from the drug delivery device **160** or other patient monitoring device to provide the appropriate conditioning and controlling of the various front end components of the sensors **120**. Data transmitted between the depth of consciousness monitor **140**, the drug delivery device **160**, the sensors **120** and any other associated components, devices, or systems in communication with the depth of consciousness monitoring system **100** may be communicated by the devices using one or more interfaces, e.g., electrical wires, wireless communication, optical communication, RFID, LAN networks, or other electronic devices for communicating data known in the art. In one embodiment, a drug delivery device interface can include any one or more of electrical wires, wireless communication, optical communication, RFID, LAN networks, or other electronic devices for communicating data known in the art. In one embodiment, a multi-parameter physiological monitor interface can include any one or more of electrical wires, wireless communication, optical communication, RFID, LAN networks, or other electronic devices for communicating data known in the art.

The depth of consciousness monitor **140** may also include various front end components to enable the depth of consciousness monitor **140** to process the various signals received by the various sensors **120** that may be communicating with the depth of consciousness monitor **140**. In an embodiment, front end components may translate and transmit instructions and control signals for driving the various sensors. In an embodiment, the front end components may translate, process, or transmit instructions and control signals to the emitting or light producing components of the sensor. The front end components may also receive and transmit data acquired by the detectors of the sensors to the microcontroller **220** or other processor **220**. The front end components can include one or more of an analog-to-digital converter, a preamplifier, an amplifier, a filter, a decimation filter, a demodulator, etc.

These front end components could include front end components for a variety of sensors **120** including for sensors that detect blood oxygenation, EEG, EMG, ECG, temperature, acoustic respiration monitoring ("ARM") sensors, such as those available from Masimo Corporation of Irvine, CA, acoustic throat respiratory sensor, and brain oxygenation. In an embodiment, a caregiver could advantageously utilize a device with the ability to monitor the plurality of above mentioned parameters to more accurately determine a depth of a patient's sedation. However, in some embodiments, the depth of consciousness monitor **140** only includes EEG and EMG front end components. In an embodiment, a front end component that would be associated with a sensor **120** that detects brain oxygenation may have a sub component dedicated to driving emitters **230** associated with a light source of the brain oxygenation sensor and a sub-component associated with the detector **230** or detectors **230** of the brain oxygenation sensor **300** for receiving and transmitting the detected signals that pass through various body tissues. In other embodiments, the light drivers and detector front end are omitted.

In an embodiment, one of the various sensors associated with the front end components of the brain oximetry unit could be, for example, a blood oxygenation sensor **310** which may be placed at various measurement sites on a patient's skin, including the earlobe, finger, forehead or other places known in the art suitable for detecting blood oxygenation. Many suitable pulse oximeter sensors **310** are known in the art such as those blood oxygenation sensors **310** commercially available from Masimo Corporation of Irvine, CA, including but not limited to those described in U.S. Pat. Nos. 5,638,818, 6,285,896, 6,377,829, 6,580,086, 6,985,764, and 7,341,559, which are expressly incorporated by reference in their entireties.

In an embodiment, a temperature sensor **320** communicates with an associated front end component of the depth of consciousness monitor **140**. The temperature sensor **320** detects the temperature of the skin, the temperature inside the ear, the temperature under the tongue, or any other temperature measurement method known in the art. In an embodiment, the temperature sensor **320** could be any suitable thermistor, or any other temperature sensor **320** known in the art capable of detecting a surface temperature of a patient's skin. Additional temperature sensor may advantageously provide feedback to the depth of consciousness monitor **140** regarding the performance or temperature of one, combinations of, or all of the emitters **230**.

An EEG sensor **330** may also be associated with the front end components of the depth of consciousness monitor **140**. In an embodiment, the EEG sensor **330** may be any of a variety of EEG sensors **330** known in the art. An EEG sensor **330** could be applied to a patient at any of a multitude of locations and measurement sites on the skin of the head of a patient. In an embodiment, the EEG sensor **330** may include electrode leads that may be placed on a measurement site in contact with the skin of the patient. In an embodiment, the EEG **330** may monitor the electrical activity of a patient's brain through any number of electrodes, electrode leads, and channels or other systems known in the art. One such EEG sensor **330** is illustrated in FIG. **3** and described in greater detail below.

In an embodiment, the EEG sensor **330** may monitor and collect data from a patient's brain using 4 channels and 6 electrodes. In another embodiment, the EEG **330** may use 3 channels and 5 electrodes. In another embodiment, any variety or combination of sensors maybe be used that are suitable for obtaining an EEG signal, such as those described in U.S. Pat. Nos. 60/164,444, 6,654,626, 6,128,521, which are incorporated by reference in their entireties.

A brain oxygenation sensor **300** may also be associated with the front end components of the depth of consciousness monitor **140**. In an embodiment, the brain oxygenation sensor **300** includes a light source **230**, and a detector **260**. The light source **230** of the brain oxygenation sensor **300** includes emitter(s) that would emit light, sonic or other radiation into the forehead at one, two or other plurality of measurement sites located on the skin of the patient at a plurality of predetermined wavelengths. In an embodiment, the brain oxygenation sensor **300** would include a detector **260** with photodiodes or other radiation detection devices to detect the radiation emitting from the patient at a one or two or a plurality of measurement sites on the skin of the head of a patient. Many suitable brain oxygenation sensors **300** and cerebral oximeters are known in the art including those disclosed in U.S. Pat. Nos. 7,072,701, 7,047,054, which are expressly incorporated by reference in their entireties.

