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(54) **Methods and apparatus for monitoring consciousness**

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METHODES ET DISPOSITIF POUR DIRIGER LA CONSCIENCE

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to diverse methods and apparatus including systems incorporating same, for selectively monitoring the state of mind, or state of consciousness of human and other sentient subjects. More particularly the present invention relates to novel sensors and suites of sensors for accurately monitoring, sensing, tracking, analysing, storing, logging and/or displaying data related to combinations of physiological senses of a sentient subject. The physiological senses may include mind state and arousal of the subject including frequency, phase, amplitude and/or activity of one or more electro-encephalogram (EEG) signals.

[0002] The apparatus may be used in various configurations for applications including, inter alia, depth of consciousness, depth of unconsciousness, depth of anaesthesia, state of a subject's alertness, depth of sedation, hypnotic state, state of concentration, state of vigilance and state of attention. In a particular application, the present invention may be adapted to monitor a subject for depth of anaesthesia and/or present state of consciousness during anaesthesia administration so that eg. the subject may be properly sedated during a medical procedure. In addition, various data collecting and processing techniques are described pursuant to the present invention, as well as dynamic, re-configurable and adaptable display configurations for such data. An operator may reference such data as most optimally relates to the application (or applications) set forth herein in readily understandable format including suitable alarm signalling, threshold monitoring and the like.

[0003] The present invention may utilize sleep analysis, EEG bispectral analysis (incorporating bi-coherence) and audio evoked potential (AEP) analysis in an integrated fashion for improved monitoring of, inter alia, a subject's consciousness, audio sensory systems, movement, arousal, muscle activity, eye movement, eye opening, stress and anxiety levels, vital sign parameters, and/or audio-visual recall. The monitoring systems preferably are arranged such that associated physiological electrode attachments are minimized.

[0004] The present invention is related to systems disclosed in PCT application AU99/01166 filed on 24 December 1999 entitled "Vigilance Monitoring System".

BACKGROUND OF THE INVENTION

[0005] William Thomas Gordon Morton first demonstrated what is today referred to as surgical anaesthesia. However, a comprehensive or detailed understanding of how anaesthesia works is still unknown today. It is known that anaesthesia acts upon the central nervous system by reacting with membranes of nerve cells in the brain in order to shut down responses such as sight, touch and awareness, but the precise mechanisms and affects of this sensory process are still a subject of research.

[0006] In Australia about 1 million people a year undergo general anaesthesia. Of these 1 million people about 5 people die each year, as a direct result of the anaesthesia, while about 3000 more will be inadequately anaesthetised. These inadequately anaesthetised people will experience a range of symptoms from hearing recall while undergoing a medical procedure, sight recall from premature recovery and the early opening of eyes, stress and anxiety from experiencing paralysis. Some degree of mental awareness to the medical procedure being instigated, memory recall from having some degree of consciousness, and operation mishaps can occur in cases where the subject's state of paralysis is not adequate leading to movement of the subject's body during incision, for example.

[0007] A typical general anaesthetic procedure may involve a pre-medication or sedative, after which the patient is wheeled into the operating theatre where the anaesthetist applies a blood-pressure measurement cuff to the patient's arm, an oximeter probe to the patient's finger for the measurement of oxygen saturation, and ECG or electrocardiogram leads to a patient's chest for monitoring of heart-rate.

[0008] An intravenous cannula is then inserted into the patient's arm, and a mixture of drugs are infused into the bloodstream in order to put the patient to sleep, control pain and relax muscles. Within about 30 seconds the patient will typically transition from a state of consciousness to unconsciousness. Once the patient is unconscious, the anaesthetist typically reverts the patient to a gas delivery mask, which contains an "inhalation" anaesthetic that is breathed, by the patient through the mask. The patient may also be attached to a ventilator that will assist or support the patient's ventilation during the operation. The surgeon's intent is to commence the medical operation procedure when the patient is unconsciousness and can feel no pain.

[0009] The current state of the art provides an array of systems to monitor a patient whilst undergoing anaesthetic drug delivery, but none of these accommodate monitoring and validation of the range of sensory parameters satisfactory to monitor for "shut-down" or unconscious state of neural recall (including state of hypnosis, unconsciousness and sleep), auditory recall state (including Audio Evoked Potential and complex frequency and sensitivity state), muscle paralysis, movement and arousal state (including arousal and body movement analysis), visual recall state, (including eye opening and eye movement analysis state), anxiety and stress state (including temperature, blood-pressure, oxygen saturation-

SA02, heart-rate variability, skin galvanometry resistance analysis).

[0010] Some prior art systems provide analysis of unconsciousness state (Aspect Monitoring) and other systems analyse electro-encephalograph signal activity (Physiometrix). Moreover experiments have been conducted and apparatus devised to monitor audio response (Audio Evoked Potential) together with a range of neurological analysis. However, the working of the brain's responses to anaesthetics and subsequent "shut-down" of the body's sensory systems still remains a mystery.

[0011] US6067467 discloses a system for determining the state of consciousness of a sentient subject or living body by obtaining physiological measures from said sentient subject or living body comprising: means for acquiring raw EEG data; stimulus devices for stimulating at least one EP signal in said sentient subject or living body; means for obtaining said at least one EP signal from said raw EEG data; means for calculating a Patient State Index (PSI) from a Z-transformed EEG signal; and means for weighting EEG and EP measures.

[0012] The present invention may measure not only the state of consciousness of the sentient subject but also various states of sensory systems. In particular emphasis may be applied to measurement and monitoring of the sensory systems that are potentially most vulnerable to incidence of recall during an anaesthetic procedure. The present invention may provide a primary measure or guide to a clinician for optimal anaesthetic drug dosage by monitoring consciousness (such as associated with EEG and BSAEP parameter measurement), while also providing a "last line of defence" by monitoring the subject's sensory systems including sight, hearing, movement, taste and sound, for minimizing risk of recall associated with an anaesthetic/medical procedure.

[0013] Allan Rechtschaffen and Anthony Kales, describe in "A Manual of Standardized Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects", Brain Information Service/Brain Research Institute, University of California Los Angeles, California 90027, (R&K) (34) a method of scoring human sleep physiology. Further descriptions of the behaviour of the brain's electrical energy in terms of half-period amplitude analysis are disclosed by Burton and Johns in AU Patent 632932 (45).

[0014] These earlier techniques were utilised for defining stages of a human's sleep and were predominantly applied to a subject in sleep, as recognised by conventional stages of sleep including stage 1, stage 2, stage 3, stage 4 and REM sleep (as distinct from hypnotic or in-depth of anaesthesia states). In particular the first stage of sleep detection with R&K standardised sleep staging techniques relies upon specific physiological sequences of events, such as the subject's rolling of the eyes or slow moving electro occulogram and changes in the electro-encephalogram frequency spectrum. It is apparent that significant changes in human physiology leading to the subject entering stage one of sleep represent a dramatic change in a subject's state of consciousness. This dramatic state of consciousness may be too late in detection where the aim is, for example, to determine onset of a lack of vigilance for a pilot of an aircraft or other critical job function. In other circumstances a subject could enter a hypnotic state where the driver of a car, for example, lapses into a type of "trance" and the state of vigilance and the subject's environment could become critical and highly dangerous. The phases of human physiology periods (leading up to stage 1) of non-sleep are not specifically described in R&K teachings.

[0015] Even hospitals such as Melbourne's Alfred Hospital, which demonstrated one of the world's lowest reported incidences of consciousness under general anaesthesia, still have an incidence rate of 1 in 1000 patients (91). The chances of being aware and experiencing pain are even lower but the consequences can be devastating. Side effects of consciousness while under anaesthesia can range from nightmares to recall of pain, stress, visual and audio recall during a medical procedure.

[0016] The present invention may address these limitations by providing specialised R&K and bicoherence monitoring during application of general anaesthesia. The present invention may also provide methods of artefact rejection to allow more precise monitoring and analysis of neurological and other bicoherence and sleep variables from the subject.

[0017] Until now there has been no way to determine whether a patient is asleep during a medical procedure, according to University of Sydney-Australia's Web site, introductory paper on anaesthesia (92).

[0018] In 1942 Canadian anaesthetists discovered that neuromuscular blocking drugs could be developed. Sir Walter Raleigh had known in 1596 that the indigenous people of Bolivia had been using an American plant derivative called curare to cause paralysis. Since 1942 these drugs have revolutionised surgery, particularly abdominal and chest operations where muscle contraction had made cutting and stitching almost impossible.

[0019] By deactivating the muscles, anaesthetists can make lighter and safer anaesthetic drugs whilst still keeping the patient unconscious. These muscle blocking drugs are now used in up to half of all operations. However, the downside of the application of these muscle drugs is that a patient is paralysed so that conscious or unconscious movement is impossible. In circumstance where a patient is awakening or is in a state of consciousness during a medical procedure, the patient is unable to move and defend him/herself or alert anyone of a potentially horrific experience that the patient may be encountering.

[0020] Anaesthetists tend to overestimate the amount of anaesthetic drug usage by up to 30%. This overestimation has consequences in relation to a patient's health, recovery time and financial costs to health services (94).

[0021] The present invention may address the limitations of the prior art by providing an apparatus and method for

monitoring and analysing arousal and body movement of a patient throughout anaesthesia. Furthermore the present invention may provide means to position electrodes and sensors for monitoring arousal and body movements from any location on the patient's body. If, for example, a chest operation requires extreme absence from movement due to a critical incision procedure, electrodes or sensors may be placed around sensitive chest muscles non-invasively or via inter-operative methods.

[0022] The challenge to monitor for appropriate or optimum anaesthesia is demonstrated with classic experiments such as that of psychiatrist Bernard Levin in 1965, when 10 patients who were read statements during anaesthesia, later had no recall of the statements when questioned after surgery. However, of the same patients under hypnosis four could quote the words verbatim and another four could remember segments, but became agitated and upset during questioning (95). An adequately anaesthetised patient should not "feel", "sell", "see" or "taste" anything until they regain consciousness (96).

[0023] In 1998 Dr David Adams of New York's Mount Sinai Medical Centre replayed audio tapes of paired words (boy/girl, bitter/sweet, ocean/water...) to 25 unconscious heart surgery patients. Approximately four days after the operation, the patients listened to a list of single words. Some of these words had been played while they were unconscious during their former operation. The patients were asked to respond to each word with the first word that came into their minds. The patients were found to be significantly better at free-associating the word pairs they had already encountered than those they had not. It was apparent that the patients had heard the information and remembered it (97).

[0024] It appears that while a smaller number of patient's have conscious memories of their experiences on the operating table, a larger number have unconscious recollections. While positive messages during surgery may have desired consequences others can have undesirable results (98).

[0025] The present invention addresses the limitations of the prior art by providing in one form an apparatus and method for monitoring auditory sensory system while the patient is undergoing anaesthesia. Furthermore the present invention may provide a comprehensive means of analysing both frequency response and sensitivity response of one or both auditory sensory systems of the patient during anaesthesia. This may provide monitoring and a means of replay as evidence of the state of the subjects auditory system throughout anaesthesia to reduce the risk of auditory recall.

[0026] The present invention may provide a method and apparatus for monitoring and/or analysing a patient's eye movement and eye opening to minimise or eliminate the risk of visual recall after anaesthesia.

[0027] The present invention may provide a method and apparatus for monitoring a patient's stress and anxiety levels together with a range of vital parameters to minimize the risk that the patient is undergoing undue stress, anxiety and health conditions during anaesthesia, and subsequently reducing or eliminating the incidence of these states.

[0028] Previous studies present a relationship between human treatment and changes in physiological states, as associated with anxiety or stress. In particular such studies link respiration rate, skin resistance and finger pulse volume to anxiety (53). Other studies present relationships between salivary cortisol levels and activities accompanying increased cardiovascular activity (54).

[0029] Studies also present relationships between heart rate variability (HRV), and people reporting anxiety and perceived stress and between a subject's blood pressure and heart rate, and activities associated with increased stress (55, 56, 57). Vagal modulation of heart-rate period was found to be sensitive to a person's emotional stress. Other studies present relationships between a subject's blood pressure and heart rate, and activities associated with increased stress (58).

[0030] The present invention may measure, analyse and display in near real-time graphical or numerical representation of skin resistance, oxygen saturation, pulse-transit-time arousal, blood pressure, heart rate, heart rate variability and temperature. Furthermore, the present invention may measure, monitor and analyse these variables and present an index and/or other graphical and tabular display means, to assist an anaesthetist or other medical personnel in the assessment of a subject's depth of anaesthesia.

[0031] The present invention may record, monitor and analyse in near real-time effects of cortisol salivary content and changes thereof as an indicator of stress or anxiety, as may be associated with increased heart rate as may occur with premature awaking during anaesthesia.

[0032] The present invention may also measure, analyse and display in near real-time graphical or numerical representation of vagal modulation of heart-rate period. Furthermore, the present invention may measure, monitor and analyse this variable which may be represented in terms of HRV frequency de-composed into various frequency components; ie. LF-.05-.15Hz, HF-.15-.5Hz, using spectral analysis; and may present an index and/or other graphical and tabular display means, to assist an anaesthetist or other medical personnel in assessing a subject's depth of anaesthesia.

[0033] The present invention may record, monitor and analyse in near real-time effects of blood pressure and heart rate, and changes thereof as an indicator of stress or anxiety as may be associated with changes in blood pressure and heart rate, as may occur with premature awaking during anaesthesia.

