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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 May 2007 (24.05.2007)

PCT

(10) International Publication Number
WO 2007/059248 A2

(51) International Patent Classification:
A61B 5/04 (2006.01)

(21) International Application Number:
PCT/US2006/044414

(22) International Filing Date:
15 November 2006 (15.11.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/736,772 15 November 2005 (15.11.2005) US

(71) Applicant *(for all designated States except US)*: **HOSPIRA, INC** [US/US]; 275 NORTH FIELD DRIVE, Lake Forest, IL 60045-2579 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **MARRO, Dominic, P.** [US/US]; 57 COLONIAL AVENUE, North Andover, MA 01845 (US). **ORTEGA, Henry, R.** [US/US]; 22 LANCASTER ROAD, Hampstead, NH 03841 (US).

(74) Agents: **WOODWORTH, Brian, R.** et al.; 275 North Field Drive, NLEG, H1, Lake Forest, IL 60045-2579 (US).

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2007/059248 A2

(54) **Title:** SYSTEM FOR MONITORING AND SEPARATING EEG AND EMG SIGNALS

(57) **Abstract:** A method for measuring a patient's level of sedation. The method includes the step of providing a plurality of electrodes constructed to be placed on a patient's body. The plurality of electrodes define a plurality of electrical channels therebetween. The method further includes the step of mounting the plurality of electrodes on a patient's body. The plurality of electrodes, and the electrical channels defined therebetween, are then used to detect EMG and EEG signals on each of the plurality of electrical channels. The EMG and EEG signals detected on each of said plurality of electrical channels are then compared, and at least one of the plurality of channels with a lower signal magnitude is identified. The signal received by the identified channel or channels is used to calculate a patient's level of sedation using known techniques for performing such calculations.

SYSTEM FOR MONITORING AND SEPARATING EEG AND EMG SIGNALS

Cross Reference To Related Application

[0001] This application claims priority based upon United States Provisional Application Serial No. 60/736,772 filed November 15, 2005 which is expressly incorporated herein by reference in its entirety.

Field of the Invention

[0002] The present invention relates to a system and method for acquiring and analyzing EEG and EMG signals to determine a patient's depth of sedation. In particular, the present invention relates to a system and method for identifying channels that are free from, or are minimally affected by, EMG activity and utilizing the signals on such identified channels to determine a patient's depth of sedation.

Background of the Invention

[0003] Most patient sedation monitoring devices use acquired electroencephalograph ("EEG") signals as the basis for calculating a patient's depth of sedation. EEG signals are acquired from surface electrodes placed on the forehead of a patient. The signals acquired from these electrode sites typically are comprised of both EEG and electromyograph ("EMG") signals generated by the patient. The EEG spectrum used to determine a patient state index (PSI), bi-spectral index (BIS), and Spectral Entropy (described below) spans the frequency space from 0.5 Hz to just below 50 Hz and represents the summation of electric fields created by the pyramidal cells of the patient's cerebral cortex. An EMG measurement from the same electrodes will span the frequency space from 12 to 500 Hz. EMG signal power can exceed EEG signal power at frequencies above 12 Hz. (See Figure 1), thereby interfering with determinations of a patient's sedation level based upon the patient's EEG signals. Signal frequencies above 50 Hz are sometimes corrupted by environmental electromagnetic interference from the various electronic devices used in medical facilities, particularly in operating rooms. Baseline electrode and amplifier noise can also be a limiting factor for EEG measurements in deeply sedated patients.

[0004] The term "EEG Spectrum" refers to the power (or magnitude) as a function of frequency in an EEG signal.

[0005] The term "Spectral Entropy" is a term used in connection with Datex-Ohmeda's patient sedation monitoring systems. As used and defined by Datex-Ohmeda, Spectral Entropy incorporates two elements that are used to define a patient's sedation state. The first element is State Entropy which is representative of the patient's hypnotic state. State Entropy is reflective of signal activity in the 0.5 – 32 Hz frequency range. Response Entropy reflects signal activity in the 0.5 to 48 Hz range and thereby includes signals in the EEG Gamma band (25 – 50 Hz) and signals reflecting EMG activity. Thus, Response Entropy is more reactive than State Entropy because of its sensitivity to signals in the 32 – 48 Hz range.

[0006] An EEG based hypnotic index provides an estimate of the patient's level of hypnosis or sedation. An EMG signal may provide an indication of the patient's level of stress but provides no direct indication of a patient's level of hypnosis or sedation. EMG activity may be cognitively induced when the patient is aware of his surroundings, or it may be physiologically induced from painful stimuli or reduced body temperature. The presence of this stress indicator, i.e., the EMG signal, may of the need for an appropriate intervention, e.g., administration of additional anesthesia or muscle relaxants to the patient. However, the presence of EMG signals (whether caused by pain stimuli or hypothermia) may interfere with an accurate determination of the patient's hypnotic index. Exclusion of EMG signal's effect upon the EEG signal should reduce the incidence of falsely elevated PSI, BIS or State Entropy readings for patients. The clinical significance of EMG during hypothermia has not been established.

[0007] An awake patient presents a relatively flat EEG spectrum, as indicated by the dashed black plot in FIG. 1. Under "patient awake" conditions, the gamma band EEG power (25 to 50 Hz) can mask underlying EMG signals due to their relative amplitudes. On the other hand, in sedated patients, EMG signals can mask or otherwise be confused with the gamma band EEG signal because EEG amplitudes are significantly reduced when the patient is sedated. In normothermic sedated patients, as indicated in FIG. 1, EMG signals, as represented by the blue and green plots in FIG. 1, can mask an underlying EEG signal in the spectral band above 25Hz. EMG signals can be present anywhere in the full span of consciousness from the awake state through the deep sedation state, including electrocerebral silence.

[0008] By way of example, during cardiopulmonary bypass procedures, hypothermia increases the probability of both significant EMG activity and low EEG power. When this happens, the spectral signature of the EMG signal can mask the presence of EEG down to approximately 12 Hz. Processed EEG parameters that are derived under these circumstances from the spectral properties of EEG above 12 Hz, such as PSI, BIS, and State Entropy, can give a false indication of a higher arousal state because of the presence of increased EMG signals caused by hypothermia and possibly caused by the surgical procedure itself. (See Figure 1). In short, current methods for determining the sedation state of a patient using EEG signals can be significantly affected by the presence of EMG signals, particularly when the patient is under sedation.

[0009] Current methods for the detection of facial EMG utilizing only one or two leads are unreliable because of the focal properties of EMG. EMG signals appear randomly at one or another of multiple facial electrodes (i.e., are "focused"), but do not usually appear at all of the electrodes, or multiple electrodes, simultaneously at the same magnitude. In contrast to the focused nature of EMG activity, EEG activity tends to be symmetrical across all of the electrodes.

[0010] Figure 5 provides an example of an EEG measure sensitive to the presence of EMG. Figure 5 demonstrates the non-uniform distribution of EMG in a typical four-channel montage. EMG power is not distributed with the same symmetry or uniformity as EEG across the forehead. Unlike the EEG, EMG, when present, is measured at different levels on any combination of channels. This property of the EMG makes its detection from a single channel unreliable, thereby reducing its consistency as a measure, and ultimately calling into question its utility. Currently available patient sedation monitoring systems do not dependably identify and separate EMG signal power from the EEG component to produce a reliable hypnotic index.