In an embodiment, the light source **230** of the brain oxygenation sensor **300** may include an emission detector **260**. In an embodiment, the emission detector **260** detects the light emitted from the light source **230** before passing through or contacting the measurement site of the patient. In an embodiment, an output from the emission detector **230** would be communicated to the micro-controller **220** of the depth of consciousness monitor **140** in order to calculate an approximate output intensity of the light emitted by the emitter(s) **230**. The micro-controller **220** or other processor **220** could calculate the output intensity based on the output of the emission detector **260** by comparing the data to calibration data. In an embodiment, the calibration data could include measurement of intensity of light emitted from the emitter(s) **230** and corresponding measurements of output from the emission detector **260**. This data could then be correlated to real time output from the emission detector **260** while the oxygenation sensor **230** is in use to determine an actual or approximate intensity of light or radiation being emitted by the emitter(s) **230** utilizing a calibration curve or other suitable calculation or processing method. In an embodiment, the calibration data may be stored in an EPROM or other memory module in the depth of consciousness monitor **140** or other patient processing module or device associated with the patient monitoring system **100**.

In an embodiment, the detector **260** detects light or other radiation emitted from the light source **230** after, in an embodiment, some of the light has entered the measurement site on the patient and has been attenuated by a patient's tissue. In an embodiment, the detector **260** could be any number of detectors known in the art for detecting light or other radiation including photodiodes or other types of light or radiation detectors. In one embodiment, the detector **260** may convert detected light or other radiation into a signal, for example, an electrical output signal, which may represent the intensity or other attributes of the radiation. In an embodiment, the signal from the detector **260** may be sent to a brain oxygenation detector **260** front end located in the depth of consciousness monitor **140** for processing, conditioning or transmitting to a pulse oximeter (not shown) or other patient monitoring processor. In one embodiment, the signal may be converted into a digital format by an analog to digital converted located in the depth of consciousness monitor **140**. In an embodiment, the data from the detector **260** of the brain oxygenation sensor **300** may be processed to determine the cerebral oxygenation of a patient's brain tissue. In an embodiment, the processing of the data may include determining the changes of intensity between various wavelengths of emitted and detected light of the cerebral oxygenation sensor **300**.

In an embodiment, a cerebral oximeter or multi-parameter monitor (not shown) acquires data from the depth of consciousness monitor **140** or sensor **120** derived from physiologically relevant parameters. In an embodiment, the pulse oximeter could provide visual quantitative or qualitative assessments of the patient's well-being based on one or more of the various parameters or physiological attributes measured.

In an embodiment, a caregiver may utilize various physiological parameters to make a quantitative assessment of the patient's depth of sedation as indicated by an index based on for example, a patient's temperature, electroencephalogram or EEG, brain oxygen saturation, stimulus response, electromyography or EMG, respiration based on acoustic through sensors, body oxygen saturation or other blood analytes, pulse, hydration, blood pressure, perfusion, or other parameters or combinations of parameters. In another embodiment, various aspects of sedation could be assessed quantitatively or qualitatively based on a visual representation of the patient's sedation in the aspects including hypnosis, responsiveness, muscle relaxation or other clinically relevant facets of depth of anesthesia.

In an embodiment, the functionality of the depth of consciousness monitor **140** could be optionally controlled by the drug delivery device **160**. In an embodiment, the data and qualitative and quantitative assessments of a patient's wellness being could be displayed on one or more of the depth of consciousness monitor **140**, the drug delivery device **160**, or any other device or system in communication with the depth of consciousness monitoring system **100** (e.g., a pulse oximeter, physiological patient monitor, nurse station, etc.). Also, audible alarms and other indicators could be displayed on either or both the depth of consciousness monitor **140** and drug delivery device in response to various threshold breaches based on the assessment of the patient's wellness and depth of consciousness as determined from the various monitored parameters.

FIG. **3** illustrates one embodiments of a sensor **120** in the form of an EEG sensor **410**, which is configured for placement on a patient's forehead to generate an EEG signal. Disposable and reusable portions of the sensor **410** may be connected and overlayed on top of one another. The EEG sensor **410** includes six EEG electrodes **440** with two reference electrodes (along the central axis of the EEG sensor **410**) and four active channel electrodes (two on each side of the EEG sensor's central axis). In some embodiments, light source(s) and light detector(s) (not shown) may be incorporated into the EEG sensor **410**, as well. All or some of the above mentioned sensor components including the EEG electrodes **440**, leads from the electrodes **440**, and blood oxygen detecting light emitters and detectors (when provided) may communicate with one or more chips **420** that enables transmission of acquired signals and drive signals. In some embodiments a single chip **420** is provided. In other embodiments, each component communicates with its own individual chip through wires, or printed circuits, or other suitable electrical connections.

The EEG electrodes **440** may be any suitable electrodes for detecting the electro-potentials on the surface of the skin of a patient's head. In one embodiment, EEG electrodes **440** include a metal or other suitable conductor and utilize leads contacting the surface of the skin. In another embodiment, the electrodes **440** are gelled electrodes that make contact through the skin via gel and have metal leads that come into contact with the gel. In still yet another embodiment, the EEG electrodes **440** may be glued to the forehead with any suitable patient dermal adhesive for connecting the EEG electrodes **440** and may have electrical conductivity. In an embodiment, potentials from the EEG electrodes **440** are transmitted to the depth of consciousness monitor **140** for further conditioning, transmitting or processing.