[0034] The current field of sleep medicine is not precise in scoring or quantifying human sleep physiology. The degree of "inter-scorer" agreement in determining sleep classification of human physiology is of the order of 80 to 90 %. Monitoring and analysing the state of a patient during anaesthesia treatment, and subsequent accurate determination of the patient's

state depth of anaesthesia at any point in time is important to ensure efficacy of the patient's anaesthetic treatment. To this end, accurately defining the mechanisms, sequence or sensitivity of the sentient mind "shutting down" or re-awakening as associated with vigilance or response to administration of anaesthetics including the mind's recall of such events is important for ensuring optimal administration of anaesthetic agents. The science and knowledge associated with sleep staging or scoring of human sleep is still relatively primitive in terms of understanding the mechanisms of sleep and consciousness. In particular it appears that the science and knowledge associated with details and the sequence of "shutting down" of consciousness and human sensory systems including sight, hearing, smell, consciousness and muscle activity or arousal necessary to avoid potential recall of a patient's experiences associated with anaesthesia, is still relatively young and inexperienced.

[0035] The present invention recognizes the prior art limitations, and may be configured to monitor and analyse combinations of a subject's sensory systems during, inter alia, an anaesthesia procedure.

[0036] The present invention may improve the probability of determining a subject's consciousness by applying two or more independent methods of analysis including bi-coherence based analysis and Brain Stem Audio Evoked Potential or Steady State Evoked Potential based analysis, and arbitrating, cross-checking and integrating results of the two or more methods of analysis using a further independent method of EEG analysis such as spectral based EEG analysis, including optimised bi-spectral analysis and optimised R&K sleep-wake analysis, to improve accuracy in determining the consciousness status of the subject. In conjunction with determining the consciousness status of the subject, the present invention may analyse consciousness/hypnosis/vigilance with the aid monitoring and analysis of brain waves together with various combinations of sensory monitoring and analysis including auditory, muscle movement and/or arousal including micro-arousal, eye opening & eye movement.

[0037] Other parameters, which may optionally be included in depth-of-anaesthesia monitoring and analysis determination, include anxiety & stress levels, heart rate variability, galvanomic skin resistance, temperature, respiration rate variability and blood pressure and/or oxygen saturation.

[0038] The present invention may include an apparatus for monitoring, analysing, recording and replaying a subject's consciousness state in conjunction with critical physiological sensory status of the subject. In this context critical refers to sensory systems that are critical for minimising the risk of recalling the experience or senses, associated with a medical procedure while under anaesthesia.

[0039] The combinations of multiple sensory monitoring and analysis may include a provision for a user to configure, select or operate the present invention with one or more channels of input data from a subject together with a range of system set-ups or montages, consistent with the complexity of signal attachment to the subject, the critical nature of the monitoring including the duration of an operation and risk associated with administration of anaesthesia or muscle paralysis medication to the subject, the skill and training or experience of the user, the sensitivity of the subject to anaesthetic or muscle paralysis medication, and variability of different subjects in relation to susceptibility to premature awakening or consciousness including recall of auditory or visual stimuli, anxiety or arousal.

[0040] The present invention may provide unique wireless connected electrode systems to reduce conventional wiring and risk of entanglement

[0041] In some instances patient or subject specific data may substantially affect monitoring or analysis methods associated with the present invention. To the applicants knowledge, no one has linked critical parameters such as weight, age and sex of a patient to sensitivity and weighting of depth of anaesthesia monitoring. The present invention may include a capability to adapt weighting or sensitivity of the analysis to the physiological parameters being monitored. An example of this may include the manner in which the weight or sex of a subject affects the optimal band of concentration of an anaesthetic agent.

[0042] The present invention may utilise data associated with the subject, such that its sensitivity or important thresholds may be adjusted from one subject to the next. In this context "utilisation" of data refers to compensation of critical display threshold levels and sensitivity of various user displays. In other-words the user displayed thresholds and associated variations in sensitivity may be changed in accordance with critical (for example, in depth of anaesthesia monitoring) sensitivity to certain anaesthetic agents.

[0043] Surface electrode connections have been applied in the past to monitoring applications associated with various physiological parameters. However one problem with surface electrode connections is that the quality of the connection to the subject can deteriorate due to a number of conditions including patient sweat, movement or drying out of the connecting electrolyte solution between electrode and subject. The problem of electrode quality may be more critical in applications such as those associated with intensive care and operating theatre environments, than is the case with depth of anaesthesia monitoring systems. To date, no one has used connection of redundant electrodes, automatic validation of electrode connection quality and validation by way of routine impedance measurements and other signal validation techniques (refer Fig. 18 - MFD Block 7) including automatic substitution of poor electrode connections with redundant or spare electrode connections (refer Fig. 35 - IAMES or Fig. 37 - ISES). The present invention may include redundant electrodes together with integrated electrode-sensors and wireless/rechargeable electrode-sensors to minimize the number of electrodes and sensors (as few as 3 sensor-electrodes in some embodiments) for depth of anaesthesia

monitoring and analysis (where the quantity, reliability and simplicity of electrode-sensor attachments may be highly critical) including monitoring and analysis of physiological states such as mind-state, auditory sensory, visual sensory, arousal sensory, anxiety sensory and vital states.

[0044] Eye movement sensors (such as piezo or PVD movement sensors) and electrodes (such as EOG) have been used in the past for detecting eye movement or eye-lid movement respectively. However one problem associated with depth of anaesthesia monitoring is that some patients awaken prematurely during a medical procedure and opening of the eyes can lead to distressing views and subsequent recall or nightmare occurrences. A further problem exists where the patient may litigate in such instances, in which case an objective and accurate recording of the patient's state and amount of eye opening may be important. A system that allows the user to calibrate such an eye-opening sensor would also be of value. The present invention may provide such a sensor (refer Fig. 34 - EOS) for detecting in a calibrated manner a degree of eye opening of a subject.

[0045] In accordance with general literature a predominant prior art method for detecting anaesthesia is bi-coherence analysis of EEG waveforms. Aspect Monitoring, which is a main supplier of in-depth anaesthesia monitoring systems deploys this technique. Aspect Monitoring has trademark applications for BIS and Bi-spectral Index. Bi-spectral Index is based on the technique of bi-coherence analysis.

[0046] Functioning of the brain in the transition of states from consciousness to subconsciousness and from unconsciousness to consciousness is recognised as a non-linear transition in relation to the generation of electrical brain activity. Accordingly, the bi-coherence method of monitoring EEG has been shown to be an affective method for predicting the state of consciousness and the subsequent state of depth of anaesthesia.

[0047] However, even with improved analysis of EEG data as described above, another prior art limitation exists. This limitation is related to the fact that while the combined frequency and phase analysis of EEG data may provide an improved method for monitoring a patient's state of consciousness, it has been found (4) that Audio Evoked Potential (AEP) provides a more informative measure of a subject's transition from unconsciousness to consciousness, while EEG based bi-spectrum analysis provides a more informative measure from consciousness to unconsciousness. Accordingly, the present invention may automatically detect whether the patient is transitioning from consciousness to unconsciousness or visa versa and may apply or weight bispectrum analysis (bicoherence/bispectrum/triple product) or AEP analysis (such as Brain Stem Auditory Evoked Potential- BAEP) respectively.

[0048] The present invention may address the limitations of the prior art by applying R&K analysis as a type of "independent arbitration" agent for determining which analysis type is optimal, based on the context and sequence of analysis change or transitions. For example, R&K detection of wake state, suggests a probable transition from consciousness to unconsciousness, which in turn suggests that the optimal or higher weighting of consciousness state determination should be derived from BIC (bi-spectral analysis incorporating bi-coherence) analysis. In contrast, R&K detection of a sleep state (stage 1, 2, 3, 4, REM, for example) suggests a probable transition from unconsciousness to consciousness, which in turn suggests that optimal or higher weighting of consciousness state determination should be derived from AEP analysis.

[0049] Barr and colleagues describe in British Journal of Anaesthesia June 2000 (1), a Coherence index (CHI) used to assess depth of anaesthesia during fentanyl and midazolam anaesthesia for coronary bypass surgery in which BIP decreased during anaesthesia, but varied considerably during surgery. Schraag and colleagues describe in Anesth Analg April 2000 (2), "that both BIP and AEPi are reliable means for monitoring the level of unconsciousness during propofol infusion. However, AEPi proved to offer more discriminatory power in the individual patient. The implication is that both the coherence index of the electroencephalogram and the auditory evoked potentials index are good predictors of the level of sedation and unconsciousness during propofol infusion. However, the auditory evoked potentials index offers better discriminatory power in describing the transition from the conscious to the unconscious state in the individual patient."

[0050] Gajraj RJ describes in British Journal of Anaesthesia May 1999 (3), "Comparison of bi-spectral EEG analysis and auditory evoked potentials for monitoring depth of anaesthesia during propofol anaesthesia." In this study, Gajraj & colleagues compared the auditory evoked potential index (AEPindex) and bi-spectral index (BIS) for monitoring depth of anaesthesia in spontaneously breathing surgical patients." "The average awake values of AEP-Index were significantly higher than all average values during unconsciousness but this was not the case for BIS. BIS increased gradually during emergence from anaesthesia and may therefore be able to predict recovery of consciousness at the end of anaesthesia. AEP-Index was more able to detect the transition from unconsciousness to consciousness."

[0051] Gajraj RJ, describes in Br J Anaesth Jan 1998 (30), "Analysis of the EEG bispectrum, auditory evoked potentials and the EEG power spectrum during repeated transitions from consciousness to unconsciousness." In this study, Gajraj & colleagues describe: "We have compared the auditory evoked potential (AEP) index (a numerical index derived from the AEP), 95% spectral edge frequency (SEF), median frequency (MF) and the bi-spectral index (BIS) during alternating periods of consciousness and unconsciousness produced by target-controlled infusions of propofol." "Our findings suggest that of the four electrophysiological variables, AEP index was best at distinguishing the transition from unconsciousness to consciousness and therefore may be able to predict the transition unconsciousness to consciousness."

[0052] The present invention may address the limitation of prior art methods of EEG sleep analysis, by applying multiple independent methods of analysis and processing including methods based on auditory evoked potential (AEP) index (a numerical index derived from the AEP), 95% spectral edge frequency (SEF), median frequency (MF) and coherence index (CHI) and R&K sleep staging, together with a unique method of context analysis to provide improved decision making with respect to which of the multiple analysis processes are most suitable for optimal tracking of each phase of the monitored stages of consciousness.

[0053] Witte H, describes in: Neurosci Lett Nov 1997 (5), "Analysis of the interrelations between a low-frequency and a high-frequency signal component in human neonatal EEG during quiet sleep." In this study, Witte and colleagues describe: "It can be shown that dominant rhythmic signal components of neonatal EEG burst patterns (discontinuous EEG in quiet sleep) are characterised by a quadratic phase coupling (coherence analysis). A so-called 'initial wave' (narrow band rhythm within a frequency range of 3-12 Hz) can be demonstrated within the first part of the burst pattern. The detection of this signal component and of the phase coupling is more successful in the frontal region. By means of amplitude demodulation of the 'initial wave' and a subsequent coherence analysis the phase coupling can be attributed to an amplitude modulation, i.e. the envelope curve of the 'initial wave' shows for a distinct period of time the same qualitative course as the signal trace of a 'lower' frequency component (0.75-3 Hz)."

[0054] The present invention may address the limitation of categorisation of neonatal neurological patterns by including within the decisions of sleep-wake categorisation information such as the age of a subject. In turn this information may be used to weight analysis processes within the neurological data. In the above case the age of the subject may prompt the analysis processes to recognise unique markers such as 'initial wave' and to use recognition of these unique markers to provide improved accuracy for categorising and detecting EEG patterns and associated sleep staging of neonatal human subjects.

[0055] It is apparent that no one singular method for determining a subject's state of vigilance is appropriate. R&K standardised criteria for sleep staging can be important in recognizing a subject's sleep state, coherence analysis can accurately describe a patient's transition from wake to sleep, auditory response can describe a subject's transition from sleep to wake, "initial wave" can assist in detecting a subject's transition into hypnotic state, and movement detection can describe a subjects state of rest or relaxation. Furthermore, accuracy in detecting and tracking a subject's vigilance state can be improved by recognizing a subject's age and in appropriate cases utilizing a subject's personalised calibration and learning functions. While conventional methods of vigilance analysis as described above, each have specific benefits associated with various forms of sleep state, hypnotic or vigilant state, the present invention is designed to incorporate concurrent or selective combinations of analysis in accordance with the users specific requirements.

[0056] The present invention recognises that the linear amplitude and spectral analysis methods utilised by R&K for sleep state analysis of a subject are indifferent to the non-linear coherence analysis method more suited for entry and exit from sleep or hypnotic states of the subject.

[0057] The present invention may utilise any combination of spectral edge frequency analysis, Coherence analysis, R&K standardised sleep staging criteria, auditory response monitoring, initial wave monitoring, arousal analysis and specialised input parameters derived from the calibration or specific subject configuration and system configurations such as the subject's sex and age data. A learning function and application of neural networks may provide a means to weight the vigilance analysis format in a manner which is most appropriate for a specific subjects vigilant state such as wake, sleep, and transition from wake to sleep or sleep to wake.

[0058] The present invention may analyse a subject's neurological data for purpose of coherence analysis and R&K spectral analysis that may also include electro-occulogram and electro-myogram physiological data. In particular the present invention may process transition stages of the subject's vigilance to determine the most appropriate method of analysis and display of the subject's hypnotic, sleep or vigilance state.

[0059] For example, the subject may be detected as being in wake state by means of R&K analysis (preferred method for sleep/wake detection), followed by on-set of hypnotic state (preferred method of monitoring and analysing exit of hypnotic/sleep state) as detected by the coherence index, enter sleep state by means of R&K analysis stage 1 detection (preferred method for sleep/wake detection), exit sleep state by means of firstly R&K wake state detection, and then tracking depth of hypnotic state by means of AEP index and auditory response (preferred method of monitoring and analysing exit of hypnotic/sleep state).