[0011] Changes in EEG and EMG activity in response to patient exposure to sedative drugs, painful stimuli, and hypothermia occur independently. EEG and EMG derived terms are most useful as measures of patient sedation state if they can be quantified independently. An artifact free EEG, without an underlying pathology, has significant spectral symmetry between homologous scalp-placed or forehead-placed electrode pairs in sedated patients. See figures 2a & 2b. EMG may be present throughout the continuum of consciousness including isoelectric EEG.

[0012] The current techniques used to identify and separate EMG from EEG are inadequate, as above-discussed. For example, US Patent No. 6,032,072 (assigned to Aspect Medical Systems, Inc.) discloses an anesthesia monitoring system configured to detect both EEG and EMG signals in order to provide an enhanced ability to monitor the EEG signal. Aspect Medical Systems' anesthesia monitoring system uses signals in the range of 70 – 110 Hz to detect EMG from a single channel. The Aspect Medical anesthesia monitoring system incorporates a frequency domain based technique that utilizes an additional electrode to identify and EMG activity and distinguish it from EEG activity. However, the EMG activity can only be detected and accounted for by the Aspect Medical system when the EMG signal is detected at the electrode used to detect EMG activity.

[0013] Datex-Ohmeda's anesthesia monitoring system uses signals in the range from 32 – 48 Hz to detect EMG and/or EEG gamma band power from a single channel. The Datex-Ohmeda anesthesia system does not separately detect EMG or otherwise account for the possibility that the EEG signal is being masked by EMG activity.

[0014] The SEDLine™ patient sedation monitor (Hospira Sedation, Inc.) uses spectral and temporal measures from the processed EEG to estimate a level of sedation. The Hospira Sedation system measures the power of the signal (including EEG and EMG components) within a defined band. When that power is greater than zero, the power is averaged with the measured power on other channels in order to provide a power index. When the power index is above a threshold, it is identified as EMG and displayed as a single value and as an EMG trend. However, the Hospira Sedation system does not utilize the EMG power index in calculating a patient's level of sedation. The hypnotic state of the patient is preferably computed primarily from EEG derived terms that are unaffected by EMG signals. Increasing or fluctuating EMG power associated with a response to excessive stimulation from pain or other stresses such as hypothermia may negatively affect the analysis of EEG signals, thereby producing a false reading of a patient's level of sedation. Although this response may be predictive of a change in patient hypnotic state, it is not an indication of patient hypnotic state. The present invention addresses these EMG-related issues.

Summary of the Invention

[0015] A method for measuring a patient's level of sedation is provided by the present invention. The method includes the step of providing a plurality of electrodes constructed to be placed on a patient's body. The plurality of electrodes define a plurality of electrical channels therebetween in accordance with well known EEG techniques. The method further includes the step of mounting the plurality of electrodes on a patient's body in accordance with well known EEG techniques. The plurality of electrodes, and the electrical channels therebetween, are then used to detect EMG and EEG signals on each of the plurality of electrical channels defined by the plurality of electrodes. The EMG and EEG signals detected on each of said plurality of electrical channels are then compared, and at least one of the plurality of channels with a lower signal magnitude is identified. The signal received by the identified channel or channels is used to calculate a patient's level of sedation using known techniques for performing such calculations.

[0016] The present invention further provides a method for monitoring a patient's EMG signal. The method includes the step of providing a plurality of electrodes constructed to be placed on a patient's body. The method further includes the step of mounting the plurality of electrodes on a patient's body whereby pairs of the plurality of electrodes define a plurality of electrical channels therebetween. The EMG signals from two or more of the plurality of electrical channels defined between the plurality of electrodes are identified and used to calculate a patient's normalized EMG index.

Brief Description of the Figures

[0017] FIG. 1 depicts a plot of amplitude versus frequency for a plurality of electrode pairs (i.e., a plurality of electrical channels) for EEG and EMG signals received from patients in varying environmental and sedation conditions;

[0018] FIG. 2a depicts a plot of amplitude versus frequency for a plurality of electrical channels in a system in which no significant EMG activity is present;

[0019] FIG. 2b depicts a plot of amplitude versus frequency for a plurality of electrical channels in a system in which no significant EMG activity is present, and represents the basis for determining a constant K_1, as disclosed in detail herein;

[0020] FIG. 3 depicts a plot of amplitude versus frequency for a plurality of electrical channels in a system in which moderate EMG activity is present;

[0021] FIG. 4 depicts a plot of amplitude versus frequency for a plurality of electrical channels in a system in which significant EMG activity is present;

[0022] FIG. 5 depicts a z-score normalized value of the B2 band power across four channels of the Physiometrix PSA4000 system;

[0023] FIG. 6 depicts a difference between an optimized single channel system for detecting EMG activity and a system constructed in accordance with the present invention; and

[0024] FIG. 7 depicts EEG and EMG activity detected by a system constructed in accordance with the present invention.

Detailed Description of the Invention

[0025] The present invention can be used in any known EEG based patient hypnotic index system for measuring PSI, BIS, and/or State Entropy. For example, the present invention can be used in connection with systems configured for providing a Patient Sedation Index (PSI) (and electrode arrays associated therewith) as disclosed in US Patent Nos. 5,479,934; 5,520,603; 5,540,722; 5,718,719; 6,128,521; 6,301,493;

6,317,627; and 6,403,437, each of which is hereby expressly incorporated by reference.

[0026] The system of the present invention can employ two or more channels for the detection, quantification, and trending of EMG and EEG signals. In one embodiment of the present invention, four channels are used for the detection, quantification, and trending of EMG and EEG signals. Although the present invention will be disclosed and discussed herein in connection with a four channel embodiment, it is to be understood the present invention can be used in conjunction with any EEG system having two or more channels. The system of the present invention also is constructed to identify the channel, or channels, least affected by EMG activity and therefore best suited for computing an EEG based patient hypnotic index such as PSI, BIS or State Entropy. Identification of the channel (or channels) least affected by EMG allows the system of the present invention to provide a patient sedation level reading that is less affected by EMG signals than currently available systems. As above-discussed, this is an important advancement of over prior art systems that do not fully consider the impact of EMG activity.

[0027] In a four channel embodiment of the present invention, six electrodes are provided. Each electrode is configured for attachment to a preselected position on a patient. Standard placements of EEG electrodes are well known and understand by those of ordinary skill in the art. The six electrodes include four electrodes, i.e., electrodes 1 – 4, a reference electrode, and a ground electrode. The four channels are defined by (i) the voltage between electrode 1 and the reference electrode; (ii) the voltage between electrode 2 and the reference electrode; (iii) the voltage between electrode 3 and the reference electrode; and (iv) the voltage between electrode 4 and the reference electrode. The determination of the voltage between electrodes is well known and understand by those of ordinary skill in the EEG art. The system of the present invention can employ any known type of electrode and any known system and method for determining the voltage difference between electrodes 1 – 4 and the reference electrode.