The sensor **410** may also include one or more temperature sensors (not shown). The temperature sensor may be any suitable sensor that can detect the temperature of the surface of the skin or other patient temperatures. In an embodiment, the temperature sensor may include a thermistor attached to a reusable portion of the sensor **410**.

In an embodiment, the sensor **410** includes an interface **450** to couple the sensor **410** to the depth of consciousness monitor **140**. The interface **450** may be any suitable electrical or data connection or communication port or device including, for example, a pin connector and receiver. Various other communication or electrical connections known in the art may be utilized. In an embodiment, the interface **450** may include an inductance connection utilizing transformers to couple a data and electrical connection across an insulator. In another embodiment, the interface **450** provides a data or electronic coupling between a reusable portion and a disposable portion of the sensor **410**.

In some embodiments, the sensor **410** includes a disposable portion (not shown) removably attached to a reusable portion (not shown). In an embodiment, the disposable portion attaches to a measurement site of a patient's head and provides a base to which the reusable portion may be docked, mated or connected. The disposable portion houses the components of the sensor **410** that may be less expensive than at least some of the components contained in the reusable portion, and therefore may be disposed after a single or multiple uses, either on the same patient or different patients. The disposable portion of the sensor **410** includes a tape substrate that provides a base or substrate to which at least some of the components of the disposable portion may adhere or be integrated. In an embodiment, the tape can be constructed from any suitable disposable material that will effectively hold the components includes in the disposable portion to a patient's forehead or other measurement site. In an embodiment, the tape includes a suitable dermal adhesive on a patient side of the disposable portion for temporary adhesion of the sensor to a patient's skin.

In an embodiment, the sensor **410** may include an adhesive tape **430** that supports the EEG electrodes **440**. In one embodiment, the EEG electrodes **440** may be fastened to the tape **430**. In an embodiment, the EEG electrodes **440** could be embedded in the tape **430** by any known adhesive in the sensor arts or any other suitable means for connecting the EEG electrodes **440** that would allow the EEG electrode **440** leads to be exposed on a patient side of tape **430** in an appropriate position to come in close proximity to a measurement site of a patient's skin. In an embodiment, EEG electrodes **440** may be gelled so that the gel contacts the electrodes and a measurement site of a patient's skin to provide an electrical path between the measurement site of the patient's skin and the EEG electrodes **440**. In an embodiment, the leads of the EEG electrodes **440** are connected to a chip **420** by wires or other suitable electrical connections, such a as a printed circuit, flex circuit, etc.

The sensor **410** may also include a temperature sensor (not shown). In an embodiment, the temperature sensor includes a thermistor with the thermistor leads exposed on a patient contacting side of the tape **430**, in order to facilitate the contacting of the leads of temperature sensor to a measurement site of a patient's skin. In an embodiment, the temperature sensor is connected to single chip through wires or other suitable electrical connections such as a flexible printed circuit. In an embodiment, the temperature sensor may be located anywhere on the tape **430**, the disposable portion or the reusable portion of the sensor **410** (if the sensor is provided with disposable and reusable portions). In an embodiment, the leads for the temperature sensor may be near the center of tape **430** or anywhere on the periphery of tape **430**.

In some embodiments, the sensor **410** includes a pulse oximeter sensor (not shown). The pulse oximeter sensor can include an ear pulse oximeter sensor that emits and detects radiation to determine the oxygenation of the blood travelling through the arteries of the ear. Many suitable ear pulse oximeter sensors are known in the art such as those sensors commercially available from Masimo Corporation and disclosed herein with reference to U.S. Pat. No. 7,341,599, which is expressly incorporated by reference in its entirety. In another embodiment, the pulse oximeter sensor may be a forehead pulse oximeter sensor or any other suitable pulse oximeter known in the art or disclosed herein. The pulse oximeter sensor may be connected to the sensor **410** through electrical wires, wirelessly or other suitable electrical or data connection. Data collected from the pulse oximeter sensor may be transmitted to the depth of consciousness monitor **140**, pulse oximeter, or both for conditioning and further processing.

In some embodiments, signal processing and conditioning circuitry of depth of consciousness monitor configured to monitor the EEG signals of a patient and providing feedback on the depth of sedation or awareness of a patient undergoing anesthesia, may be partially or entirely incorporated into the sensor **410**. Sedation brain function monitors, including those similar to the SEDLINE sedation monitor commercially available from Masimo Corporation of Irvine, CA, as well as those described in U.S. Pat. Nos. 6,128,521, 6,301,493, 6,317,627, 6,430,437, all of which are expressly incorporated by reference in their entireties. For example, the sensor's connector or interface **450** may house the circuit board, with six channels for six detectors and a processor configured to determine depth of consciousness.

Integration of all or the majority of the associated circuitry and processing components of several different patient monitoring sensors in a single sensor advantageously provides a caregiver a simple device that can be attached to the patient's forehead and/or other areas on the patient, to provide minimal discomfort to the patient and minimal amount of wires and connections to cause electrical interference with instruments in the hospital environment. Additionally, the caregiver will spend less time attaching various sensors to a patient where each would otherwise require its own associated monitoring station. Furthermore, integration of sensor processing components allows some of the processing components to have shared functionality and therefore saves considerably on manufacturing costs. For example, memory chips, processors, or other electrical components may be shared by the various sensors.