[0060] The present invention may automatically allocate an optimal processing means for determining a subjects transition of consciousness state or sleep state by applying simultaneously one or more processing techniques for determining the most appropriate measure of the subjects state in accordance with the transition of the subjects consciousness.

[0061] Furthermore the present invention may include frequency analysis (R&K analysis) (34) spectral analysis-SEF-MF, ½ period analysis (46), (FFT) as a means to determine the transition and the current state of a subject in order to determine which method of consciousness analysis (BIP, AEP for example) is the most accurate and subsequent indicator for identifying and tracking the subject's vigilant state.

[0062] An ideal embodiment of the present invention may provide an independent measure of both sleep state and

brain activity in both wake and sleep states. Furthermore the ideal embodiment may detect when a non-valid sleep state was recognised (per International standard R&K) so that brain activity or consciousness measures should be utilised (BIP and AEP index). Furthermore the ideal embodiment may include a simple non-ambiguous readout for users. The present invention includes improved analysis of depth of anaesthesia/consciousness/patient state with optimised sleep-wake R&K analysis, optimised bi-spectral analysis and optimised AEP analysis. Phase based analysis may be combined with frequency band - amplitude analysis (spectral analysis) to provide an improvement on phase only or frequency based analysis (refer Figs. 16, 17, 18, 34, 35, 37, 41, 42, 45).

[0063] To the applicants knowledge no one has used combinations of Sleep-wake ½ period analysis or other forms of R&K or modified R&K analysis, unique artefact processing (refer Fig. 18 - MFD block 21) combined with specially weighted (in accordance with empirical clinical data) and optimised bi-coherence, triple product and bi-spectral index (refer Fig. 18 - MFD Block 10), and AEP analysis to improve the accuracy in determining the state of a subject's consciousness.

[0064] The present invention may, within a single monitoring device and single electrode device, simultaneously provide a combination of analysis types (and displays thereof) including BIS analysis, AEP index analysis, estimated R&K analysis, arousal analysis, eye movement analysis and eye opening analysis.

[0065] A common problem with frequency-based analysis methods (be it sleep-wake or bicoherence/bispectrum/triple product) in analysing neurological data, is that the results of the aforementioned types of analyses can change significantly with seemingly stable physiological conditions. For example, substantial increases in EEG activity in the 12 to 18 Hz (theta) frequency band may be observed with administration of anaesthetic agents in the low to medium concentrations, but high doses of the same agents may lead to sudden reduced activity in the 12-18 Hz frequency band and increased activity in the 0.5 - 3.5 Hz band, followed by burst suppression at extremely high concentrations. Similarly, bicoherence/bispectrum/triple product analysis relies upon "relatively new principles" for determining the subject's state of consciousness. In contrast, a well documented and validated method for sleep staging such as presented by R&K, utilises analysis techniques which, although being highly validated, are subject to misleading frequency effects, as described above. Apparatus based on the R&K method combines real-time optimised (34, 45) R&K analysis with optimised bi-spectral analysis to increase accuracy beyond conventional Bi-spectral Index™ (52). Application of optimised spectral analysis may provide a meaningful basis for determining consciousness state, where R&K analysis has been formulated to provide sleep stage (or depth of sleep) or wake state (referred to herein as sleep-wake analysis) as opposed to varying degrees of subconsciousness, as a subject approaches sleep or an unconscious state. R&K analysis on the other hand may provide a well validated method for determining a subject's depth of sleep. Furthermore modified R&K analysis (refer Fig. 18 - MFD Block 10) may improve artefact rejection, making determination of the patient state more reliable or less dependent on artefacts or noise, often evident during monitoring of a patient. The artefacts may include sweat artefact, amplifier blocking artefact, and mains noise signal intrusion, for example. The present invention may weight optimised R&K and optimised bi-spectral analysis in accordance with the strengths and weaknesses of each of these processes to provide overall improved accuracy and probability of determining the subject's depth or state of anaesthesia.

[0066] The present invention may reduce the effects of over reliance on frequency based changes of neurological data from a patient, by utilising both frequency based EEG (sleep-wake analysis) and phase based EEG analysis (bicoherence/bispectrum/triple product).

[0067] The present invention may provide automatic selection or weighting of BIC and AEP analysis by means of R&K or similar frequency based analysis as an arbitration agent in the decision path for weighting analysis types.

[0068] The present invention may be adapted to automatically detect whether the patient is transitioning from consciousness to unconsciousness or visa versa and to apply or weight bi-spectrum analysis (bi-coherence/bi-spectrum/triple) or audio evoked potential analysis (such as Brain Stem Auditory Evoked Potential-BAEP) respectively.

[0069] The present invention may monitor and detect the state of the subjects consciousness. In particular real-time and concurrent processes ideally suited to both non-linear and linear analysis techniques may be applied. The present invention may include bi-coherence (non-linear) analysis for depth of consciousness monitoring in conjunction with Audio Evoked Potential (more linear based) analysis for monitoring transition of a subject between conscious and unconscious states. The present invention may provide improved monitoring and analysis for application in detection, system alerts and alarms associated with depth of anaesthesia, hypnotic state; sedation depth, fatigue or vigilance of a subject, with as few as 3 surface electrodes. Combined or separate indexes or display methods may provide accurate tracking of the subject's state of consciousness and transition of conscious state. The present invention may assign patient states of sleep, wake, depth of consciousness, depth of anaesthesia and vigilance in accordance with analysis states derived from a combination of analysis types, including in particular BIC and AEP based analysis. Prior art systems (such as Aspect Monitoring) are limited as they are not as precise or responsive as an AEP, arousal or EEG activity based system for detecting transition and AEP responsiveness to transition but not as gradual a measure (as BIC) for predicting consciousness state.

[0070] However a limitation of this prior art method is that the gradual change of the bicoherence measure may, by nature of the type of the non-linear analysis prevent a clear or significant emphasis of the subject's transition state. The

transition state is when the subject changes from consciousness to unconsciousness or visa versa. This is a critical state when monitoring a subjects depth of anaesthesia as a subject who is on the verge of waking up may need urgent administration of anaesthesia in order to avoid a serious incident such as the subject awakening during a surgical operation.

[0071] For example, a time based curve or graph of the bi-coherence processed signal can produce a relatively gradual and consistent change when compared to other validated methods of consciousness monitoring, such as Audio Evoked Potential (AEP) monitoring techniques.

[0072] In the case of AEP monitoring, a subject wears a headphone attachment and is presented with audio stimulus clicks, while at the same time the auditory nerve is monitored. By monitoring the amplitude of the response of the monitored (via non-invasive surface electrodes attached to a subject's near ear) auditory nerve signal and averaging this signal by summing a sequence of overlaid traces of this auditory signal, it is possible to measure a degree of the subject's consciousness. In this particular example consciousness may be determined by a measure of the subjects hearing responses. One advantage of this method is that it is recognised to provide superior transition state information, where the transition state is the actual determinant of whether the subject is in a state of consciousness or unconsciousness. A disadvantage of this method is that the state of transition based on AEP analysis is relatively sudden due to the sudden response of the auditory nerve during the transition of a subject's state from unconsciouness to consciouness (30). However, an advantage is the explicit or obvious nature of the data curve transition between the two states.

[0073] Therefore the recognised methods of tracking consciousness and unconsciousness of a subject each have different advantages and disadvantages (33).

[0074] However the applicant is not aware of any prior art system or method that is able to provide an ideal solution. Such solution would need to have non-linear gradual measurement and prediction abilities associated with bi-coherence analysis, together with immediate indication associated with the transition state as depicted by AEP analysis.

[0075] The present invention may automatically detect whether the patient is transitioning from consciousness to unconsciousness or visa versa and apply or weight bi-spectrum analysis (bi-coherence/bi-spectrumltriple product) or audio evoked potential analysis (such as Brain Stem Auditory Evoked Potential- BSAEP) respectively. The present invention may address prior art imitations by applying R&K analysis as a type of "independent arbitration" agent for determining which analysis type is optimal, based on the context and sequence of analysis change or transitions. For example, R&K detection of wake state, suggests a probable transition from consciousness to unconsciousness, which in turn suggests that optimal or higher weighting of consciousness state determination should be derived from the BIC (bi-spectral analysis incorporating bi-coherence) analysis. In contrast, R&K detection of a sleep state (stage 1, 2, 3, 4, REM, for example) suggests a probable transition from unconsciousness to consciousness, which in turn suggests that optimal or higher weighting of consciousness state determination should be derived from AEP analysis.

[0076] An ideal system for monitoring depth of anaesthesia or vigilance or depth of sedation or hypnotic state should be able to present a single or simple index, display reference or monitoring technique which clearly depicts both a prediction of depth of anaesthesia and a current state and transition of states of a subject. In particular the ideal system hould be able to utilise a method of combining AEP and bi-coherence analysis techniques into a single monitoring measure. The present invention may achieve this scenario by weighting the AEP transition state and the bi-coherence analysis value so that a single combined reference is obtained.

[0077] The present invention may weight the transition state heavily when a subject transitions his/her mind-state from unconsciousness to consciousness (AEP, arousal and eye opening wake analysis is heavily weighed) so that an anaesthetist can have a guide in predicting the depth of anaesthesia utilising the bi-coherence factor, but if the subject changes or approaches a change in state as indicated via AEP analysis, the anaesthetist may be given immediate and obvious display indication and can avert a potentially serious incident such as the subject awakening during a surgical operation.

[0078] The present invention may assign patient states of sleep, wake, depth of consciousness, depth of anaesthesia and vigilance in accordance with analysis states derived from a combination of analysis types including R&K analysis (34), AEP (30), spectral analysis-SEF-MF (4), Bi-coherence (BIC) analysis (33), initial wave analysis (5), auditory response

[0079] (4,30), arousal analysis (35) and body movement analysis (34,26), 95% spectral edge analysis (36) and anaesthetic phase and spectral energy variance measurement in association with a subject's state of consciousness (30), Pulse Transient Time (PTT) based arousal detection (31), PTT measure and PTT based blood-pressure reference measure, PTT based heart rate and blood pressure with simple non-invasive oximeter (31, 32), PAT analysis for sympathetic arousal detection (104-108), EEG spike-Kcomplex-wave-activity-event categorisation (47) and bio-blanket-heart- temperature-PTT blood-pressure-respiration-breathing sound (49).

[0080] The present invention may include automatic consciousness state context determination (refer Figs. 16, 17, 18, 34, 35, 37, 41, 42, 45). The present invention may provide trend or sequence analysis with improved qualification of a subject's depth or level of various mind states by incorporating preliminary analysis or preview analysis context determination. In particular the present invention may apply concurrently and in real-time EEG frequency (26,30,36,47), EEG phase (33) and EEG amplitude analysis (30).

[0081] For the purpose of "context" determination, the present invention may apply concurrently and in real-time a combination of methods of analysis including R&K analysis (34, 45,46), AEP (30), spectral analysis-SEF-MF (4,30), Bi-coherence (BIC) analysis (33), initial wave analysis (5), Auditory Evoked Response (30), arousal analysis (35) and body movement analysis (34), 95% spectral edge analysis (36) and anaesthetic phase and spectral energy variance measurement in association with a subject's state of consciousness. (36), Pulse Transient Time (PTT) based arousal detection (31, 32), PTT measure and PTT based blood-pressure reference measure, PTT based heart rate and blood pressure with simple non-invasive oximeter, PAT analysis for sympathetic arousal detection (104-108), EEG spike-K-complex-wave-activity-event categorisation (47) and bio-blanket-heart-temperature-PTT blood-pressure-respiration-breathing sound (49), to determine the context of a subject's state of mind. In particular the "context' may include that a subject is in a state of wake or consciousness and whether or not the subject is entering or approaching a state of unconsciousness or sleep, for example. Where a subject is in a state of unconsciousness or sleep, an ideal depth and state of consciousness monitoring system may emphasise or highly weight a change of state where (for example), this change of state could represent a subject awakening during an operation procedure, for example.

[0082] There are a number of limitations associated with current standards for staging human sleep (R&K standardised sleep criteria) (34). Some of these limitations arise, for example, from the fact that it has been found that infants exhibit higher amplitude of EEG frequency bands such as deltawave than do more elderly patients. It has also been found that in infants conventional methods of scoring sleep are not an accurate indication of the child's sleep physiology.

[0083] The present invention may address the limitation of prior art methods of EEG sleep analysis with an ability to concurrently analyze and process a selection of, or combination of methods of sleep/hypnosis/arousal/vital signs monitoring including:

- ♦ R&K analysis (34),
- ♦ EEG pattern recognition
- ♦ AEP (30),
- ♦ spectral analysis-SEF-MF (4),
- ♦ Bi-coherence (BIC) analysis (33),
- ♦ initial wave analysis (5),
- ♦ auditory response (30),
- ♦ arousal analysis (35),
- ♦ body movement analysis (34),
- ♦ 95% spectral edge analysis (36),
- ♦ anaesthetic phase and spectral energy variance measurement in association with a subject's state of consciousness. (30),
- ♦ Pulse Transient Time (PTT) based arousal detection (31),
- ♦ PTT measure and PTT based blood-pressure reference measure (31,32),
- ♦ PTT based heart rate and blood pressure with simple non-invasive oximeter(31,32)
- ♦ PAT analysis for sympathetic arousal detection (104-108),
- ♦ EEG spike-K-complex-wave-activity-event categorization (47),
- ♦ bio-blanket- heart- temperature-PTT blood-pressure-respiration-breathing sound (49).