[0028] Identification of the channel, or channels, least affected by EMG activity requires that the system of the present invention be configured to compare the signals received from each of the channels. Such a comparison can be accomplished using a CPU or other computer system well known to those of ordinary skill in the art. The

PCT/US06/44414

CPU analyzes the signals from each of the channels and identifies the channel or channels containing the least amount of EMG activity. EEG signal tends to be relatively symmetrical, thus the EEG contribution to the signal received on each channel is relatively constant. In contrast, and as above-discussed, EMG signals tend to be focused and therefore are not relatively constant on each of the channels. Accordingly, the system of the present invention detects the channel or channels affected by EMG activity by comparing the magnitude of the signals detected by each channel. The channel or channels having the lowest magnitude signal are the channel or channels least-affected by the EMG signal. The channel least-affected by EMG signal will tend to provide the most accurate calculation of a patient's sedation state. The EEG signal from the channel or channels thus identified by the CPU are then used to calculate a patient's sedation state. Such calculations can be undertaken using any of the known systems for determining a patient's sedation state, including systems currently marketed by Aspect Medical, Datex-Ohmeda, and Hospira Sedation, Inc.

[0029] The system of the present invention is configured to provide for the detection and quantification of EMG signals, as well as for the separation of EEG from EMG, thereby providing a more reliable measure of a patient's level of sedation. Separation of the EEG signal from the EMG signal produces a relatively artifact-free EEG signal. EMG lacks the spectral symmetry present in the EEG and this property is mathematically exploited to identify its presence. See Figures (2-4).

[0030] The system and method of present invention identify the channel, or channel, with minimal to no EMG activity, as explained above. Each channel is established between an electrode that can be mounted on a patient, preferably on the patient's forehead,. and a common reference electrode that also can be mounted on the patient, for example, at the patient's nasion.

[0031] The channels with minimal to no EMG power are used to compute a more precise estimate of a true EEG based level of hypnosis. See Figure 5.

[0032] In one embodiment of the present invention, the identification of the channel or channels least affected by EMG activity is identified by determining the standard deviation ($STDEV_N$) between the channels where N is an integer reflecting the number of channels being used by the system and comparing the standard deviation to a predetermined constant, "A". For example:

[0033] a. If $STDEV_N < A$, then no EMG is present. The PSI, BIS, or State Entropy is computed based upon the average spectrum computed from normalized homologous pairs of electrodes, i.e., according to standard, known methods for performing such computations.

[0034] b. If $STDEV_N \geq A$, then eliminate the channel with the highest power in the B2 band and recompute the $STDEV_{N-1}$. The B2 band can be any preselected band in which EMG activity may be present. For example, the B2 band can be in the 25 Hz – 50 Hz frequency range, a range in which EMG activity is present. It is to be appreciated that the B2 band should be a band that includes EMG activity. As above-discussed, EMG activity is typically present at frequencies of 12 Hz and higher.

[0035] c. If $STDEV_{N-1} < A$, then no EMG is present on the N-1 channels. The PSI, BIS, or State Entropy is then computed from the average spectrum computed from remaining normalized channels.

[0036] d. If $STDEV_{N-1} \geq A$, then eliminate the channel with the highest power in the B2 band and recompute the $STDEV_{N-2}$ for the remaining channels.

[0037] e. If $STDEV_{N-2} < A$, then no EMG is present on the N-2 channels. The PSI, BIS, or State Entropy is then computed from the average spectrum computed from remaining normalized channels.

[0038] f. If $STDEV_{N-2} \geq A$, then eliminate the channel with the highest power in the B2 band and recompute the $STDEV_{N-3}$ for the remaining channels. Continue this process until the STDEV is less than A and then compute the PSI, BIS, or State Entropy using the average spectrum of the remaining normalized channels.

[0039] As used in the foregoing example, "A" is a population based constant establishing a threshold for significance and is preferably higher than $STDEV_P$ where $STDEV_P$ is the standard deviation of a system operating in an EMG-free sedated patient population. It will be appreciated that "A" can be varied dependent upon the level of sensitivity desired. For example, "A" can be equal to 1.2 – 2.5 times $STDEV_P$. In one embodiment, "A" is equal to approximately s times $STDEV_P$.

[0040] Alternatively, the channel with the least (or no) EMG activity can be identified simply by comparing the voltages of the signals for each channel and selecting the channel or channels having the lowest signal magnitude. Using standard designations for electrode pairs (and thus channels) used in known EEG systems, the following is an example of how such a comparison and identification of the least-affected channel or channels can be undertaken:

[0041] a. Compute the B2 power from the bipolar derivations of F8-FP2 and F7-FP1.

[0042] b. If the absolute value of $|B2_{(F8\text{-}FP2)} - B2_{(FP1\text{-}F7)}| > A$, determine which hemisphere has the lowest power in the B2 band.

[0043] c. Select the signal processing montage with the lowest hypnotic index resulting from B2 asymmetry.

[0044] d. If $[B2_{(F8\text{-}FP2)} - B2_{(FP1\text{-}F7)}] \leq A$, use the average of or either spectrum to compute the patient's EEG-based hypnotic index.

[0045] The present invention also can be configured to provide an estimate of the EMG power associated with the signals being received by the electrodes. The EMG power can then normalized to generate an EMG index.

[0046] The following defines a normalized EMG index derived from a plurality of symmetrically placed electrodes. The index is scaled from 0 to 100. (See Figure 6)

[0047] EMG Index = (((M-STDEV) + K2) * STDEV/8.8)*100-THR2. where:

[0048] M is the Mean Spectral Power in a defined spectral band from selected leads.

(e.g., M = [(FP2+FP1)/2 + K1 + (F8+F7)/2]/2.) (By way of example, and not by way of limitation, the spectral band B2 used can be from 25 – 50 Hz. Frequency bands and/or coefficients can be adjusted to provide similar or improved EMG detection sensitivity and noise immunity.)

[0049] STDEV = Standard Deviation Spectral Power in a defined band from selected leads.

[0050] K1 is a population-based normalization constant used to adjust for a fixed offset between homologous electrode pairs. (By way of example, for the Physiometrix PSA™ array, K1 represents the population-based difference between the Fp1/Fp2 pair and the F7/F8 pair. Alternatively, K1 may be derived by computing the difference between these homologous pairs by averaging the power in a band unaffected by EMG, such as the band defined by the dominant peak frequency +/- 2 Hz which for normothermic patients is between 8 & 12 Hz.)

[0051] K2 = a scaling coefficient, e.g., K2 = 3.9

[0052] THR2 = a cutoff threshold selected to minimize EMG false positive indication, e.g., THR2 = 7.

[0053] In another embodiment of the present invention, an alternative approach to computing an EMG index is provided, The alternative approach incorporates the normalization of EMG into the calculation of Spectral Power Ratio $\beta2/\alpha$ where the α term is essentially free from the influence of EMG. It eliminates the need for using the population based offset correction K1 to adjust for a fixed offset between homologous electrode pairs. It also minimizes or eliminates the need to use symmetrically placed electrodes. In the absence of EMG or underlying brain pathology, the Spectral Power Ratio $\beta2/\alpha$ is essentially equal across all specified electrodes. It also eliminates a potential source for error due to an individual patient's variation from the population norm. Artifact free EEG, without an underlying pathology has significant spectral symmetry between electrode pairs in sedated patients. See figures 2a & 2b.