EEG Signal Processing

Referring again to FIG. **2**, the depth of consciousness monitor's processor **220** is configured to receive at least an EEG signal from an EEG sensor **330** using an interface, such as an EEG interface **332** and process the EEG signal to determine the patient's depth of consciousness. In some embodiments, the processor **220** determines an index value between 0 and 100 to indicate depth of consciousness. The depth of consciousness monitor **140** may include a display, such as a monitor, LED, speaker, etc., to indicate the patient's depth of consciousness, e.g., the index value.

In some embodiments, the processor **220** determines the frequency content of the EEG signal prior to administration of any sedatives as well as during sedation. FIG. **4** illustrates one embodiment of a graph **500** showing the patient's EEG's frequency content or frequency spectrum prior to sedation as curve **510** and during sedation as curve **530**. Shifting of the curve **510** amplitude at frequencies below 10 Hz, a drop in curve slope at frequencies above 10 Hz, and the formation or increase in the frequency curve **510** to form a local maximum (e.g., local maximum **540**) at 10 Hz each indicates that the patient has entered a sedated state.

Indeed, in one embodiment, the processor **220** determines whether the patient is adequately sedated by monitoring for the presence of a local maximum **540** in the frequency curve **530** above a predetermined threshold value, at 10 Hz. However, the shape of the frequency curve **530** can vary based upon several factors, such as any one or more of the patient's age, age classification (e.g., pediatric, adult, geriatric, etc.), sex, weight, body-mass index, genetic factors, etc. The shape of the frequency curve **530** can also vary based upon one or more physiological parameters associated with the patient, such as the patient's temperature, blood oxygen concentration, EMG signal, etc. Furthermore, the shape of the frequency curve **530** can also vary based upon the particular drug administered to sedate the patient. For example, the drug type, drug class (e.g., hypnotic, analgesic, opiate, etc.), mechanism or method of delivery (inhalant, intravenous, ingestible, etc.) and/or particular active ingredient (e.g., Propofol (TIVA), Sevoflurane, nitrous oxide, morphine, etc.) can each affect the shape of the frequency curve **530**. Variations in the frequency curve **530** make it more difficult for the depth of consciousness monitor **140** to accurately determine whether the patient is adequately sedated.

Therefore, to improve accuracy, in one embodiment the depth of consciousness monitor's processor **220** analyzes the frequency curve **530** by considering one or more curve profiles associated with the patient and/or the drug administered. For example, in one embodiment, the processor **220** obtains physiological information regarding the patient from sensors **120** attached to the depth of consciousness monitor **140**. In other embodiments, the processor **220** obtains physiological information regarding the patient via a data port.

For example, the data port can receive temperature, blood oxygen saturation, respiration rate, and/or other physiological parameter information from an separate monitor. In addition, the depth of consciousness monitor **140** can receive additional information regarding the patient and the drug via the data port, as well.

For example, in some embodiments, the data port includes a wireless radio, a network adapter, a cable, an Ethernet adapter, a modem, a cellular telephone, etc., to receive patient and/or drug information. The patient and/or drug information is provided to the processor **220** to accurately interpret the frequency curve **530** derived from the EEG sensor **330** signal. In one embodiment, the data port includes a keyboard or other data entry device that allows the clinician to manually inter data relating a patient or drug parameters, such as those examples described above. Indeed, the processor **220** can include one or more EEG processing engines that are configured based upon the patient and/or drug data received by the depth of consciousness monitor **140**, as discussed in greater detail below.

In some embodiments, the patient's frequency response graph **500** is processed as four distinct, non-overlapping frequency bands **550**, **552**, **554**, **556**. For example, the first frequency band, sometimes referred to as the delta band, is the portion of the graph **500** between 0 and 4 or about 4 Hz. The second frequency band, sometimes referred to as the theta band, is the portion of the graph **500** between 4 or about 4 Hz and 7 or about 7 Hz. The third frequency band, sometimes referred to as the alpha band, is the portion of the graph **500** between 7 or about 7 Hz and 12 or about 12 Hz; and the fourth frequency band, sometimes referred to as the beta band, is the portion of the graph **500** greater than 12 or about 12 Hz.

In some embodiments, the depth of consciousness monitor **140** determines whether there is a peak **540** greater than a predetermined threshold in the frequency curve **530** anywhere within the alpha band **554**. If so, the monitor **140** may determine that the patient is adequately sedated. However, in some cases, the peak **540** can shift and appear outside of the alpha band **554**. For example, a sedated patient that is experiencing hypothermia may not manifest a peak in the alpha band; instead, the peak may shift to the theta or beta bands.

Therefore, in one embodiment, the depth of consciousness monitor **140** does not limit its search for a peak **540** to a particular frequency value (e.g., 10 Hz) or a particular frequency band (e.g., alpha band **554**). Instead, in such an embodiment, the depth of consciousness monitor **140** scans across all frequencies (or a larger subset of frequencies than just those within the alpha band) to search for a peak **540** (e.g., across two or more frequency bands). A detected peak may be used to determine alone (or in combination with other patient and/or drug data) whether the patient is adequately sedated.

The peak **540** can be defined in any of a variety of clinically-relevant manners. For example, the peak **540** can be defined based upon the slope of the curve segment on one or both sides of the peak **540**, the relative magnitude of the peak compared to the curve values at predetermined locations or offsets on either side of the peak **540**, the relative magnitude of the peak compared to the frequency curve **510** of the patient obtained prior to sedation, etc.