[0084] In addition to the above analysis techniques the present invention may access any combination of one or more of the above analysis techniques concurrently and determine the:

- context,
- physiological vigilance or sleep or wake or consciousness transition; and
- predict "probability of transition" of a subject's vigilance state.

[0085] The "context and predictive" analysis includes providing a validation of the subject's sleep or hypnotic state by referencing a combination of the above analysis techniques in terms of the current vigilance phase and a trend or sequence vigilance phase. If, for example the present invention determines that the subjects current vigilance state does not qualify for classification under conventional rules as depicted by R&K analysis (34), but was detected by way of BIC coherence analysis (33) as progressing to a deeper stage of hypnotic state or a deeper state of unconsciousness (as with deeper state of in-depth anaesthesia state), then the present invention may make a more accurate decision based on predictions from the context of the R&K and BIC analysis past and current trend data. In this particular case the prediction may be that the subject is entering a phase of deeper unconsciousness or hypnotic state (by way of no R&K state and BIC analysis), and accordingly has a higher probability of predicting that the subject is more likely to be approaching a transition of unconsciousness to consciousness. This aforementioned prediction may alert the present invention that the most accurate method of analysis in the phase from unconsciousness to consciousness is likely to be

Auditory Evoked Potential response. The present invention may "self-adapt" the analysis method in accordance to the sequence of the subject's vigilance state transitions in order to provide improved accuracy for monitoring a subjects vigilance or to more appropriately classify same into a sleep, hypnotic or consciousness state of the subject being monitored. "Self adaptation" in this context refers to the capability of the present invention to initially weight vigilance analysis towards BIC as the preferred method for analysing a subject's transition from wake to unconsciousness, and then subsequently weight Audio Evoked Potential response as the preferred method of analysing a patient's transition from unconsciousness to consciousness.

[0086] The present invention may determine the most probable transition states by evaluating the trend or sequence of data output from more than one analysis type. Example of vigilance transition states include:

- consciousness to unconsciousness
- unconsciousness to consciousness
- sleep to wake
- wake to sleep
- deepening of unconsciousness (or hypnotic) state
- exiting of unconsciousness (or hypnotic) state

[0087] Examples of analysis types that may be automatically allocated based on a subject's current vigilance transition state and current state include:

TRANSITION STATES	AUTOMATIC PREFERRED ANALYSIS TYPE
Consciousness to unconsciousness	BIP
Unconsciousness to consciousness	AEP
Sleep to wake	1)R&K, 2)BIC
Wake to sleep	1)R&K, 2)BIC
Deepening of unconsciousness (or hypnotic) state	BIC
Exiting of unconsciousness (or hypnotic) state	AEP

CURRENT STATE	AUTOMATIC PREFERRED ANALYSIS TYPE FOR STATE CLARIFICATION
Consciousness or wake	1)BIC, 2)R&K
Unconsciousness	AEP
Sleep state	R&K
Wake state or consciousness	1)BIC, 2)R&K

[0088] The present invention may take into account the instantaneous and trend analysis outputs from one or more analysis type to determine a subjects most probable transition state and may then select the most qualified or accurate analysis type as the primary decision weighting of a subject's state of consciousness (hypnotic state), wake, sleep or vigilance.

[0089] The present invention may include a learning capability and pattern recognition to enable different combinations of analysis type and different combinations of trends of analysis, to determine the most appropriate analysis type for determining the patient's vigilance.

[0090] Furthermore the present invention may recognise combinations of analysis output to improve accuracy of detecting a subject's vigilant state or transition of the subject's vigilant state.

[0091] The present invention may apply both FFT and ½ period amplitude analysis in consecutive 1 second intervals (can be set to greater values, particularly where lower frequency response characteristics are being utilized). The FFT analysis (i.e. 95 % spectral edge (36)) has an advantage of providing power distribution of the EEG signal frequencies but the disadvantage of not presenting mixed frequency EEG signals for assessment under scoring criteria such as per R&K analysis EEG (34,45,46). An example of where ½ period amplitude analysis may provide an advantage over frequency analysis is where a 30 second epoch contains a high amplitude Delta wave and the Delta wave does not constitute greater than 50% of the 30 second epoch, but due to excessively high amplitude of the Delta wave, would appear to dominate the 30 second epoch. In this case use of FFT would suggest that this epoch is, say stage 4 (greater

than 50% of the epoch time with high amplitude Delta wave in accordance with R&K analysis (34,45,46). However if for example, the epoch consisted of greater than 50% of the epoch in Alpha EEG waves as would be more evident (than FFT analysis) with ½ period amplitude analysis then this epoch should in accordance with R&K human sleep scoring criteria, not be scored as stage 4 of sleep. In other words the ½ period amplitude analysis more correctly represents the method of scoring sleep in accordance with R&K than FFT in such instances and utilization of FFT and ½ period analysis (45) may provide improved accuracy for determining a subject's consciousness state (33) and sleep state (34) in the present invention.

[0092] The present invention may include automatic Input Signal Validation, Optimisation & Compensation (ASVC) including automatic substitution of poor quality electrode connections (refer figs.17, 18,34,35,37,41,42,45). This function may enable the present invention to automatically validate input signals (physiological variables in the present application but applicable to other industries involving monitoring or analysis of signals in general) of a subject's monitored variables. Validation may be by way of automatic impedance measurement, frequency response, mains interference, signal to noise and signal distortion and other measured signal characteristics as part of the analysis algorithm for monitoring, detecting or predicting a subject's state of consciousness, sedation or vigilance.

[0093] Furthermore the present invention may automatically determine signal conditions during operation of the present invention, and invoke subsequent signal processing to compensate or reduce artefacts caused by unwanted signal distortion or interference such as noise. Furthermore, in order to allow the present invention to display to the user on-going signal validation and signal quality issues, signal status and subsequent compensation (or signal correction), signal trends or progressive deterioration of signal quality and existing signal quality issues, both current and trend signal status may be displayed in real-time and stored, with both modified and compensated signal data.

[0094] The present invention may provide trace ability (or an audit trail) of all signal modifications so that the user can validate any automatic signal compensation decisions both in real-time and in later study review. A further feature of the present invention is a capability to provide the user qualification, at all times, relating to detected signal deterioration and subsequent signal compensation. A further capability may allow the user of the present invention to automatically or manually (upon the user's discretion or agreement with qualification of signal deterioration and proposed compensation) invoke signal compensation for optimising or improving signal quality. Due to time synchronised (with recorded signals) trace ability (audit trail) of signal validation and subsequent signal compensation, modified signals may be revoked (unmodified) to original signal format where required.

[0095] Furthermore, signal validation may provide a means to optimise signal quality for improved application of various signal-processing algorithms.

[0096] The present invention may adapt or re-assign redundant or spare electrode channels in substitution of identified poor quality signal channels. In particular the present invention may automatically alert a user of the quality of all attached electrodes and sensors. Where any poor signal quality is detected the present invention may advise the user of recommendations or hints to quickly identify and resolve signal quality problems.

[0097] Surface electrode connections have been applied in the past for various physiological parameters and monitoring applications. However one problem associated with surface electrode connections is that the quality of the connection to the patient can deteriorate as a result of a number of conditions including patient sweat, movement, or the drying out of the connecting electrolyte solution between electrode and patient. In particular the problems of electrode quality may be particularly critical in applications such as those associated with intensive care and operating theatre environments, as is the case with depth of anaesthesia monitoring systems.

[0098] To the applicant's knowledge, no one has used connection of redundant electrodes, automatic electrode connection quality and validation by way of routine impedance measurements and other signal validation techniques (refer Fig.18 - MFD Block 7) and automatic substitution of poor electrode connections with the redundant (spare) electrode connections (refer Fig.35 (IAMES) or 37 ISES)). The present invention may utilise redundant electrode systems together with integrated electrode-sensors and wireless/rechargeable electrode-sensors to minimize the quantity of electrodes and sensors (as few as 3 sensor-electrodes) for depth of anaesthesia monitoring (where the quantity, reliability and simplicity of electrode-sensor attachments is very critical) and analysis including mind-state, auditory sensory, visual sensory, arousal sensory, anxiety sensory and vital signs physiological states.

[0099] The present invention may include automatic Analysis Validation, Compensation, Optimisation, Adaptation of Format and Analysis and Probability Assignment (AAVCOAFA)(refer Figs.16, 17,18,34,35,37,41,42,45). The present invention may adapt algorithms for determining the subject's state of consciousness (and vulnerability to anaesthesia procedure recall) while simultaneously in substantively real-time allowing the present invention to determine and display to the user the signal analysis methods being deployed (such as R&K derived from optimised BIC -outer malar bone surface electrodes- as opposed to C3 EEG signal) signal status, trends or progressive deterioration of signals (such as detailed in (AVCOADSP), or analysis quality caused by, for example, input signal connection deterioration, or connection of improved signal inputs. In other words the present invention may determine the most appropriate (accurate and reliable) analysis method (algorithm type) by way of validating input signal quality and automatically or manually activate a changed analysis method or format that is the most suitable for the validated signal channels. The analysis methods

may be determined according to presence, status and quality of the patient signals being monitored.

[0100] A further capability of automatic analysis validation is that the present invention may adapt or re-assign variants or substitute analysis formats where the existing analysis format requires change, such as when an input channel connection(s) deteriorate.

[0101] The present invention may automatically alert the user of the quality and probability of the applied analysis processes. The present invention may also advise the user of recommendations or hints to quickly identify and resolve analysis validation deterioration or issues.

[0102] The present invention may display to the user on-going analysis validation status, progressive deterioration of analysis quality and subsequent analysis variation or analysis compensation due to signal deterioration, for example.

[0103] Furthermore once analysis types have been activated, weighting techniques may be applied in order to determine the probability associated with different analysis methods. For example, BID. (outer malbar bone, surface electrode placement) derived R&K EEG analysis does not produce as high a probability as C3 (surface electrode) derived R&K EEG analysis.

[0104] The present invention may provide an automatic analysis format linked to signal validation, such as in the case of sleep and wake analysis where the analysis parameters applied may depend on the validated signals. If, for example, only EEG outer malbar electrodes are validated, then frequency optimised EEG outer malbar signals may be utilized for analysis, as opposed to more complex analysis signal combinations including EMG and EOG signals.

[0105] The present invention may include Patient Data-Linked Analysis (PDA)(refer Figs. 16,17,18,34,35,37,41,42,45). The present invention may adapt the analysis algorithms used for determining a subject's state of consciousness (and vulnerability to anaesthesia procedure recall) in accordance with critical data such as the subject's body mass index (weight, height), sex and age. Such Patient Data-Linked (PDA) analysis may enable patient specific data such as the subject's body mass index, age, sex, medical history and other relevant information to be utilised in analysis algorithms for monitoring, detecting or predicting the state of consciousness, sedation or vigilance of the subject.

[0106] Patient specific data is entered in prior art patient monitoring systems. However in some instances patient specific data can substantially affect monitoring or analysis methods associated with the monitoring system. To the applicants knowledge, no one has linked critical parameters such as weight, age and sex of a patient to the sensitivity and weighting of depth of anaesthesia monitoring. The present invention may change the weighting or sensitivity of analysis of the physiological parameters being monitored. An example of this is where the weight or sex of a subject affects (in accordance with empirical clinical data), the optimal band of operation of a given concentration of an anaesthetic agent, due to the effects that sex and weight have on these parameters.

[0107] The present invention may utilise certain patient data, which may vary the sensitivity or important thresholds associated with variations between one patient and the next. The "utilisation" of this data refers to compensation, for example, of critical display threshold levels and sensitivity of various user displays. These user display thresholds and associated sensitivity variations may change in accordance with critical applications, for example when using the present invention to monitor sensitivity of depth of anaesthesia to certain anaesthetic agents.

[0108] Table A below shows one example of Patient Specific Data Entry Parameters:

Table A

PATIENT SPECIFIC INPUT DATA
Age:
Weight:
Height:
SEX:
BMI:
History file:
Calibration file:
Calibration-file anesthetic type:

[0109] The present invention may include Calibration-Linked Analysis (refer Figs.16, 17,18,34,35,37,41,42,45). The present invention may adapt the analysis algorithms used for determining a subject's state of consciousness (and vulnerability to anaesthesia procedure recall) in accordance with the subject's critical calibration data, such as how the subject responds to various preliminary or pre-test studies. This "calibration data" may include thresholds and parameters derived from a specific patient's preliminary study, in order to determine the characteristics of the subject's physiological

parameters for more accurate consideration of variations between different subjects.

[0110] This capability may be important where, for example, a subject undergoes a critical operation. To minimise the risk associated with anaesthesia administration, a preliminary calibration study can be conduced. This study may include a capability to store tables of values or specific drug administration versus analysis state (BIC/AEP/R&K/95% spectral edge or other) coefficients or specific analysis values associated with varying degrees of drug administration.

[0111] The present invention may include localized or general motor and sensory nerve and muscle response and arousal analysis (refer Figs.16, 17,18,34,35,37,41-45). The present invention may adapt algorithms used for determining a subject's state of consciousness (and vulnerability to anaesthesia procedure recall) in accordance with monitoring and detection of the subject's arousals (typically detected from shifts in frequency and amplitude in monitored signals) or muscle responses (for example during an operation or medical procedure). The present invention may apply this data as an alert or detection means for the subject's transition state or physiological and mind-state response to a medical procedure and a means of consciousness state detection. In other words the muscle changes or arousal events may be indicative of muscle responses of the subject, which in turn may indicate the subjects localised anaesthesia effectiveness or the subject's state of consciousness and local muscle response.