[0054] 1. EMG may be present throughout the continuum of consciousness including isoelectric EEG.

[0055] 2. EMG lacks the spectral symmetry present in the EEG and this property is mathematically exploited to identify its presence. See Figures (2-4).

[0056] 3. The presence of EMG will measurably increase the Spectral Power Ratio $\beta 2/\alpha$.

[0057] 4. This methodology is used to identify the signal lead, or leads with insignificant or minimal EMG signal magnitude.

[0058] 5. The leads with minimal to no EMG signal magnitude can be used to compute a more precise estimate of a true EEG based level of Hypnosis. See Figure 5.

[0059] 6. The mathematical tool used provides an estimate of the EMG signal magnitude, which is then normalized to generate an EMG index.

[0060] The following equation defines a normalized EMG term derived from a plurality of symmetrically placed electrodes. The index is scaled from 0 to 100. (See Figure 6b).

[0061] $\text{EMG} = (M_{\beta RAT} / \alpha_M) * \text{STDEV} - \text{THR4}$

[0062] By way of example and not by limitation, the spectral bands $\beta 2$ from (25 – 50) Hz and α from (8-12)Hz are used for the following analysis. These frequency bands and coefficients may be adjusted to provide similar or improved EMG detection sensitivity and noise immunity. α_M is the Mean Spectral Power from selected electrodes where α represents the total power in the specified electrode in the frequency band from (8 – 12) Hz.

[0063] $\alpha_M = [\alpha_{FP2} + \alpha_{FP1} + \alpha_{F8} + \alpha_{F7}]/4$

[0064] $M_{\beta RAT}$ is the Mean Spectral Power Ratio $\beta 2/\alpha$ from selected electrodes where $\beta 2$ represents the total power from a specified electrode in the frequency band from (25 – 50) Hz and α represents the total power in a specified electrode in the frequency band from (8 – 12) Hz.

[0065] $M_{\beta RAT} = [(\beta 2/\alpha)_{FP2} + (\beta 2/\alpha)_{FP1} + (\beta 2/\alpha)_{F8} + (\beta 2/\alpha)_{F7}]/4$

[0066] STDEV = Standard Deviation Spectral Power Ratio $\beta 2/\alpha$ from specified electrodes.

[0067] THR4 = cutoff threshold to minimize EMG false positive indication.

[0068] The following or a similar expression can be used to select the channels with minimum EMG power for the purpose of computing a more accurate EEG based hypnotic index:

[0069] a. If $STDEV_4 < A$, then no EMG is present. The computed index is preferably derived from the average spectrum computed from normalized homologous pairs of electrodes.

[0070] b. If $STDEV_4$ =/> A, then eliminate the channel with the highest Spectral Power Ratio $\beta 2/\alpha$ and recompute the STDEV.

[0071] c. If $STDEV_3 < A$, then no EMG is present. The computed index is preferably derived from the average spectrum computed from remaining normalized electrodes.

[0072] d. If $STDEV_3$ =/> A, then eliminate the channel with the highest Spectral Power Ratio $\beta 2/\alpha$ and recompute the STDEV.

[0073] e. If $STDEV_2 < A$, then no EMG is present. The computed index is preferably derived from the average spectrum computed from remaining normalized electrodes.

[0074] f. If $STDEV_2$ =/> A, then no EMG is present. The computed index is preferably derived from the spectrum computed from the remaining channel.

[0075] Alternatively, simpler methods can be used to select channel pairs with minimum EMG power for the purpose of computing an EEG based hypnotic index. One such method is described below.

[0076] a. Compute the Spectral Power Ratio $\beta 2/\alpha$ from the bipolar derivations of F8-FP2 and F7-FP1.

[0077] b. If $[(\beta 2/\alpha)_{(F8\text{-}FP2)} - (\beta 2/\alpha)_{(FP1\text{-}F7)}] > A$.

[0078] c. Determine which hemisphere has the lowest Spectral Power Ratio $\beta 2/\alpha$.

[0079] d. Select the signal processing montage with the lowest hypnotic index resulting from $\beta 2/\alpha$ asymmetry or use the montage with the lowest Spectral Power Ratio $\beta 2/\alpha$.

[0080] e. If $[(\beta 2/\alpha)_{(F8\text{-}FP2)} - (\beta 2/\alpha)_{(FP1\text{-}F7)}] =/< A$, use the average or either spectrum.

[0081] In one embodiment of the present invention, the expression of EMG by the patient can be responsive to the application of a provocative stimulus, as described in "PATIENT SEDATION MONITOR" U.S. Serial No. 11/211,349 filed August 25, 2005. This application is hereby expressly incorporated by reference. This application discloses an electronic glabellar tap stimulating and measuring system. In the example provided, presentation of a provocative stimulus, i.e., electrical stimulus to a specific area of the patient's forehead, causes an EMG response in addition to the glabellar reflex, which can be detected using the methods described in paragraph 4 above. A change in EMG power of more than approximately 2 standard deviations would be considered a positive response to an electrical or mechanical stimulus. This response can be used to further assess the patient's wakefulness in the absence of paralytic agents. See Figure 7 for an example of a response to a mechanical stimulus.

[0082] Although the system and method of the present invention have been disclosed herein in the context of certain embodiments, one of ordinary skill will appreciate that various modifications can be made without departing from the spirit and scope of the invention set forth in the appended claims.

Claims:

What is claimed is:

1. A method for measuring a patient's level of sedation , the method comprising:

providing a plurality of electrodes constructed to be placed on a patient's body, said plurality of electrodes defining a plurality of electrical channels;

mounting said plurality of electrodes on a patient's body;

detecting EMG and EEG signals on each of said plurality of electrical channels using said plurality of electrodes;

comparing the EMG and EEG signals on each of said plurality of electrical channels and identifying at least one of said plurality of channels with a lower signal magnitude;

and

calculating a patient's level of sedation using a signal detected from said at least one of said plurality of electrodes with a lower signal magnitude.

2. A method for measuring a patient's level of sedation in accordance with Claim 1, wherein said step of identifying at least one of said plurality of electrodes with a lower signal magnitude comprises the steps of:

determining a first magnitude of a signal received by a first channel of said plurality of electrical channels;

measuring a second magnitude of a signal received by a second channel of said plurality of electrical channels;

adding a population derived or patient derived offset term K_1 to each of said first and second magnitudes to establish a first offset corrected magnitude and a second offset corrected magnitude;

comparing said first and second offset corrected magnitudes; and

identifying which of said first and second offset corrected magnitudes is lower.

3. A method for monitoring a patient's EMG signal, comprising:

providing a plurality of electrodes constructed to be placed on a patient's body;

mounting said plurality of electrodes on a patient's body whereby pairs of said plurality of electrodes define a plurality of electrical channels therebetween;

detecting an EMG signal from two or more of said plurality of electrical channels defined between said plurality of electrodes;

calculating a patient's normalized EMG index using plurality of detected EMG signals.