In one embodiment, the processor **220** processes the patient's frequency spectra curve **510**, **530** as deformable curves by utilizing motion vector processing. For example, the processor **220** compares each point (or a predetermined number of points) in the pre-sedation curve **510** to points within the sedation frequency curve **530** to match points having the greatest similarity (e.g., relative position with respect to its neighbors, pattern matching, sum of absolute differences, any pattern matching technique, etc.). The processor **220** determines one or more motion vectors **560** to describe the motion of the points from one curve **510** to the next **530**. Each motion vector **560** includes both direction and amplitude (e.g., distance traveled) information. Although the graph **500** includes curve **510**, **530** illustrated in the frequency domain (the x-axis represents frequency), the motion vectors **560** include time domain information. For example, the processor **220** can look at multiple frames of data (e.g., multiple graphs **500**) and employ pattern matching techniques (e.g., sum of absolute differences) to determine which points in the graphs **500** and their curves **510**, **530** to use to define the respective motion vectors **560**. In some embodiments, the motion vectors **560** are determined at 0.5, 1, 2, or 2.5 Hz intervals.

One or more motion vector **560** profiles may be constructed based upon particular drug and patient data. For example, each drug used for sedation may be characterized by a unique set of motion vectors. When a patient is treated with a particular drug, and the patient's motion vectors match those of the drug (e.g., the drug profile), the processor **220** can determine that the patient is adequately sedated. Such profiles may be determined for any one or more of the patient's age, age classification (e.g., pediatric, adult, geriatric, etc.), sex, weight, body-mass index, genetic factors, etc., physiological parameters associated with the patient, such as the patient's temperature, blood oxygen concentration, EMG signal, etc., the particular drug administered to sedate the patient, the drug type, drug class (e.g., hypnotic, analgesic, opiate, etc.), mechanism or method of delivery (inhalant, intravenous, ingestible, etc.) and/or particular active ingredient (e.g., Propofol (TIVA), Sevoflurane, nitrous oxide, morphine, etc.). Such profiles may be stored within the depth of consciousness monitor's memory, or they may be retrieved from one or more data repositories stored at one or more remote locations (e.g., over a computer network, over the Internet, from a server, from the cloud, etc.).

In another embodiment, the EEG front end circuitry is configured not to eliminate or filter out low frequencies. The EEG front end circuitry instead allows the processor **220** to determine slow waves (e.g., time-domain signals at or below 1, 0.5, and/or 0.2 Hz). The processor **220** can employ one or more phase coherence methods to detect phase coherence between one or more slow waves and one or more patient signals falling within one of the frequency bands **550**, **552**, **554**, **556**. For example, in some embodiments, phase coherence between a slow wave and a signal from the theta band **552** indicates that the patient is awake. Once the slow wave and signal from the theta band **552** are out of phase, the patient is sedated. In other embodiments, phase coherence analysis is performed to compare phase coherence between a selected slow wave and a different frequency band's signals (e.g., the delta band **550**, the alpha band **554**, and/or the beta band **556**). In some embodiments, the processor **220** performs phase coherence analysis between a selected slow wave and multiple signals between 4 and 50 Hz, e.g., every 0.2, 0.5, 1, or 2 Hz. In other embodiments, phase coherence is determined along the entire frequency spectrum.

In yet another embodiment, the processor **220** generates and/or utilizes a mathematical or electrical model of brain activity to determine whether the patient is adequately sedated. The model can be used to predict what the EEG of a sedated patient should look like based upon a particular drug, drug delivery mechanism, concentration (or any other drug parameter, including those discussed above). Actual EEG signals may be compared to the signal predicted by the model to determine whether the patient is adequately sedated. The model can be constructed of various combinations of electrical components (e.g., resistors, capacitors, amplifiers, etc.) or computing elements.

In one embodiment, brain modeling occurs by storing EEG signals from sedated patients in a memory location and categorized the EEG signals based upon any of a variety of drug and patient data information. For example, sedated EEG signals may be categorized based upon the particular drug, dosage, concentration, delivery method, etc. used to treat the patient. A brain response model is constructed by combing the various data into a single model.

In some embodiments, the processor **220** includes a pre-processor **602**, a compute engine **604**, and a post processor **606**, as illustrated in FIG. **5**. The patient's EEG signal is received by the pre-processor **602**. The pre-processor **602** performs front end processing, such as one or more of filtering, amplification, A/D sampling, decimation, demodulation, etc. of the EEG signal. In some embodiments, the pre-processor **602** includes the EEG front end functionality discussed above with respect to FIG. **2**. The compute engine **604** determines the level of patient sedation and/or depth of consciousness utilizing, for example, any of the techniques described herein. In one embodiment, the compute engine **604** determines an index value representative of the patient's sedation level. The post-processor **606** provides an indication of the patient's sedation level as well as other relevant information (e.g., system delay, as discussed above, other physiological parameter information, pass-through signals, etc.) for display to the clinician and/or transmission to a drug delivery device or other physiological monitor or information display station. In some embodiments, the post-processor **606** stores patient sedation, EEG signals, patient data and drug information in a memory location.