[0112] In particular localised monitoring and detection of muscle movement or activity may provide a means to localise the arousal and muscle monitoring, relative to the responsive or sensitive areas associated with a medical procedure, and consequently may provide immediate feedback where an anaesthetised area of a subject indicates muscle or nerve responses consistent with inadequate anaesthetic drug administration. The present invention may include accurate monitoring and recording of the effect of local anaesthetic by detecting the subject's motor and sensory responses in conjunction or time-linked with an incision or other medical procedure. The latter feature may provide a means of monitoring and analysing both the state of a subject's mind and the response from selected ear related (cochlear) procedures where a subject's state of anaesthesia and performance or response of the auditory system can be monitored and analysed throughout an operation procedure. Industry standard techniques (for example, Canadian Task Force) (35) for detecting arousals may be utilized in the present invention.

[0113] The present invention may include an electrical stimulus pulse (evoked potential) and test of the nerve or muscle response of a subject while undergoing an operation or medical procedure. The electrical stimulus pulse may be applied at a selected excitation location on the subject's body, and the response (nerve or muscle) can function in a dual-monitoring mode whereby determining the subjects state of consciousness or vigilance (as in depth of anaesthesia monitoring) and determining the response and performance of selected muscles or nerves of the subject may be performed simultaneously. This '"dual-monitoring" function may be particularly useful when a subject is undergoing a delicate and precise medical operation or procedure.

[0114] The present invention may include an Integrated Anaesthesia Monitoring Electrode System (IAMES)(refer Figs. 16, 17,18,34,35,37,38,41-45). IAMES may be wired or wireless. IAMES may include a simple, low cost and minimally intrusive electrode system, which may be disposable or reusable with a connector interface to a replaceable EAS. Alternatively EAS may be integrated with a Wireless Electronic Module (WEM). A version which is completely disposable would typically be lower in cost and may not in some lower cost options, include a wireless interface. The lower cost completely disposable versions may include a low cost data logging system with low cost display means. Low cost display means for completely disposable versions, may include once of display output for index measure, for example, or digital interface or data card for information retrieval.

[0115] The IAMES system may be divided into two components including an electrode attachment system (EAS) and the WEM section. Completely disposable systems may include integrated WEM and EAS sections for further cost reduction.

[0116] The EAS system is a remote patient attached electrode transceiver monitoring station, which contains a means of inputting patient data to the WEM module (refer below). EAS incudes a code identification system allowing system configuration to be set up in accordance with the specific electrode type (ie.EEG, EOG, EMG, EEG or other).

[0117] EAS includes conductive surfaces which may be easily attached to a patient's skin surface for electrical pick-up of physiological variables associated with a subject including a combination of left and right, outer malbar placed electrodes for detecting typical bicoherence EEG variables, left and right outer carantheous eye electrodes for detecting EOG electrical signal associated with eye movements, chin sub-mental EMG electrodes for detecting the subject's chin muscle activity and state of restfulness, A1 or A2 electrodes (dependent on the format of the electrode system) for providing an electro-physiological reference signal and eye lid position sensors for detecting eye opening activity and percentage of eye opening.

[0118] A combination (hybrid) system may provide R&K and/or bicoherence signal attachment in one wireless hybrid device, thus opening up avenues for large scale home monitoring of sleep disorders, more critical applications such as medical procedures and operations or vigilance monitoring of workers or air/land/sea transport personnel. Options may include sub-mental EMG and/or auditory sound output devices (ear-piece, headphones or speaker) and/or auditory signal pick-up devices (surface electro-physiological electrode).

[0119] A Wireless Electronic Module (WEM) system may include a small, low power and lightweight module designed

to snap connect to an EAS module). The WEM module may provide the following functions:

- interface for one or more channels of patient data emanating from the EAS module;
- electrode and sensor amplification (DSP and/or analogue methods);
- filtering (DSP and/or analogue methods);
- calibration testing including generation of one or more (different waveshapes, frequency and amplitude) local test waveforms;
- impedance measurement;
- signal quality measurement;
- input DC offset measurement;
- wireless data transceiving and DSP or micro-controller data processing capabilities; and
- reference code identification detailing electrode type (eg.EEG,EOG, EMG,EEG or other).

[0120] The WEM transceiver module may transmit physiological signals and various test data such as the impedance value across the electrode signals, quality measure of signal or data such as a reference code detailing electrode type (ie. EEG, EOG, EMG, EEG or other). The EAS transceiver module may also receive various control and test commands such as requests to measure impedance, generation of test or calibration waveforms, a measure of signal quality and other data.

[0121] The WEM system may be powered via any combination of rechargeable or single use batteries, self powered electrodes with a capability of charging via RF or EMF induction during use or as a charging procedure.

[0122] A WEM module may be directly attached to an EAS module, or it may be attached to an EAS module via an intermediate wireless link or wired attachment. Alternatively, patient worn or patient attached device(s) such as headband, head-cap or hat, wrist-worn or other devices may incorporate an EAS and/or WEM module.

[0123] The WEM module may be self powered with Radio Frequency or Electromagnetic frequency providing a power supplement. The latter system may utilise radio or electromagnetic signals as a means for recharging the power source in the WEM module.

[0124] The IMES device may be wirelessly linked to close proximity or distant monitoring systems equipped with a wireless data interface capability to IMES. Close proximity monitoring devices may include the headrest of a car seat where a self-powered IMES system (typically EMF power recharge system) may be wirelessly linked to a transceiver device contained within the driver's seat headrest or other convenient or appropriate location(s). The WEM may be wirelessly linked to remote computer devices wherein WEM data may be stored, displayed and/or analysed. The remote WEM device may also provide a controlled interface to the WEM module for calibration and impedance testing. WEM may also be wirelessly linked to mobile phones or wireless modems or a network interface including an Internet connection.

[0125] The IMES device, when incorporated with local (incorporated in WEM module) or remote (wireless or wire-linked) BIC analysis may provide analysis for detecting vehicle or machine operator vigilance with a wireless electrode option.

[0126] The present invention may include an Eye Opening Sensor (EOS)(refer Figs.34, 35,37,42). The EOS system may provide an improved device for sensing and measuring Eye Opening. Eye movement sensors (such as piezo or PVD movement sensors) and electrodes (such as EOG) have been used in the past for detecting eye movement or eye-lid movement respectively. However one problem associated with depth of anaesthesia monitoring is the fact that some patients awaken prematurely during a medical procedure and opening of the eyes can lead to distressing views and later recall or nightmare occurrences. A further problem is the patient may litigate in such instances. An objective and accurate recording of the patient's state and amount of eye opening is therefore desirable. A system that allows the user to calibrate such an eye-opening sensor may also be of value. The present invention may include such a sensor (refer Fig.34) for detecting in a calibrated manner the degree of opening of a subject's eye.

[0127] The EOS system includes an eyelid position monitor and an EOG sensor. The EOS system may include conventional surface electrode electro-physiological signal sensing in conjunction with a capability to detect the position of a subject's eyelid at any point in time. Combined sensing of eye movement and eye opening may provide a simple, minimally invasive sensing system ideally suited to a subject's eye region to provide eye blink details and rate, eye open percentage and eye movement information. The sensor can be wire or wireless connected to a monitoring system. The EOS system may also be provided in an embodiment, whereby EOG sensing is achieved within the same sensor attachment system. Special design variations may provide simple self-applied sensors, which can be safely and easily applied in a manner similar to attaching a band-aid.

[0128] A further option exists using self-applied electrodes where the electrodes may include a low cost disposable component and a more expensive reusable component. For example the connector and electronics circuit may be reusable, while the applied section of the sensor may be disposable.

[0129] The present invention may also provide an improved capability for calibrating eye position at commencement or at any stage during a subject's use of the EOS sensor. Calibration may be applied by determining (measuring, storing

and determining calibration data versus corresponding eye opening status) the output of the EOS sensor under varying conditions, eg. by asking a subject to close their eyes, and storing the responding EOS signal. The EOS system may incorporate the format of the WEM and the EAS.

[0130] The present invention may include an Integrated Sleep Electrode system (ISES)(refer Figs.35, 37,42). The ISES device may provide a self-applied electrode system for sleep/wake analysis of a subject. The electrode system may attach outer malbar or any two EEG electrodes to a subject's forehead as part of a monolithic self-adhesive and self-applied electrode system. An analysis method may be applied to the ISES device's signal output to provide sleep/wake or bicoherence analysis. A flexible insert may facilitate elasticity to accommodate different patient sizes. Electrodes may include varieties including an attachable version and disposable dot surface re-usable electrodes (such as from 3M) and reusable/disposable electrodes. The ISES system may include the format of the Wireless Electrode Module (WEM) and the Electrode Attachment System (EAS).

[0131] The present invention may include a user programmable device with real-time display of integrated analysis index and incorporating at least two weighted and combined modes of analysis (refer Figs.16, 17,18,34,35,37,41-45). The apparatus may include a capability to output one or more analysis algorithms including a combination of simultaneous, real-time analysis of R&K analysis (34), AEP (30), spectral analysis-SEF-MF (4), Bi-coherence (BIC) analysis (33), initial wave analysis (5), auditory response (30), arousal analysis (35) and body movement analysis (34), 95% spectral edge analysis (36) and anaesthetic phase and spectral energy variance measurement in association with the subject's state of consciousness (30), Pulse Transient Time (PTT) based arousal detection (31), PTT measure and PTT based blood-pressure reference measure, Pulse oximetry SA02, PTT based heart rate and blood pressure with simple non-invasive oximeter, PAT analysis for sympathetic arousal detection(104-108), EEG spike-K-complex-wave-activity-event categorisation (47) and bio-blanket heart-temperature-PTT blood-pressure-respiration-breathing sound (49). The specific types of analyses can be determined by way of signal validation, user's selection of analysis requirement (such as depth of anaesthesia, vigilance, sleep-wake and other) and electrodes input to the system.

[0132] The present invention addresses the limitation of the prior earlier art by presenting a simple mode of display to the user which represents a simple measure of the subject's current state of consciousness or hypnotic state. This particular aspect of the present invention may communicate to the end-user a simple measure of the subject's consciousness despite a vast range of complex analysis measurements, as detailed herein. In addition to providing a simple overall measurement and display method the present invention may also provide a means of storing and displaying all recorded raw data and outputs of each analysis method for complete system verification and trace ability relating to any display of conscious or vigilant state of a subject. The raw data and analysis data may be stored and available for later review, reporting and printing, as is required from time to time to verify system performance and operation.

[0133] The present invention may improve accuracy of prediction of the state of consciousness, or a subject's vigilance by comparing actual EEG amplitude variations with predicted EEG amplitude variations where predicted EEG behaviour may include predictions of EEG amplitude variation during anaesthesia drug administration against depth of anaesthesia prediction (29)(refer Firs.16, 17,18,34,35,37,41-45). The present invention may recognize EEG amplitude variations associated with physiological phenomena such as EEG bursts as opposed to EEG amplitude variations associated with movement or other forms of artefact, such as excessive beta frequencies.

[0134] The present invention may apply amplitude analysis to the EEG signals. By analysing monitored EEG amplitudes from a subject and comparing this signal to a pre-known amplitude trend or signal behaviour, it may enhance accuracy of prediction of anaesthetic drug administration. The "pre-known" behaviour trend may provide a means to predict the state of the depth of anaesthesia by referencing a known or predicted sequence or trend of EEG amplitude variation (behaviour) with the subject's actual EEG amplitude or patterns of EEG amplitude variation whilst under sedation or anaesthesia, for example.

[0135] The present invention, may reference amplitude trend predictions and signal modelling such as described by Moira L. Steyne-Ross and D.A. Steyne-Ross, of Department of Anaesthetics, Waikato Hospital, Hamilton, New Zealand (29) in a paper entitled "Theoretical electroencephalogram stationary spectrum for white-noise-driven cortex: Evidence for a general anaesthetic-induced phase transition". This paper describes an increase in EEG spectral power in the vicinity of the critical point of transition into comatose-unconsciousness. In similar context to the above-mentioned weighting methods, the present invention may weight the analysis output from amplitude analysis of the EEG signal. The EEG analysis may include comparison of actual monitored EEG signal and trends and predicted signal or trend associated with the subject's transition from consciousness to consciousness and visa versa.

[0136] The output of amplitude processing may be input to a weighting table for final consideration in the monitoring, detection and alerts associated with depth of anaesthesia, hypnotic state, sedation depth, fatigue or vigilance of the subject.

[0137] The present invention may include a Programmable Electrode Interface System (PEIS) (refer Figs.16, 17,18,34,35,37). The PEIS apparatus may provide a means for intuitive user guidance and operation. The user can select a desired function (for example depth of anaesthesia monitoring, vigilance monitoring, sedation monitoring) and the present invention may illuminate by way of LED, LCD or other display system, the required electrode connections

and recommended position on subject such as the location of various surface electrodes.

[0138] The PEIS apparatus may provide a prompting capability, indicating to the user, which electrodes require attention, eg. surface electrode may require reattachment due to excessive impedance.

[0139] In a preferred embodiment the PEIS apparatus may include a touch screen programmable electrode attachment guidance system.

[0140] The present invention may include a Biological Blanket Sensor (BBS). The BBS may enable a wired or wireless interface providing a range of measurements for assistance in determining arousal movements, body movement, breathing sounds, heart sounds, respiration, heart rate, Pulse Transient Time, Blood pressure and temperature.

[0141] The BBS apparatus may be sensitised with sensor elements whereby the sensor reacts to subject movement causing a change in impedance of a resistive element, piezo or PVD element (49).