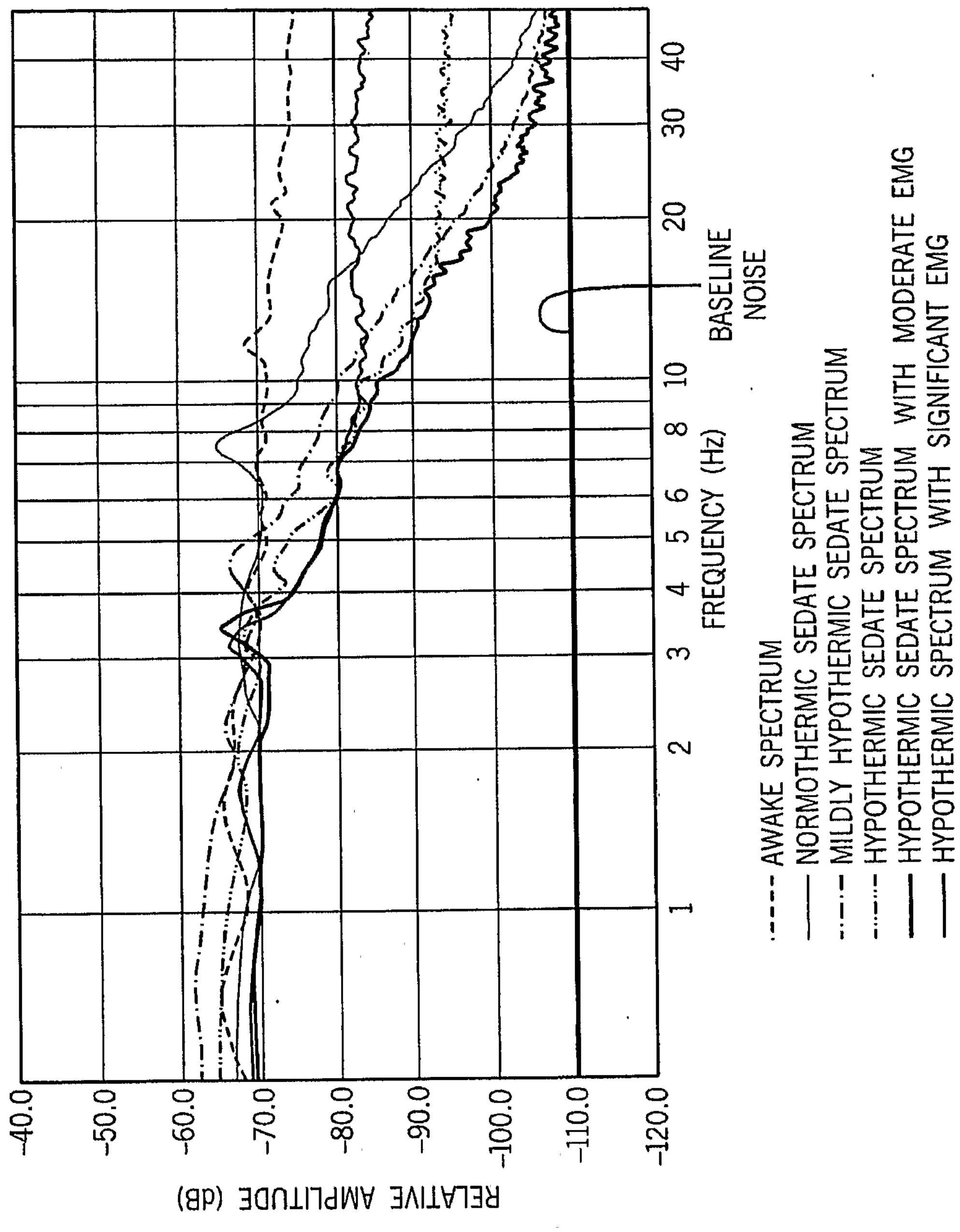
RELATIVE AMPLITUDE (dB)
-40.0
-50.0
-60.0
-70.0
-80.0
-90.0
-100.0
-110.0
-120.0
FREQUENCY (Hz)
1
2
3
4
5
6
8
10
20
30
40
BASELINE NOISE
AWAKE SPECTRUM
NORMOTHERMIC SEDATE SPECTRUM
MILDLY HYPOTHERMIC SEDATE SPECTRUM
HYPOTHERMIC SEDATE SPECTRUM
HYPOTHERMIC SEDATE SPECTRUM WITH MODERATE EMG
HYPOTHERMIC SPECTRUM WITH SIGNIFICANT EMG

FIG. 1

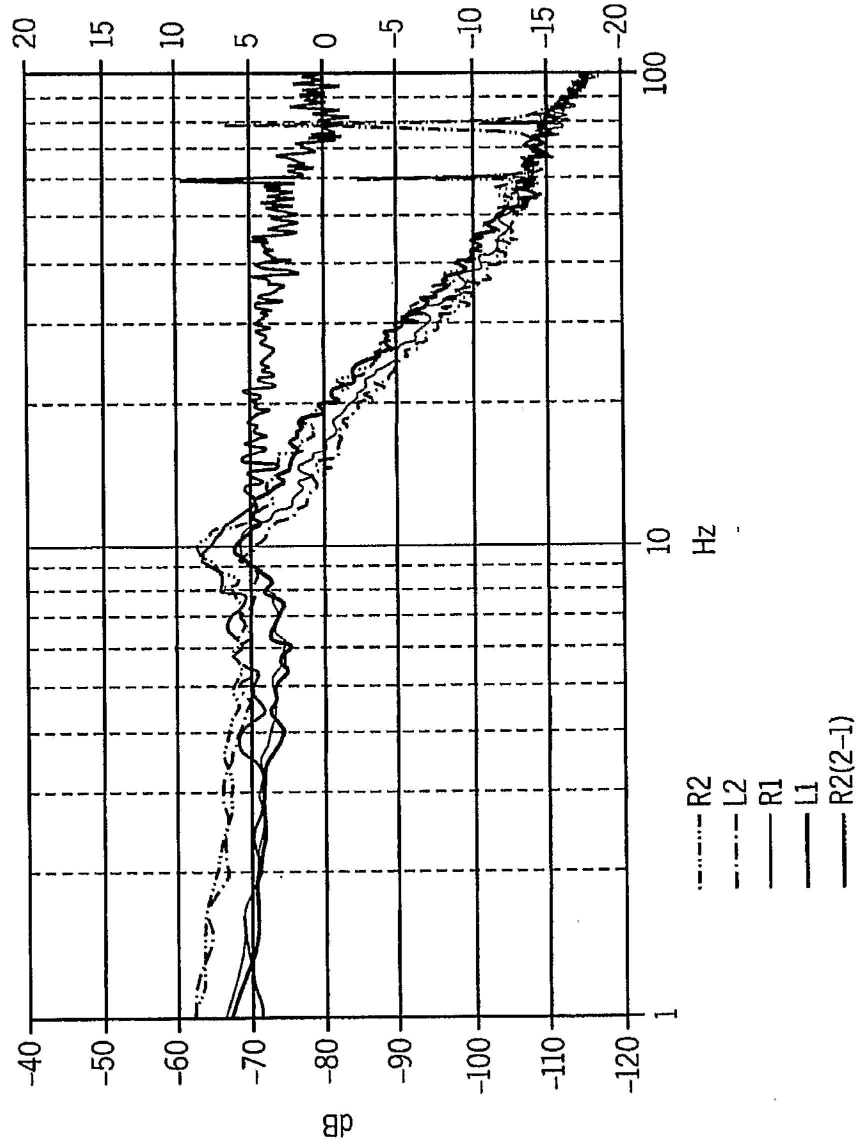
dB
Hz
-40
-50
-60
-70
-80
-90
-100
-110
-120
20
15
10
5
0
-5
-10
-15
-20
1
10
100
R2
L2
R1
L1
R2(2-1)