Another embodiment of a processor **220** is illustrated in FIG. **6**. The processor **220** includes a pre-processor **602**, multiple compute engines **604***a*, **604***b*, . . . **604***n*, and decision logic **608**. Each compute engine **604***a*, **604***b*, . . . **604***n* determines patient sedation information utilizing different processing approaches. For example, one compute engine **604** may determine patient sedation information utilizing motion vector analysis (e.g., as discussed above), one compute engine **604** may determine patient sedation information utilizing frequency coherence analysis (e.g., as discussed above), etc. Furthermore, each compute engine **604** can be drug or patient information specific. For example, the compute engine **604** may utilize historical information (either of the patient himself or from a model, etc.) to determine patient sedation. Each compute engine **604** could therefore correspond to a particular patient's age, age classification (e.g., pediatric, adult, geriatric, etc.), sex, weight, body-mass index, genetic factors, etc., physiological parameters, such as temperature, blood oxygen concentration, EMG signal, etc., the particular drug administered to sedate the patient, such as the drug type, drug class (e.g., hypnotic, analgesic, opiate, etc.), mechanism or method of delivery (inhalant, intravenous, ingestible, etc.) and/or particular active ingredient (e.g., Propofol (TIVA), Sevoflurane, nitrous oxide, morphine, etc.). The compute engines **604** may operate simultaneously to parallel process EEG information.

A decision logic module **608** receives the outputs of each compute engine **604** and applies logic to determine the best estimate of the patient's sedation level. For example, in some embodiments, the decision logic module **608** averages or weighted averages the outputs of the compute engines **604**. In other embodiments, the decision logic module **608** selects one or more compute engine outputs based upon known information about the patient and/or drug(s) used for sedation. The decision logic output **610** can indicate one or more parameters relevant to patient sedation. For example, in some embodiments, the decision logic output **610** includes suppression bar, EMG estimation, patient sedation index, drug type and patient age estimates. If any one or more decision logic outputs do not match actual drug or patient profile information, an alarm can activate. In other embodiments, the clinician manually compares the decision logic outputs to actual drug and patient profile information to confirm the accuracy of the depth of consciousness monitor **140**.

Another embodiment of a depth of consciousness monitor's processor **220** is illustrated in FIG. **7**. The processor **602** includes a pre-processor **602**, compute engines **604** and decision logic **608**, as discussed above with respect to FIG. **6**. In addition, the processor **220** includes an EEG engine **620** and an EMG engine **630**. The EEG and EMG engines receive a pre-processed EEG signal from the pre-processor **602**. The pre-processed EEG signal will generally contain both EEG and EMG content. For example, EEG content describes the electrical activity within the patient's brain and the EMG content describes the electrical activity associated with the muscular contractions in the patient's forehead, near the EEG sensor. The EEG and EMG engines **620**, **630** separate the EEG and EMG content from the pre-processed EEG signal. The outputs of the EEG and EMG engines **620**, **630** communicate with the inputs of one or more compute engines **604**. The EEG signal from the EEG engine provides an indication of the patient's hypnotic state, while the EMG engine provides an indication of the patient's analgesic response, or pain state. Separating the two provides more information about the patient's state, and allows improved depth of consciousness processing. When EMG content is included in the EEG signal, the frequency response curve is flatter at higher frequencies (e.g., at frequencies in the beta band).

FIG. **8** illustrates one embodiment of a process **700** to determine a patient's sedation level that can be implemented by any of the processors described above. The process **700** begins at block **702**. At block **702**, the process **700** receives an EEG signal from a patient. At block **704**, the process **700** receives treatment data. The treatment data may include one or more of patient data and drug profile information. The patient data can include any of the patient data or drug profile information described above. At block **706**, the process **700** selects a computing engine based upon one or more treatment data. At block **708**, the process **700** computes patient sedation information using EEG information and the selected computing engine. The patient sedation information can include one or more of a patient sedation level or index, an EMG level, a prediction of the drug used to sedate the patient, a prediction of the patient's age, etc. The process **700** ends at block **708**.

FIG. **9** illustrates another embodiment of a process **800** to determine a patient's sedation level that can be implemented by any of the processors described above. The process **800** begins at block **802**. At block **802**, the process **800** receives an EEG signal from a patient. At block **804**, the process **800** receives treatment data. The treatment data may include one or more of patient data and drug profile information. The patient data can include any of the patient data or drug profile information described above. At block **806**, the process **800** computes patient sedation information with parallel computing engines using the EEG information. The patient sedation information can include one or more of a patient sedation level or index, an EMG level, a prediction of the drug used to sedate the patient, a prediction of the patient's age, etc. At block **808**, the process **800** determines patient sedation information by selecting the output of one of the parallel computing engines, or by combining one or more computing engine outputs (e.g., averaging, weighted averaging, etc.). The process **800** ends at block **808**.

FIG. **10** illustrates one embodiment of a depth of consciousness monitoring system **1000**. The system **1000** includes a depth of consciousness monitor assembly **1002**, a multi-parameter monitor **1012**, and a sensor **1014**. The monitor assembly **1002** includes a depth of consciousness processor **1003**, which can include any of the processors described above. In some embodiments, the processor **1003** is configured to perform one or more of the methods described above.

The assembly **1002** may be provided in the form of a cable. For example, the assembly **1002** may include one or more cables **1004** (or cable portions) that terminate in connectors **1005**, **1008** located at the cable ends **1006**, **1010**. In the illustrated embodiment of FIG. **10**, the assembly **1002** includes two cables **1004**. The first cable **1004** has two ends and is coupled to the processor **1003** at one end and terminates at a connector **1005** at the other end **1006**. In one embodiment, the connector **1005** (which is one embodiment of an interface, such as a multi-parameter monitor interface) is configured facilitate communication between the processor **1003** and a medical device, such as a physiological monitor, display instrument, and/or a multi-parameter monitor **1012**, etc. In some embodiments, the connector **1005** receives power from a multi-parameter monitor **1012** to power the depth of consciousness processor **1003**. In some embodiments, the processor **1003** is configured to consume less than about 250 mW, 500 mW or 1 W at about 4.75 V, 5 V or 5.25 V.