[0142] The present invention may include a Biological Sensor Oximeter with Integrated and Wireless-Linked ECG and Pulse Transient Time (PTT) Monitoring and Analysis (refer Fig. 33). The latter apparatus may monitor a subject's blood pressure variation, micro-arousal detection for detecting sleep or consciousness fragmentation (particularly useful but not limited to depth of anaesthesia consciousness monitoring and analysis), oximetry, temperature, ECG waveform and analysis, heart rate variability and cardio-balistogram respiratory monitoring output and respiratory event detection.

[0143] Prior art non-invasive blood pressure devices utilise techniques such as finger attachment probes. These finger attachment systems apply pressure to a patient's finger and can become uncomfortable after a period of attachment to the patient. Other non-invasive blood pressure measurements have been presented including qualitative methods. One such qualitative method is a qualitative derivation of Pulse Transit Time (PTT) by means of a calculation utilising the electrocardiograph (ECG) waveform and the pulse waveform of the subject. The ECG waveform is typically derived from a chest located ECG surface electrode attachment. The pulse waveform may be derived from the plethysmograph pulse waveform of a pulse oximeter probe attachment at a location such as a patient's finger. The calculation for deriving qualitative blood pressure value is based on the relationship, which exists between PTT and Blood pressure. Plethysmograph data may also be used to establish sympathetic arousal conditions (104), which may be related to stress or anxiety and which are physiological signs of premature awakening.

[0144] However a number of patient monitoring applications require continuous and close to real-time blood pressure measures of the subject to detect a significant physiological blood-pressure change or related event.

[0145] Furthermore existing minimum invasive methods for blood-pressure measurement typically involve a cuff device placed around the subject's upper arm. The cuff device may be inflated and deflated to measure blood pressure. This method of measuring blood pressure may be applied to a patient on a periodic basis. Other methods for minimally invasive blood-pressure measurement include wristband cuffs with similar inflatable and deflateable bands. Whilst these wristband cuff blood pressure systems, are potentially less invasive than upper arm cuff type systems, it is apparent that measurement reliability of wrist systems is more vulnerable to sensitivity of positioning and difficulty in obtaining a consistent and reliable measurement. Both cuff type systems are not used routinely for real-time and continuous blood pressure monitoring applications (such as depth of anaesthesia, respiratory disorder and sleep disorder monitoring) due to obvious discomfort and complexity and inconvenience of such measurement techniques.

[0146] An object of real-time blood pressure, measurement technique is to apply a 3-point wireless localised network (raw data and analysis results may be transmitted to a remote computer, if required) to provide a minimally non-invasive, minimally obtrusive blood pressure measurement apparatus. One aspect of this apparatus is that the clinically accepted standard for upper-arm cuff iriflation/deflation measurement may provide calibration and absolute blood pressure measurement, while the oximeter finger (for example - another location for oximeter pulse) SAO2 measurement together with plethysmograph (provides pulse waveform for measurement of pulse transit time) and ECG surface electrode may provide a reference heart signal to be used in conjunction with the oximeter finger pulse signal to produce a calculation in real-time for pulse transit time. Pulse transit time is recognised as a means of qualitative blood pressure measurement (31, 32).

[0147] In contrast to the prior art the present invention may apply periodic cuff attached (arm, wrist or other patient attachment location) blood-pressure measurement system, in conjunction with an oximeter pulse waveform and ECG waveform (for PTT calculation). The method of utilising the PTT (by way of oximeter pulse wave and ECG waveform) together with periodic cuff based blood-pressure measurement may provide a means to derive a quantitative blood-pressure measurement from the cuff value, and a qualitative blood-pressure measurement from the PTT calculated signal. In other words the baseline quantitative blood-pressure value may be derived from the cuff blood-pressure value, while a continuous and qualitative blood pressure value may be derived from the PTT value. The benefit of this type of system is accuracy and a continuous blood pressure monitoring capability, while maintaining patient comfort by implementing cuff inflation and deflation only at periodic time intervals.

[0148] Furthermore the present invention may simplify user operation with application of wireless interconnection of the pulse oximeter, ECG electrode and blood pressure cuff. Wireless interconnection may allow calculation of continuous blood pressure at a remote wireless or wire-linked site (such as a patient monitoring device), at the ECG electrode attachment site, at the oximeter finger probe site or the blood pressure cuff site.

[0149] The present invention may include an audiovisual recall and speech sensory validation system (refer Fig. 43). The latter may provide audiovisual recall or replay and time synchronisation with depth of anaesthesia analysis data and raw data. Audiovisual recall may provide a means to correlate physiological or analysis data associated with depth of anaesthesia monitoring.

[0150] The audiovisual system may be configured in several options. One option may include a capability to store more than one audio channel synchronised with the subject's measured physiological data. The stored and monitored (and optionally analysed or condensed) audio channel may include sound or speech associated with the subject, to accommodate monitoring and detection associated with the subject's speech sensory system. This function may be deployed as a last line of defence where a partly anaesthetised patient is attempting to notify the medical team, in case of partial or complete consciousness associated with potential undesired recall of a medical procedure.

[0151] The user may select physiological events or combinations of physiological events as event markers. The event markers may form the basis of time markers pointing to significant or relevant events. The event markers may be associated with specific audio and/or video related events. The "audio" and/or "video" related events include physiologically related or environmental related events. Physiologically related events include combinations of or single patient data changes which may be related to the patient's significant (i.e. the level exceeds a certain threshold condition) or relevant (to the users or the programmed detection threshold) changes in consciousness state. The time synchronisation between video, audio, physiological data and analysis data may provide a means for audio and video to be recalled and analysed in conjunction with the subject's state of consciousness as indicated by the status of eye opening, AEP, arousal, bi-coherence analysis, and other analysed states.

[0152] One example of an audio and/or video "relevant" event may be where a threshold level (user set or system default set) is exceeded indicating a potential for onset of consciousness. Detection that the audio evoked threshold is exceeded may be linked to detection of "environmental" and/or system generated audio threshold being exceeded, where "environmental" audio denotes audio recorded in the operating theatre from music, speech or other sources of noise. "System- generated audio" refers to the audio stimulus click, which may be applied to the patient's ear or ears during an operating procedure.

[0153] The present invention may detect incidence of exceeding a preset environmental audio threshold in conjunction with a physiological event such as audio evoked potential amplitude exceeding a certain threshold condition (typically a certain averaged amplitude measured with a certain time delay from a trigger point). This "capability" may provide an efficient (subject to system or user threshold programming) method for validating or evidence of a likely incidence of audio recall associated with a procedure involving application of anaesthesia. The present invention may present in a condensed graphic or numeric form an association between the subject's hearing status (as detected from an audio sensory nerve monitoring signal) associated with incidence of environmental sound (as detected from the recording of audio within the operating theatre environment). This "association" may allow the user to efficiently investigate correlation of a patient's hearing response and actual alleged audio recall. For legal purposes this facility may detect whether a subject's audio sensory nerve was indeed active (as opposed to inactive during an unconscious state) and whether the alleged audio recall of specific music or words was indeed probable. The "environmental audio" recording may be achieved by means of a patient attached microphone, such as a microphone attached to an outward side of the patient's earpiece or headset speaker system (as applied for generating an audio click for Auditory Evoked Potential). This type of method has an advantage of providing a dual-purpose sensor/speaker system, while also providing specific and directional audio pick-up associated with the patient's hearing system.

[0154] Similarly, where a subject claims visual recall during an operation, an appropriately placed theatre camera that is time synchronised with physiological data and analysis may record the alleged vision. Vision recall may be compared to Systems detection (manual, automatic or computer assisted) of a subject's eye opening for example. For legal purposes this facility may detect whether a subject's alleged vision recall was indeed possible as opposed to impossible, such as when the patient's eyes are both closed.

[0155] In other words, the present invention may allow audio validation- i.e. if the subject's AEP data indicated that the alleged audio recall was coincident with inactive auditory evoked potential, for example, this may support data for medical defence against audio recall operation claims. Similarly video of the patient could disclose whether or not visual recall claims coincided with patient eye open status.

[0156] In another example, bi-coherence analysis of importance such as where specific threshold conditions are exceeded may be validated by reviewing it in a time-synchronised format with video and audio recorded during a subject's operation. This validation may allow quantitative data to substantiate claims such as audio or visual recall associated with an operation procedure.

[0157] The present invention may optionally include means for recording the subject's taste (some patient's claim taste recall, such as taste which may be associated with anaesthetic gas delivery), utilising taste biochips and again providing an association between consciousness state physiological and analysis parameters with taste and/or physiological taste sensors. In some cases the medical specialist may deem monitoring of taste sensor sensory system status as a requirement.

[0158] A further option may be to use two simultaneously acquired images, where each image is acquired at a different wavelength of light. Reflections from the patient's face may then be identical except for reflections of the eyes. By subtracting these two images, a third image consisting of the subject's eyes may be created. Finally, the image of the patient's eyes may be measured to provide a non-invasive and non-obtrusive measure of eyes opening and blink rates of the subject (99). This data utilising PERCLOS methods may be used as a relatively reliable measure in the present invention, to ensure that a subjects eye openings particularly when the subject should be anaesthetised and unconscious (100).

[0159] The eye opening value may provide a simple measure of the percentage of eye opening of a patient and may clearly indicate risk of visual recall or potential awakening of the subject, during an anaesthesia procedure.

[0160] The present invention may include a patient alarm alert system for limb-controlled alarm (refer Fig. 44). The present invention may include a wire or wireless remote device connected to or accessible by any patient limb or other location near or attached to the patient's body. This remote device may contain at least a means for detecting or alarming users or healthcare workers that the patient is in distress or requires attention. This remote device may allow the subject or patient a form of "final line of defence" to premature wakening or consciousness onset. If, for example, a patient is undergoing a local anaesthetic procedure, which does not allow verbal notification of pain experience by the patient, the present invention's remote device may allow the patient to signal experience of pain level to the operator(s). Various forms of pain or consciousness level notification may be possible. One such form is where the patient is provided a simple squeeze control such as a rubber ball, and where the pressure resulting from squeezing, signals pain experience and the level of such pain experience. Other forms (subject to type of medical procedure and anaesthetic application, for example) may include, for example, an attachment for detecting foot movement, eye movement or other appropriate means of pain or consciousness signalling.

[0161] The present invention may include a Wireless Electrode system with automatic quality verification, redundant electrode substitution, and minimal sensor-electrode attachment system (refer Figs. 34, 35, 37). The present invention may provide a minimally invasive method and apparatus for monitoring vigilance of people, using 2 or 3 (or as many electrodes as required in a given application) forehead located surface electrodes, wireless monitoring connection, active electrode for dry electrode minimal electrode preparation, automatic electrode impedance measurement for detecting potential electrode quality problems, redundant electrode substitution for substituting back-up electrodes for poor quality electrode connections and dynamic signal quality for detecting current or pending electrode problems (refer drawings).

[0162] Paths of data storage may include localised condensed data or secondary (analysis results) data storage, or remote raw data (minimal or no compression or condensing data techniques).

[0163] A specialised identification connection system may allow automatic identification and channel characterisation (system configuration to suit particular channel type) for matching between electrode application types. "Electrode application" types may include ECG, EMG, muscle activity, piezo movement detection, bi-coherence EEG, and EOG. "Characterisation" may include sample rates, data analysis types, data condensing formats, data storage rates, data storage format, optimal power management, and electrical and processing optimisation. Data format may include on-board electrode data storage, versus remote patient worn data storage or remote linked data storage.

[0164] Characterisation may also include aliasing filter requirements, high-pass/low-pass and notch signal biological signal filtering requirements, and calibration requirements (for DC stability and gain requirements). A further embodiment of the present invention includes a low-cost disposable wireless electrode device such as may be required for monitoring sounds provided by a PVD sensor integrated with a "band-aid" style of attachment to a subject's face for monitoring the subject's snoring or other breathing sounds. The apparatus may include a means to incorporate the microphone sensor, amplification, filtering, storage and CPU either as a throwaway disposable system or with the more expensive electronics being part of a re-usable part of the apparatus. In the case where the apparatus is provided as a totally disposable unit, a means for sensing monitoring and recording and analysing the data may be provided for in addition to a means for displaying the analysed data results. The means for displaying the analysed data results may include a low cost means such as a permanent graphical chemical reaction associated with markers, coding or other visual based system. Alternatively a digital wired connection, optical connection or magnetic means of connection may be used to download the stored data results. A device may provide a means for recording airflow or bruxism events (via vibration or cheek muscle electrical activity) either as a disposable or reuseable device or a combination of a disposable electrode section and a reuseable electronics and wireless section. The apparatus may include means to simultaneously sense (with electrodes or transducer), monitor, record and analyse bio-physiological data within a "local" (electrode device module) memory device, while transmitting data to a "remote" (wrist watch or remote computer device) device. The "local" device may provide limited storage due to size, cost and power restraints, while the "remote" device may provide a means of transmitting and storing less condensed and more comprehensive data, as may be required for clinical or research diagnosis or validation of diagnosis.

[0165] The present invention may offer any combination of very low power "self-powered" system operation. Very low power operation is possible by utilising transmitted EMF or radio energy, from a remote source, as a means to supply or supplement a source of power for the system. The apparatus may be provided in a form, which is reusable or disposable.