FIG. 2a

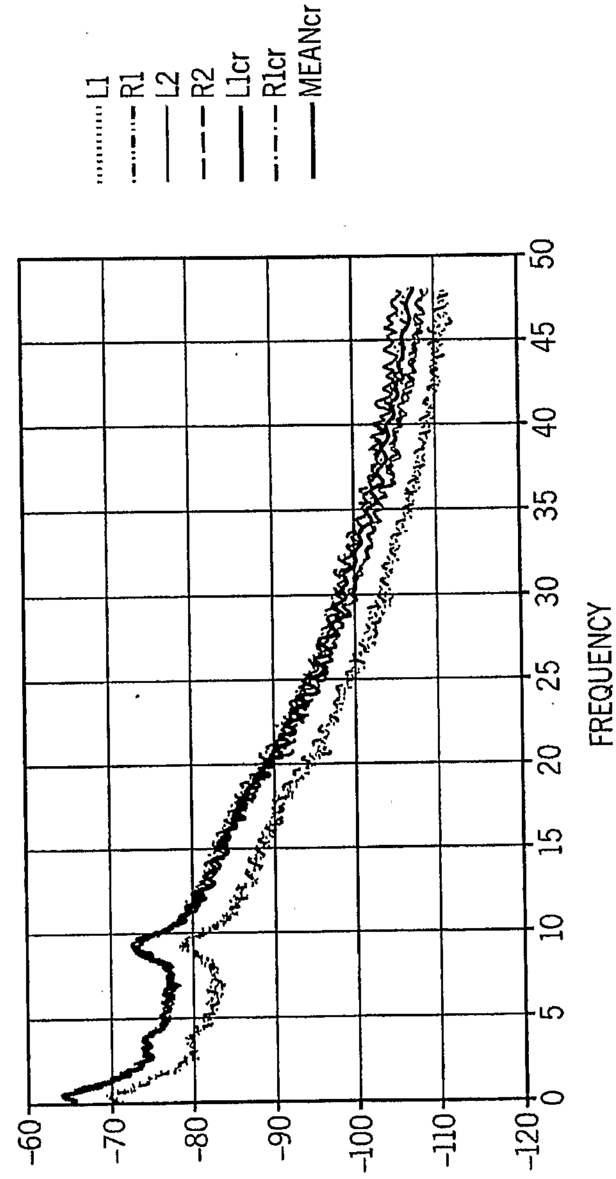
L1
R1
L2
R2
L1cr
R1cr
MEANcr
dB
-60
-70
-80
-90
-100
-110
-120
0
5
10
15
20
25
30
35
40
45
50
FREQUENCY

FIG. 2b

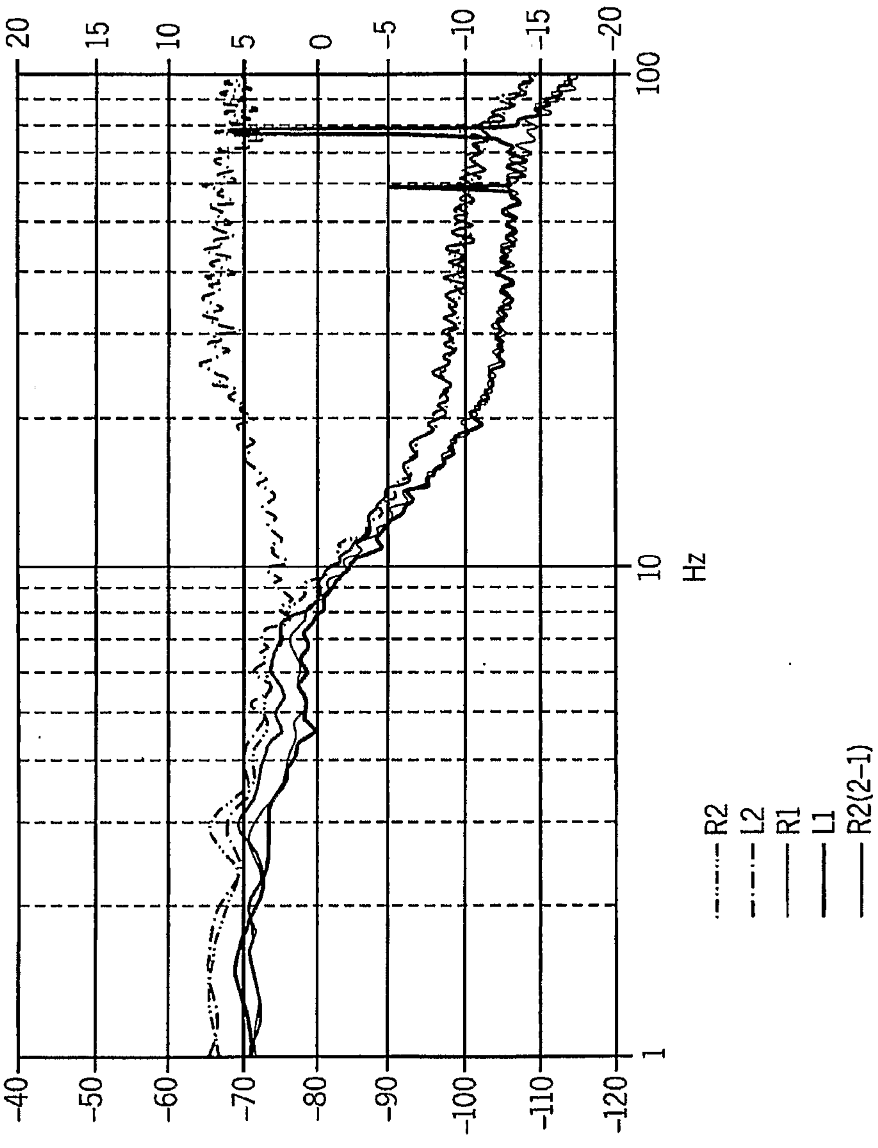
dB
-40
-50
-60
-70
-80
-90
-100
-110
-120
20
15
10
5
0
-5
-10
-15
-20
1
10
100
Hz
R2
L2
R1
L1
R2(2-1)