Physiological signals generated by the depth of consciousness processor **1003** are communicated to the multi-parameter monitor **1012** via the connector **1005**. The multi-parameter monitor **1012** is configured to display one or more of the signals generated by the depth of consciousness processor **1003**. In one embodiment, the cable **1004** that terminates at the multi-parameter monitor **1012** connector **1005** is configured to provide and/or receive power, ground, data+ and data− signals. For example, in one embodiment, the cable **1004** includes four conductors, one each for power, ground, data+ and data−.

An adapter or coupler (not shown) may be provided to facilitate coupling of the connector **1005** to the multi-parameter monitor **1012**. For example, an adapter having first and second ends can be configured to have different shapes and pin configurations to allow communication and physical coupling of the connector **1005** to the multi-parameter monitor **1012**. In some embodiment, the adapter (not shown) also includes conditioning circuitry to facilitate communication and/or power transmission between the multi-parameter monitor **1012** and the processor **1003**. For example, the adapter may provide voltage regulation, electrical isolation, signal multiplexing, etc.

The second cable **1004** has two ends and is coupled to the processor **1003** at one end and terminates at a connector **1008** at the other end **1010**. In one embodiment, the connector **1008** is configured to facilitate communication with a physiological sensor **1014**, such as an EEG sensor, and/or any other sensor described above via an interface **1015** (e.g., interface **450** of FIG. **3**). In one embodiment, power from the multi-parameter monitor **1012** is directly or indirectly (e.g., after further filtering, conditioning, pulsing, etc. by the processor **1003**) communicated to the sensor **1014**. Signals (e.g., e.g., measured patient signals) from the sensor **1014** are communicated to the processor **1003** via the interface **1015**, which can be coupled to the connector **1008**.

FIG. **11** illustrates another embodiment of a depth of consciousness monitoring assembly **1002** coupled to a multi-parameter monitor (sometimes referred to as a multi-parameter instrument) **1012**. The multi-parameter monitor **1012** is configured to receive and display a plurality of physiological parameters received from a patient monitoring device, such as, but not limited to, the depth of consciousness monitoring assembly **1002**. The multi-parameter monitor **1012** includes a display **1020**. The display **1020** is configured to display a plurality of physiological signals **1022** related to a medical patient. In some embodiments, the display **1020** can be configured to display only selected or groups of physiological signals **1022**. In some embodiments, the monitor **1012** can be configured to display a particular view or mode on the display **1020**. The view or mode can include one or more pre-selected groupings of physiological signals to display. Examples of different views that may be provided via the display **1020** are discussed below with respect to FIGS. **14-16**. Other views, in addition to or instead of those illustrated in FIGS. **14-16** may be displayed on the multi-parameter monitor **1012** display **1020**, as well.

In some embodiments, the multi-parameter monitor **1012** also includes a removable module **1024**. The removable module **1024** can include a physiological monitor configured to determine one or more physiological parameters associated with the medical patient. For example, in some embodiments, the removable module **1024** includes a respiration rate monitor, a blood oxygen saturation monitor, a blood gas monitor, a carbon monoxide monitor, an ECG monitor, an EKG monitor, a blood pressure monitor, a temperature monitor, a heart rate monitor, etc., or a combination of any one or more of the foregoing.

In the illustrated embodiment of FIG. **11**, the depth of consciousness monitor assembly **1002** only includes one cable **1004**. A first end of the cable **1004** terminates at a connector (not shown) that is attached to the multi-parameter monitor **1012**. The second end of the cable **1003** includes the depth of consciousness processor **1003** and connector **1008**, which are integrated within a single housing assembly. The connector end of a sensor **1014** is shown attached to the depth of consciousness monitor assembly's **1002** cable's **1003** second end.

FIG. **12** illustrates another embodiment of a depth of consciousness monitor assembly **1002**. The processor **1003** is positioned between the ends **1006**, **1010** of the assembly **1002**. The length of the cable **1004** attached to the connector **1008** configured to attach to a sensor (not shown) may be shorter than the length of the cable **1004** attached to the connector **1005** configured to attach to the multi-parameter monitor (not shown). The shorter sensor cable **1004** length can provide additional comfort and less pulling on the sensor when attached to the patient. FIG. **13** illustrates the depth of consciousness monitor assembly **1002** coupled to a sensor **1014**. The sensor **1014** can include any of the EEG sensors described above.

FIGS. **14-16** illustrate views of various parameters **1022** that may be displayed on the multi-parameter monitor **1012** display **1020**. The embodiment of FIG. **14** illustrates an EEG view of a multi-parameter monitor **1012**. The multi-parameter monitor **1012** view includes a numeric value indicator (e.g., EEG data, insufficient EEG data, patent state index (PSI) value), or any other value described herein, etc.), a bar-graph indicator, menu indicators, date and time indicators, message indicators, physiological waveform indicators, and system status indicators. The physiological waveform indicators can display each of the waveforms received from each electrode (e.g., R**2**, R**1**, L**1**) of an sensor **1014**, such as an EEG sensor.