[0166] In a form in which the electrode is disposable the device may be configured in a form, which can process and condense data such that the data can be stored in the device and may display various forms of index or output summary. This display may be in a form where the index can represent an amount of time detected in a sleep or wake state (could be any stage or combinations of state including REM, non-REM, stage 1, stage 2, stage 3, stage 4, wake) by means of say a pair of bi-coherence electrodes. Accordingly, the apparatus may record data representing the subject's sleep efficiency or related to the subjects sleep efficiency to inform a patient or healthcare worker whether the subject is receiving appropriate rest or quality of rest or quality of sleep. Similarly, a combination of a wristwatch based activity monitoring (86) and wireless electrode (such as for bi-coherence electrode monitoring) to wristwatch storage and processing may provide a low cost, minimally invasive and potentially highly accurate means of sleep, drowsiness or depth of anaesthesia monitoring.

[0167] The system may utilise special re-usable or disposable electrodes in conjunction with a miniature active electrode and transceiver device.

[0168] A combination of an active electrode and transceiver may provide a unique combination within the apparatus. The active electrode interface may provide a localised amplifier (close to or directly connected to the subject's surface electrode contact) to reduce stringent electrode application requirements of conventional electrode systems. The fact that the electrode amplifier is relatively close to the electrode (and thus the electrical signal derived from the said subject's skin surface) avoids noise pickup normally associated with conventional electrodes. Conventional electrodes have wires of up to 1 metre length, with the electrode amplifier being located some distance from the end of this wire. By buffering or amplifying the patient electrode directly at the point of patient skin surface attachment, a higher impedance may be used. Conventional (passive) electrode systems, on the other hand, have longer wires connected between the electrode and the electrode amplifier creates a pick-up zone for external noise. Accordingly, a lower electrode impedance is required to minimise this otherwise large external noise and artefact interference. An example of the benefits of an active electrode system in this application is that the driver of a vehicle may apply an electrode to his/her forehead with little or no preparation, similar to the application of a band-aid.

[0169] An electrode application with little or no preparation may result in an impedance of say 40 K to 100 K (thousand) ohms, as opposed to a well prepared (thorough skin cleansing and some-times light abrasion) or "conventional" electrode application impedance which would be typically 5 K - 10 K ohms impedance. A 40 K to 100 K ohms impedance would result in such large interference (in conventional passive electrode systems) that the desired monitored physiological signal could be rendered useless or unusable, while in an active electrode system a 40 K to 100 K ohms impedance could produce acceptable results.

[0170] A wireless protocol may include a capability to continually scan for new devices and allocated bandwidth requirements to accommodate incremental or decremental demands upon the number of system channels and aggregated data bandwidth requirements. Similarly, where system bandwidth has reached or approaches system limitations, the user may be alerted. In this way the physiological electrode wireless system is a virtual plug and play system, with simple and user friendly application. The wireless protocol may also manage functions such as relaying both physiological data and commands for continuous electrode impedance checking, calibration validation or associated adjustments, signal quality checking and associated adjustments, electrode substitution and other functions.

[0171] The present invention may include Spread-spectrum based wireless, active electrode system suitable for in-vehicle EEG monitoring and depth of anaesthesia monitoring amongst other applications (refer Figs. 33, 34, 37, 42, 45). Utilisation of an active electrode system for vigilance in-vehicle monitoring, in conjunction with a wireless and battery or self-powered electrode system, may provide a self-applied driver vigilance electrode monitoring system. In one embodiment, for example, a driver could apply a self-adhesive active wireless linked forehead electrode system.

[0172] The electrode system may include a re-usable section that contains the more expensive active electronics and wireless circuitry, and a disposable section that contains the surface electrodes and some form of interconnection to the re-usable section. Such apparatus may be suitable for a minimally invasive in-vehicle vigilance system where (for example) a wireless electrode monitoring device such as a forehead attached wireless electrode system may be optionally input to an existing driver drowsiness measurement system. In this manner a driver may choose to increase reliability of driver drowsiness detection by using minimally invasive EEG bi-coherence signal monitoring and analysis. This type of function may supplement or replace other on-board vehicle real-world driver drowsiness monitoring technologies associated with measurement of driver-movement and activity sensors (Burton, 1999) and eye opening measurement.

[0173] The present invention may include physiological data time delay and analysis time lag compensation. The latter may be applicable where anaesthesia drug administration can be monitored in real time against actual display changes and the apparatus is able to predict changes instantly for the user to avoid over or under drug administration associated with natural hysteresis or delay factors such as delay between the instant of drug administration and the human body's physiological parameters (as monitored by the apparatus) responding to the drug administration.

[0174] The latter is applicable to parameters such as oxygen saturation where the physiological data reading is typically delayed by between 15 and 20 seconds due to the nature of the monitoring method and the body's time delay in blood-oxygen colour change.

[0175] The present invention may include a Biofeedback loop providing automatic anaesthesia drug rate or concentration of delivery (refer Fig. 48).

[0176] The present invention may interface to various types of drug delivery systems to provide varying degrees and types of biofeedback control affecting the drug administration process. The drug delivery systems may include but are not limited to gas ventilation or ventilation or gas delivery systems, drug perfusion systems, amongst other drug delivery systems. "Varying degrees" of drug delivery may include a capability to limit drug delivery or provide degrees of drug delivery or drug delivery mixture in accordance with predetermined monitoring or analysis parameters associated with the present invention.

[0177] The present invention may include a Wireless Patient Electrode identification and Characterisation function (IDCF). This function may provide a means for the present invention to automatically identify the electrode type selected by the user. Automatic identification may be by way of wireless module scanning or electrically interfacing to some resident data (contained on the disposable or reusable sensors or electrodes, which are attached to the subject) or optical or magnetic code sequence, where a unique code is associated with each unique electrode type. Various electrode types may be identified for groups of physiological variables, which share the same characteristics and processing requirements. If a user selects an ECG electrode for example, the IDSC may alert the present invention of optimal gain, signal range filter conditioning, aliasing filter values and types, sample-rate and data bandwidth requirements for the wireless module interface, processing, acquisition, analysis, display and other functional requirements related to the electrode channel type.

[0178] This automatic identification may greatly simplify application and minimise potential user errors. An example of an application and embodiment of this present invention may be where a nurse applies a series of clearly labelled electrodes and the rest of the operation is automatically configured as the patient is wired up in accordance with the selected electrode types.

[0179] The IDCF is also useful if the application for the wireless electrode system is a wireless EEG electrode system that is self-applied to a vehicle driver's forehead for simple "fool-proof' EEG signal monitoring. The combined application of the wireless module with automatic signal characterisation in accordance with detection of the electrode type, active electrode signal handling and later analysis techniques incorporating BIC (including bi-coherence and bi-spectral analysis) may provide a unique wireless, artefact reduced and precise method for in-vehicle or other application of cognitive performance or vigilance/ fatigue monitoring.

[0180] This function may be particularly useful for depth of anaesthesia or a vehicle based vigilance system where the user needs to have a system that is as minimal and "fool-proof' as possible.

[0181] The IDCF system may also help to ensure that only known re-usable or disposable electrodes are used with the present invention and that optimal characterisation and system set-ups are automatically applied in accordance with the selected electrode types.

SUMMARY OF THE INVENTION

[0182] The present invention may provide improved accuracy in monitoring, analysis, detection, prediction, system alerts and alarms associated with, inter alia, depth of anaesthesia, depth of consciousness, hypnotic state, sedation depth, fatigue or vigilance of a subject, with as few as 3 surface electrodes. The present invention may incorporate real-time phase, amplitude and frequency analysis of a subject's electro-encephalogram. The present invention may provide a means to weight the output of various types of analysis and produce a combined analysis or display for precise indication or alert to various users of the system.

[0183] In particular the present invention may monitor, store and display two or more sets of physiological data parameters or analyse one or more combinations or calculations associated with the data to display, store, condense and summarise data for a range of applications associated with monitoring human consciousness. The present invention may analyse two or more of the physiological data to produce condensed data summaries, or indexed data (such as arousals per hour and other indexes) or tabular and graphic displays and reports associated with monitoring human consciousness. The present invention may correlate two or more sets of the physiological data or analysis results to produce tertiary analysis results associated with monitoring human consciousness.

[0184] The present invention may be applied to monitoring depth of anaesthesia for optimal administration of anaesthetic drugs, to sedation in tracking the subject's level of sedation for nurses or other medical professionals, to monitoring fatigue and hypnotic state for drivers, to monitoring vigilance for transport and machine workers and to controlling delivery systems for administering therapeutic treatment such as drugs, gas or the like to the subject.

[0185] The present invention may weight the outputs of one or more analysis algorithms including combination of simultaneous, real-time analysis of R&K analysis (34, 45, 46), AEP (30), spectral analysis-SEF-MF (30), Bi-coherence (BIC) analysis (33), initial wave analysis (5), auditory response (30), arousal analysis (35) and body movement analysis (34), 95% spectral edge analysis (36) and anaesthetic phase and spectral energy variance measurement in association with a subject's state of consciousness (29), Pulse Transient Time (PTT) based arousal detection (31), PTT measure

and PTT based blood-pressure reference measure, Pulse oximetry SAO_2, PTT based heart rate and blood pressure with simple non-invasive oximeter (31,32), PAT analysis for sympathetic arousal detection (104-108), EEG spike-K-complex-wave-activity-event categorisation (47) and bio-blanket for monitoring of heart, temperature, respiration (49), breathing sound and PTT blood-pressure. Inclusion of sympathetic arousal may provide a unique measure of stress or mental anxiety, despite the state of a patient's state of paralysis or "apparent unconsciousness".

[0186] According to a first aspect of the present invention, there is provided an apparatus for determining a state of consciousness of a sentient subject or living body by obtaining physiological data from said sentient subject or living body, said apparatus comprising: means for obtaining at least one continuous physiological signal; means for stimulating at least one evoked potential signal in said sentient subject or living body; and means for obtaining said at least one evoked potential signal from said at least one continuous physiological signal; and means for deriving a first index of consciousness from the at least one continuous physiological signal and a second index and a second index of consciousness from said at least one evoked potential signal; and means for classifying said indices as being representative of entering or leaving consciousness according to a weighting process.

[0187] The at least one physiological signal may include one or more of an EEG signal and at least one muscular activation signal.

[0188] Said muscular activation signal may include a measure of eyelid movement.

[0189] The EEG signal may include a continuous signal.

[0190] The apparatus may include means for deriving said evoked potential signal from the EEG signal.

[0191] Said means for obtaining the at least one continuous physiological signal or the means for obtaining the at least one evoked potential signal may include at least one electrode sensor.

[0192] The apparatus may include means for monitoring the at least one sensor for signal integrity; and/or may include means for monitoring the at least one sensor for signal quality.

[0193] Said means for obtaining the at least one continuous physiological signal or means for obtaining the at least one evoked potential signal may include at least one disposable or semi-disposable sensor, and optionally said at least one disposable or semi-disposable sensor may include means for activating an electrical energy source, and optionally said means for activating said energy source may include a packaging of said electrical energy source, and optionally said means for obtaining the at least one physiological signal may include an electrode sensor activatable in response to pressure from an operator or user of said apparatus.

[0194] Said means for stimulating the at least one evoked potential signal may stimulates one or more of a somato-sensory, auditory, or visual evoked response, and optionally said means for stimulating an auditory evoked response signal may include a cochlear microphone.

[0195] Said means for stimulating said auditory evoked response may induce a steady state response signal from $\frac{1}{2}\,\mathrm{Hz}$ to 100Hz.

[0196] The apparatus may include means for displaying a functional or operational status of any sensor.

[0197] Said means for inducing an auditory evoked potential response signal may include means for producing one or more of evoked response paradigms including: a) at least one type of click stimulus according to an individual patient; b) at least one response at spaced intervals within the at least one type of click stimulus; c) sounds with characteristics corresponding to white noise or speech; d) oddball sound characteristics; e) unusual sound characteristics; f) masked noise sounds; g) unanticipated noise sounds; h) composite sounds; i) familiar sounds; j) recognisable sounds with reference to said patient; wherein a combination of a sound stimulus may be generated according to a predetermined sequence, and optionally wherein said predetermined sequence is determined by determination means incorporated within said apparatus.

[0198] The apparatus may include means for alerting an operator or user of a status of at least one sensor.

[0199] According to a second aspect of the present invention, there is provided a method for determining a state of consciousness of a sentient subject or living body by obtaining, characterising and classifying physiological signals from said sentient subject or living body, said method comprising the steps of: a) obtaining at least one continuous physiological signal; b) stimulating an evoked potential response signal in said sentient subject or living body; c) deriving at least one evoked potential response physiological signal from said at least one continuous physiological signal; and deriving an index of consciousness from said continuous physiological signal and said evoked potential response signal, and optionally wherein the physiological signal is an electro-encephalogram signal.

[0200] The method may further comprising the steps of: d) transforming said at least one physiological signal according to a weighting calculation based on a mediation process; e) transforming said at least one evoked potential response physiological signal according to said weighting calculation; and f) calculating an index from said transformed physiological signal and said transformed evoked potential response physiological signal.

[0201] The present invention may be an HCM system.

[0202] The method may include:

(i) obtaining an EEG signal from the subject;
(ii) performing a frequency based analysis on the EEG signal to obtain a frequency-based signal;
(iii) performing a phase based analysis on the EEG signal to obtain a phase-based signal;
(iv) detecting by comparing the frequency based signal and the phase based signal whether the subject is in transition from said conscious state to said less conscious state or vice versa; and
(v) providing a warning signal when said subject is in said transition to said conscious state.