FIG. 3

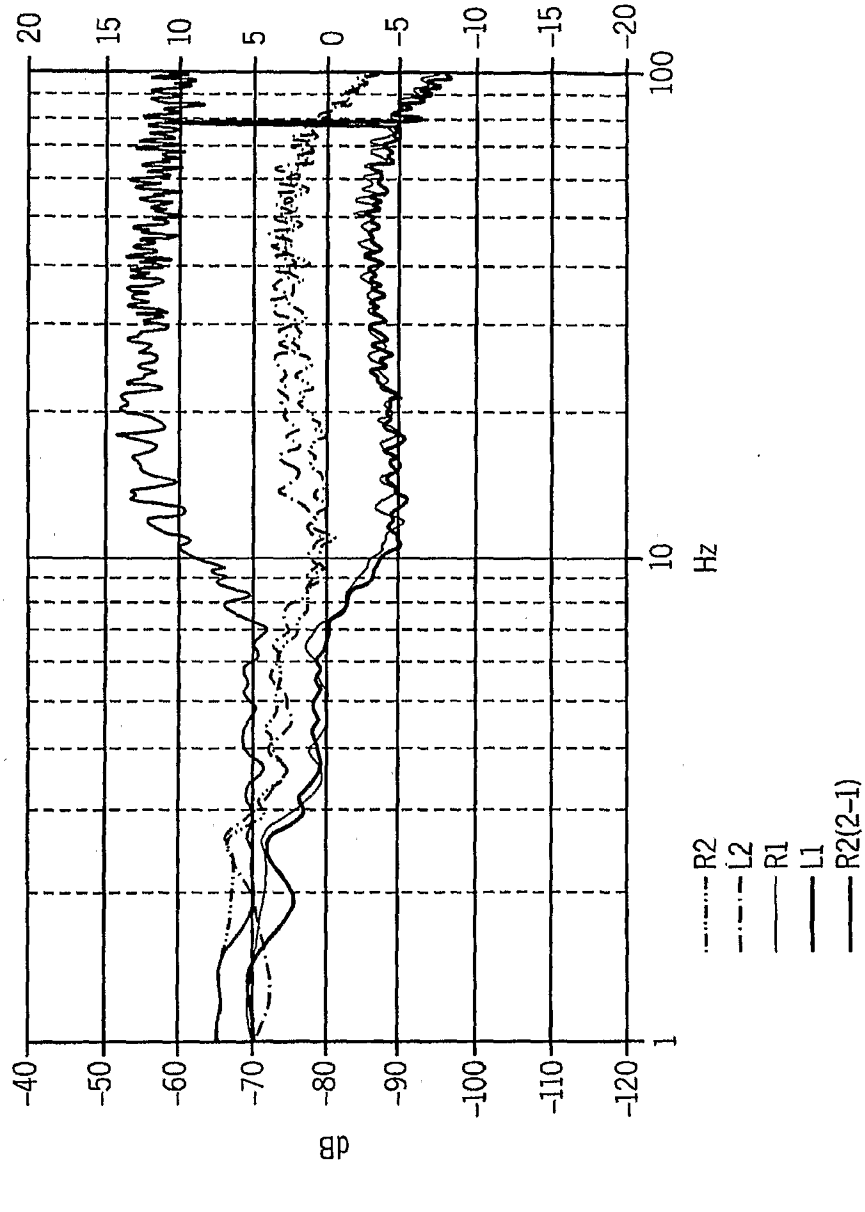
20
15
10
5
0
-5
-10
-15
-20
-40
-50
-60
-70
-80
-90
-100
-110
-120
dB
1
10
100
Hz
R2
L2
R1
L1
R2(2-1)

FIG. 4

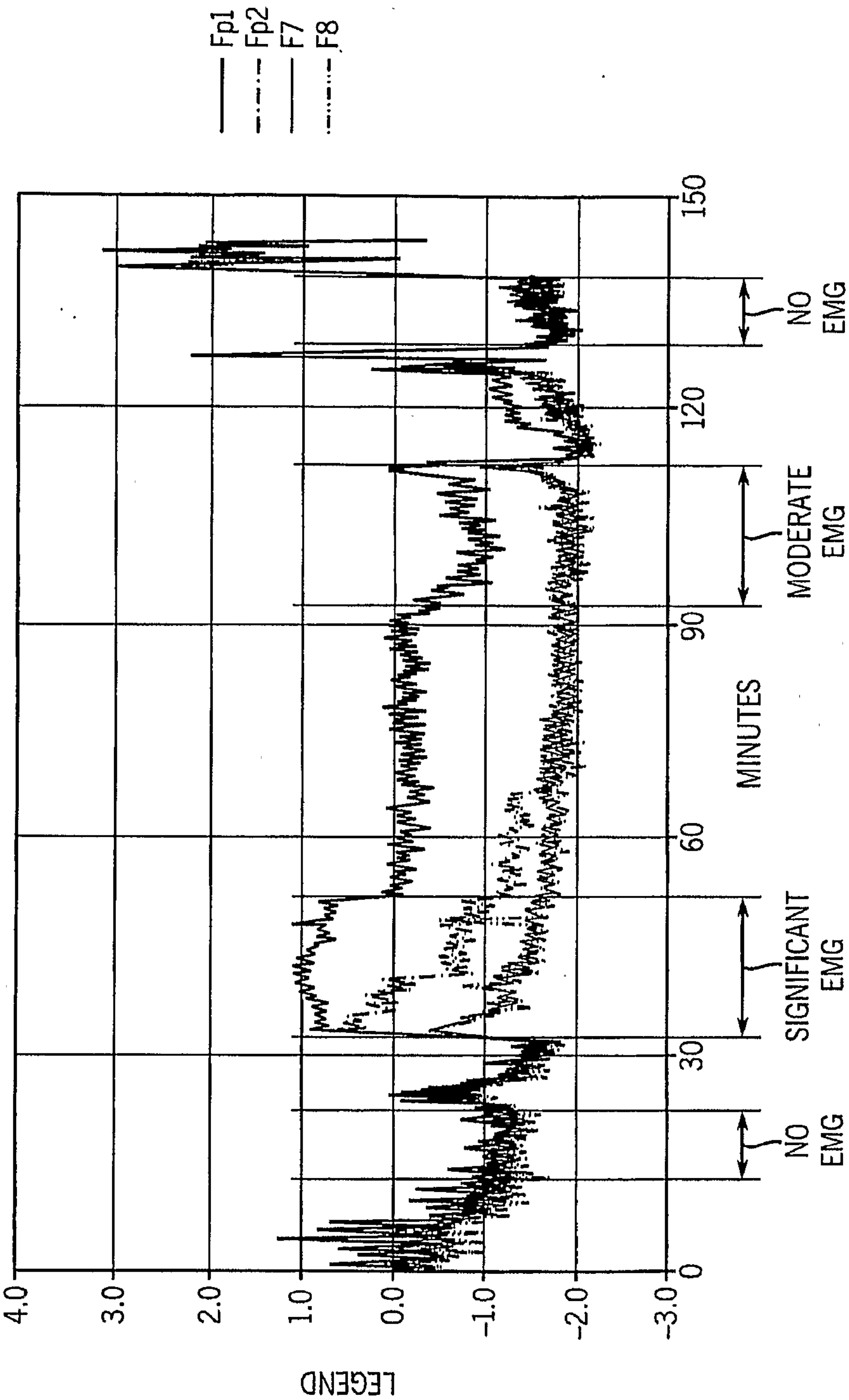
Fp1
Fp2
F7
F8
4.0
3.0
2.0
1.0
0.0
-1.0
-2.0
-3.0
0
30
60
90
120
150
MINUTES
NO EMG
SIGNIFICANT EMG
MODERATE EMG
NO EMG
LEGEND