FIG. **15** illustrates a trend view of a multi-parameter monitor **1012**. The multi-parameter monitor **1012** view includes a primary indicator or display and a secondary indicator or display. The primary indicator displays the trend of one or more physiological parameters (e.g., PSI, etc.) over time. One or more secondary indicators can display additional physiological parameters of the medical patient, including but not limited to, EMG, and SR. In one embodiment, the secondary indicators display information in the same format (e.g., waveform, solid waveform, bargraph, etc.) as the primary (e.g., trend plot) indicator, but at a smaller size. In other embodiments, the secondary indicators display information in a different format than the primary (e.g., trend plot, etc.) indicator. FIG. **16** illustrates a density spectral array view of a multi-parameter monitor **1012**. The multi-parameter monitor **1012** view includes a spectral density indicator

Each of the displayed physiological parameters can be determined by the depth of consciousness processor **1003**. In addition, the multi-parameter monitor **1012** can be configured to display any one or more of the parameters discussed above, as well as other parameters, such as signals from the removable module **1024**, when provided.

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

Depending on the embodiment, certain acts, events, or functions of any of the processes or algorithms described herein can be performed in a different sequence, can be added, merged, or left out altogether (e.g., not all described operations or events are necessary for the practice of the algorithm). Moreover, in certain embodiments, operations or events can be performed concurrently, e.g., through multi-threaded processing, interrupt processing, or multiple processors or processor cores or on other parallel architectures, rather than sequentially.

The various illustrative logical blocks, modules, routines, and algorithm steps described in connection with the embodiments disclosed herein can be implemented as electronic hardware, computer software, or combinations of both. To clearly illustrate this interchangeability of hardware and software, various illustrative components, blocks, modules, and steps have been described above generally in terms of their functionality. Whether such functionality is implemented as hardware or software depends upon the particular application and design constraints imposed on the overall system. The described functionality can be implemented in varying ways for each particular application, but such implementation decisions should not be interpreted as causing a departure from the scope of the disclosure.

The steps of a method, process, routine, or algorithm described in connection with the embodiments disclosed herein can be embodied directly in hardware, in a software module executed by a processor, or in a combination of the two. A software module can reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard disk, a removable disk, a CD-ROM, or any other form of a non-transitory computer-readable storage medium. An example storage medium can be coupled to the processor such that the processor can read information from, and write information to, the storage medium. In the alternative, the storage medium can be integral to the processor. The processor and the storage medium can reside in an ASIC. The ASIC can reside in a user terminal. In the alternative, the processor and the storage medium can reside as discrete components in a user terminal.

Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or steps. Thus, such conditional language is not generally intended to imply that features, elements and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or steps are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list.

Conjunctive language such as the phrase "at least one of X, Y and Z," unless specifically stated otherwise, is to be understood with the context as used in general to convey that an item, term, etc. may be either X, Y, or Z, or a combination thereof. Thus, such conjunctive language is not generally intended to imply that certain embodiments require at least one of X, at least one of Y and at least one of Z to each be present.

While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it can be understood that various omissions, substitutions, and changes in the form and details of the devices or algorithms illustrated can be made without departing from the spirit of the disclosure. As can be recognized, certain embodiments of the inventions described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others. The scope of certain inventions disclosed herein is indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A depth of consciousness monitor configured to determine a level of sedation of a medical patient, the depth of consciousness monitor comprising:

an EEG interface configured to receive an EEG signal from an EEG sensor;

an EEG front end configured to pre-process the EEG signal, wherein the EEG signal is assigned a first time stamp;

a processor, configured to determine the level of sedation of the medical patient based at least upon the pre-processed EEG signal, the processor comprising:

two or more parallel computing engines, each configured to receive as an input a same first time stamped pre-processed EEG signal and compute a possible sedation level according to a different processing approach, each processing approach configured to simultaneously calculate the possible sedation level using the same first time stamped pre-processed EEG signal; and

a decision logic module, configured to arbitrate the possible sedation level computations as computed by the two or more parallel computing engines on the same first time stamped pre-processed EEG signal and based on the arbitration, determine a patient sedation index corresponding to an estimated level of sedation of the medical patient, wherein the arbitration comprises selecting a subset of possible sedation levels generated by the two or more parallel compute engines, wherein the arbitration is based at least on data associated with at least one sedation drug acting on the medical patient and the selected subset of possible sedation levels generated by the two or more parallel compute engines; and

a data port configured to transmit the level of sedation of the medical patient.

2. The depth of consciousness monitor of claim **1**, wherein the data port comprises a multi-parameter physiological monitor interface configured to receive power from a multi-parameter physiological monitor and provide at least the level of sedation of the medical patient to the multi-parameter physiological monitor.

3. The depth of consciousness monitor of claim **1**, wherein at least one of the computing engines is configured to implement a motion vector process to compute one of the possible sedation levels.

4. The depth of consciousness monitor of claim **1**, wherein at least one of the computing engines is configured to implement a phase coherence process to compute one of the possible sedation levels.

5. The depth of consciousness monitor of claim **1**, wherein at least one of the computing engines is configured to utilize a brain model to compute one of the possible sedation levels.

6. The depth of consciousness monitor of claim **1**, wherein the EEG front end comprises an EEG engine and an EMG engine configured to extract EEG information and EMG information from the EEG signal, respectively.

7. The depth of consciousness monitor of claim **1**, wherein the data port comprises a display.

8. The depth of consciousness monitor of claim **1**, wherein the data port comprises a wireless communication device.

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