FIG. 5

7 /8

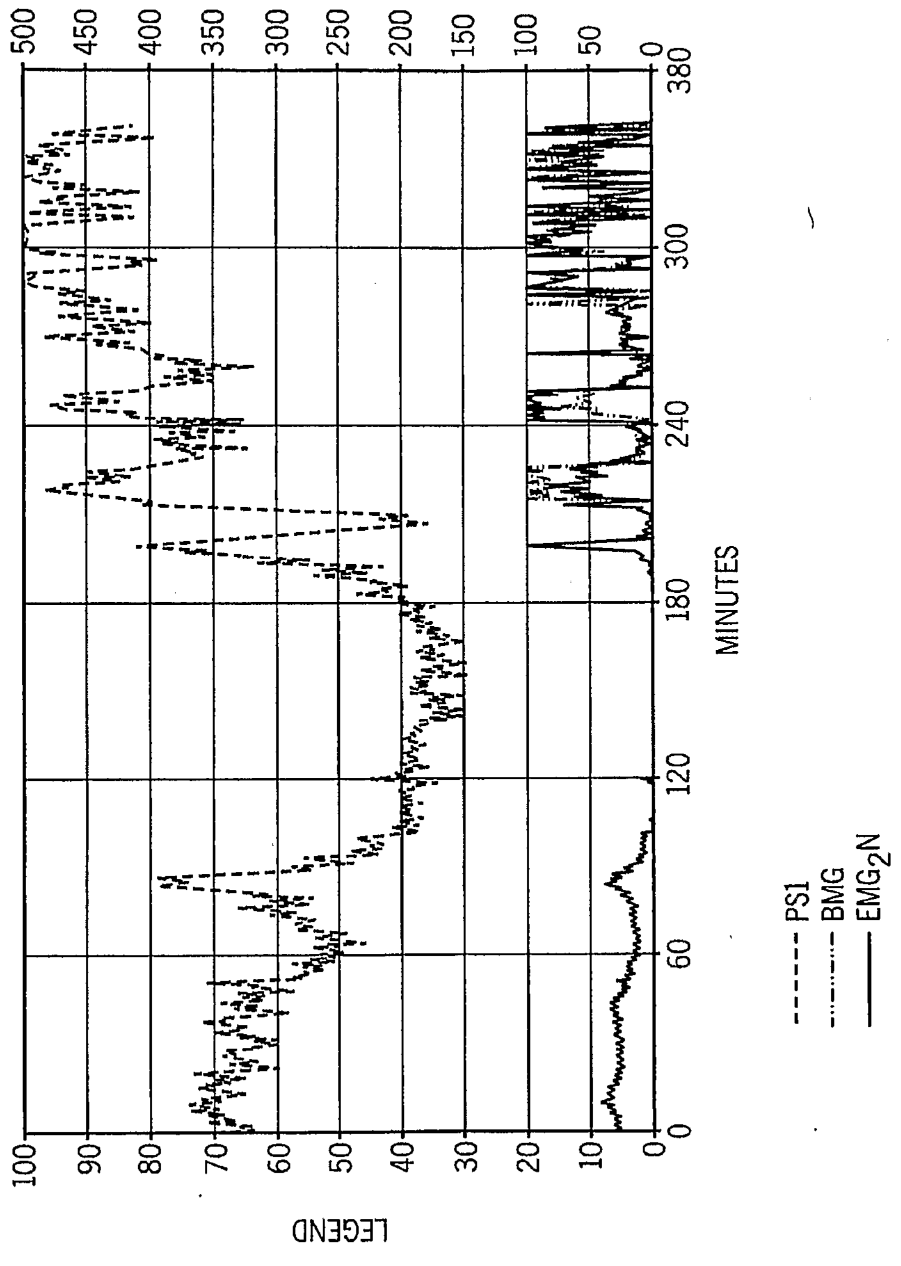
MINUTES
LEGEND
PS1
BMG
EMG_2N
0
60
120
180
240
300
380
0
10
20
30
40
50
60
70
80
90
100
0
50
100
150
200
250
300
350
400
450
500

FIG. 6

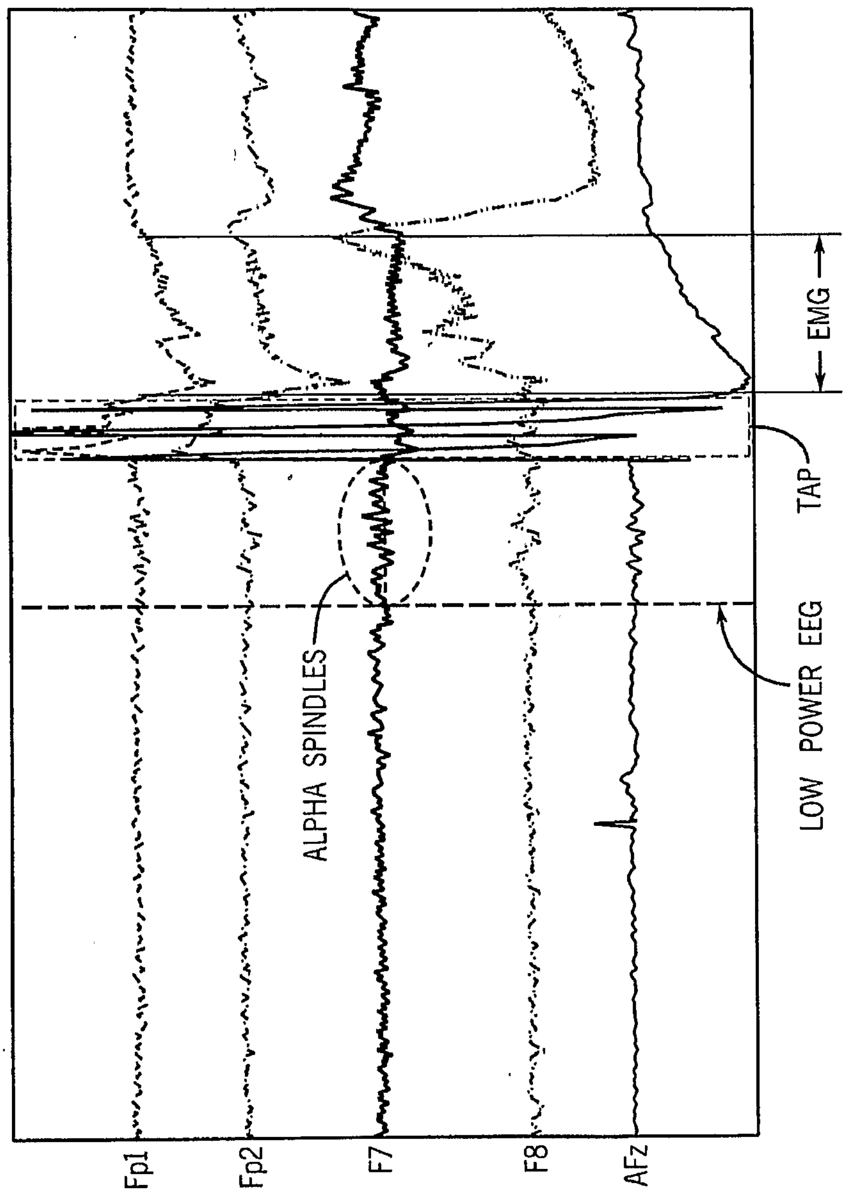

FIG. 7