[0203] The frequency based analysis may include depth of sleep analysis and said phase-based analysis may include at least one of optimized bicoherence, bispectrum or triple product analysis.
[0204] The depth of sleep analysis may include real-time optimized R&K analysis.
[0205] The step of detecting may be augmented with optimized AEP analysis.
[0206] The method may comprise means for adapting the or each analysis to parameters specific to said subject including body mass index, age and sex of said subject.
[0207] The method may be for processing a non-stationary signal including segments having increasing and decreasing amplitude representing physiological characteristics of a sentient subject, said segments including portions in which said signal changes from increasing to decreasing amplitude or vice versa, and the method may include:

(i) detecting each segment by determining time instants when a time derivative of said signal is substantially equal to zero;
(ii) performing syntactic analysis for each segment including assigning height, width and error parameters;
(iii) identifying noise segments present in said signal by comparing said width parameter to a preset threshold and said error parameter to said height parameter;
(iv) removing said noise segments by replacing each identified noise segment with a substantially straight line;
(v) sorting the remaining segments into a plurality of wavebands based on their width parameters; and
(vi) classifying said signal as belonging to one of predefined sleep states based on relative frequency of occurrence of said segments in said wavebands.

[0208] The method may include:

applying a first surface electrode to said subject to provide a first electrical signal to a remote monitoring apparatus;
applying a second surface electrode to said subject to provide a second electrical signal to said remote monitoring apparatus;
monitoring quality of said first electrical signal and in the event of a degradation in said quality of first signal;
automatically substituting said second electrical signal for said first electrical signal and in the event of a degradation in said quality of said second electrical signal and in said quality of said first electrical signal, providing a warning signal.

[0209] The second electrode may be spaced from said first electrode.
[0210] The apparatus may include:

(i) means or a detecting component for detecting each segment by determining time instants when a time derivative of said signal is substantially equal to zero;
(ii) means or a dividing component for dividing said signal into said segments including data over three consecutive time instants when said time derivative is equal to zero;
(iii) means or an assigning component for assigning to each segment, height, width and error parameters;
(iv) means or an identifying component for identifying noise segments in said signal including means or a comparing component for comparing for each segment said width parameter to a preset threshold and said error parameter to said height parameter;
(v) means or a removing component for removing said noise segments including means or a substituting component for substituting a straight line connecting first and third time instants when the time derivative of said signal is substantially equal to zero and means or a reassigning component for reassigning segments and their parameters after the substitution;
(vi) means or a sorting component for sorting the remaining segments into a plurality of wave bands based on the value of their width parameter, each wave band being defined by upper and lower frequencies corresponding to lower and upper values for the width parameter respectively; and
(vii) means or a classifying component for classifying a time interval of the signal data as belonging to one of predefined sleep states based on relative frequency of occurrence of said segments in said wave bands.

[0211] The so-called "segments" are the principal building blocks of EEG and EOG analysis. A "segment" includes a

sequence of consecutively increasing and decreasing or consecutively decreasing and increasing intervals of the signal under analysis.

[0212] All "segments" may be initially detected by applying syntactic analysis to the signal, ie. detecting all local maxima and minima. As a data structure a "segment" is represented by its orientation (ie. "upward" or downward"), width, height and error. In the context of visual signal interpretation, the last three parameters have a clear meaning. Width relates to the dominant frequency of the signal under analysis at this particular time interval, height relates to the magnitude of the signal variation and error, which is a measure of signal variation from a straight line connecting the start and end of the "segment", relates to the magnitude of noise in the signal if the "segment" is a part of the noise rather than a part of the actual signal that is under analysis.

[0213] After all "segments" are originally detected using a syntactic algorithm, those segments which are likely to be noise rather than the signal under analysis must be removed, and new signal "segments" must be reconstructed. To achieve this an iterative procedure of identifying noise "segments" and generating new signal "segments" may be employed. A "segment" may be classified as noise if its width is relatively small (which in the case of EEG signal indicates alpha, sigma and beta bands - where high frequency noise is typically prominent) and the error is relatively small (which ensures that genuine visible EEG high frequency components are retained). Various rules may be generated to represent meaningful conditions of small width and small error. This "segment" may then be approximated as a straight line and a new "segment" constructed as a result of this approximation. This procedure may be performed iteratively until no noise "segments" are detected. The described approach has a significant advantage over prior art FFT methods (which cannot discriminate between high-frequency noise and sharp slopes of genuine EEG patterns) and zero-crossing methods (which rely on DC offset and do not remove noise).

[0214] All remaining "segments" may then be sorted according to the value of their width parameter among conventional EEG frequency bands. This sorting may be performed for both "downward" and "upward" "segments," to enable accurate interpretation of asymmetrical "segments". Once the "segments" are sorted for an interval equal to one sleep study epoch, a simplified sleep/wake discrimination may be performed by calculating a total duration of "sleep-like" "segments" (sum of durations of all delta and theta "segments") and comparing it with the half epoch duration. This approach in fact represents a mathematical model of sleep/wake discrimination based on visual interpretation of an EEG epoch.

[0215] Various means for fine-tuning this technique to achieve more accurate detection of important EEG patterns and subsequently more accurate sleep/wake discrimination are disclosed below. These include algorithms for EEG artifact detection, delta wave detection, periodic pattern detection and modified sleep/wake discrimination rules which take into account a major role of EEG periodic patterns (which may vary beyond alpha band), role of context based decisions and the uncertainty associated with artifacts.

[0216] The time derivative may be equal to zero when said signal changes its direction from positive to negative or from negative to positive.

[0217] Each height parameter may be assigned by calculating an average of the signal's variations between the first and second time instants when the time derivative of said signal is substantially equal to zero, and the second and third time instants when the time derivative of said signal is substantially equal to zero.

[0218] Each width parameter may be assigned by calculating an average time interval between any data point within the segment and a second time instant when the time derivative of said signal is substantially equal to zero, said intervals being weighted according to the signal's variation between each respective data point and an adjacent data point nearest to the second time instant when the time derivative of said signal is substantially equal to zero.

[0219] The error parameter may be assigned by calculating an average deviation between current signal data and past signal data over a signal time interval.

[0220] The means for identifying noise segments may include means or a testing component for testing each segment to determine if its width parameter is less than said preset threshold and its error parameter is less than its height parameter by at least a preset ratio.

[0221] The means for reassigning may repeat a procedure of reassigning segments and their parameters and said means for substituting performs a substitution until no noise segments are identified in said signal.

[0222] The means for classifying may include means or a comparing component for comparing to a preset threshold values of weighted combinations of occurrences of said segments in said wavebands.

[0223] The apparatus may comprise means or a first detecting and processing component for detecting and processing artefact patterns in said signal, including one or more of:

means or a second detecting component for detecting flat intervals in said signal;

means or a third detecting component for detecting intervals in said signal having a relatively sharp slope, being intervals in which variation in said signal exceeds a first threshold over a time interval equal to or shorter than a second threshold;

means or a fourth detecting component for detecting intervals in said signal having a relatively narrow peak, being intervals in which the width parameter is equal to or less than a third threshold and the height parameter is equal

to or greater than a fourth threshold; and
means or a fifth detecting component for detecting other non physiological pattern in said signal, being combinations of segments having a width and height of one, the segments in the combination being less than the respective total duration and signal variation of the combination by at least preset ratios.

[0224] The apparatus may comprise means or a sixth detecting and processing component for detecting and processing wave patterns characterized by minimum amplitude and minimum and maximum durations, including:

means or a seventh detecting component for detecting a core interval of the wave pattern as a sequence of one or more segments which starts at a first time instant of a first segment when a time derivative of said signal is substantially equal to zero and ends at a second time instant of the last segment when a time derivative of said signal is substantially equal to zero, or starts at the second time instant of the first segment when the time derivative of said signal is substantially equal to zero and ends at a third time instant of the last segment when the time derivative of said signal is substantially equal to zero, with the total signal variation of at least the minimum amplitude, duration of at least a preset share of the minimum duration, less than the maximum duration and the maximum deviation from a monotonous change of at least a preset share of the total variation.

[0225] The apparatus may comprise means or an eighth detecting component for detecting a start and end of a main wave of the wave pattern by subsequent comparison with a preset threshold of a deviation of the slope of respective components of segments preceding and following the core interval from the slope of the core interval, and means or an updating component for updating the core interval if the deviation of the slope and maximum deviation from the monotonous change do not exceed respective preset thresholds, and a total updated duration is equal to at least a preset share of the minimum duration and is less than the maximum duration.

[0226] The apparatus may comprise means or a ninth detecting component for detecting one or two side waves of the wave pattern by subsequent testing of sequences of combinations of segments preceding and following the main wave for the signal duration conditions.

[0227] The means for sorting into a plurality of wave bands may be based on the detected wave patterns.

[0228] The means for classifying may include means for comparing to preset threshold values of weighted combinations of occurrences of said segments in said wave bands, artefact patterns and wave patterns.

[0229] The means for sorting into a plurality of wave bands may be based on the detected wave patterns. The means for classifying may include means for comparing to preset threshold values of weighted combinations of occurrences of the segments in the waveband, artefact patterns and wave patterns.

[0230] The apparatus may comprise means or a tenth detecting component for detecting periodic patterns with specified minimum and maximum frequencies, minimum amplitude and minimum number of waves including:

means or a selecting component for selecting combinations of a specified number of segments;
means or an assigning component for assigning for each combination, an average, minimum and maximum amplitude and an average, minimum and maximum period;
means or a first testing component for testing if the average amplitude exceeds a specified minimum amplitude for a periodic pattern;
means or a second testing component for testing if the maximum amplitude exceeds the minimum amplitude by not more than a specified ratio;
means or a third testing component for testing if the frequency corresponding to the average period is equal to or greater than the minimum frequency of the periodic pattern and is equal to or less than the maximum frequency of the periodic pattern;
means or a fourth testing component for testing if the maximum period for a combination of segments exceeds the minimum period by not more than a specified ratio;
means or a joining component for joining combinations of segments, which comply with the above criteria; and
means or a first classifying component for classifying a time interval of the signal data as belonging to one of predefined states on the basis of a comparison of the value of a weighted combination of durations of a plurality of wave bands, artefact patterns and wave patterns with threshold which is set to a different value depending on the total relative duration of periodic patterns within the time interval.

[0231] The apparatus may comprise means or a second classifying component for classifying a time interval of the signal data as belonging to one of predefined states on the basis of a comparison of the value of a weighted combination of durations of a plurality of wave bands, artefact patterns and wave patterns with a decision boundary which is set to a different value depending on the total relative duration of periodic patterns within the time interval, if the difference between the value and the decision boundary is equal to or greater than a specified margin, or otherwise, on the basis

of a comparison of this value with the respective value for the preceding or following time interval providing that that interval is already classified and the difference between the respective values is equal or less than the specified margin, or otherwise, if after subsequent passes through the data, an interval is still not resolved, on the basis of comparison of this value with a threshold which is set to a different value depending on the total relative duration of periodic patterns within the time interval.

[0232] The sensor may be for detecting position of an eye lid and may include:

first means or a movable component adapted to move substantially with said eye lid and relative to a second means or a reference component; and
means or a signal providing component for providing an electrical signal indicative of the position of said first means relative to said second means, such that said signal includes a measure of position and/or degree of opening of said eyelid.

[0233] The first and second means may be electrically coupled such that the coupling provides the measure of position and/or degree of opening of the eyelid. The first and second means may be provided by respective arms connected for relative movement. The arms may be pivot ably connected to each other. Each arm may include a capacitive element arranged such that the extent of overlap between the arms determines the coupling between the capacitive elements. Each capacitive element may include one plate of a capacitor. Alternatively each arm may include an inductive element arranged such that the extent of overlap between the arms determines the coupling between the inductive elements. Each inductive element may include a coil. The sensor may include means such as a wien bridge for measuring the capacitive/inductive coupling between the capacitive/inductive elements.

[0234] The sensor may comprise means for measuring inductive coupling between said inductive elements.

Claims

1. Apparatus for determining a state of consciousness of a sentient subject or living body by obtaining physiological data from said sentient subject or living body, said apparatus comprising:

   means for obtaining at least one continuous physiological signal (BLK30);
   means for stimulating at least one evoked potential signal in said sentient subject or living body (BLK5); and
   means for obtaining said at least one evoked potential signal from said at least one continuous physiological signal (BLK33); and
   characterized by:

      means for deriving a first index of consciousness from the at least one continuous physiological signal (BLK30) and a second index of consciousness from said at least one evoked potential signal (BLK17); and
      means for classifying said indices as being representative of entering or leaving consciousness according to a weighting process; and
      means for outputting the results of said weighting process for monitoring said state of consciousness.

2. Apparatus according to claim 1 wherein the at least one physiological signal includes one or more of an EEG signal and at least one muscular activation signal.

3. Apparatus according to claim 2 wherein said muscular activation signal includes a measure of eyelid movement.

4. Apparatus according to claim 2 or 3 wherein the EEG signal includes a continuous signal.

5. Apparatus according to claim 2, 3 or 4 including means for deriving said evoked potential signal from the EEG signal.

6. Apparatus according to any one of the preceding claims wherein said means for obtaining the at least one continuous physiological signal or the means for obtaining the at least one evoked potential signal includes at least one electrode sensor.

7. Apparatus according to any of the preceding claims including means for monitoring the at least one sensor for signal integrity; and/or including means for monitoring the at least one sensor for signal quality.

8. Apparatus according to any of the preceding claims wherein said means for obtaining the at least one continuous

physiological signal or means for obtaining the at least one evoked potential signal includes at least one disposable or semi-disposable sensor, and optionally wherein said at least one disposable or semi-disposable sensor includes means for activating an electrical energy source, and optionally wherein said means for activating said energy source includes a packaging of said electrical energy source, and optionally wherein said means for obtaining the at least one physiological signal includes an electrode sensor activatable in response to pressure from an operator or user of said apparatus.

9. Apparatus according to any of the preceding claims wherein said means for stimulating the at least one evoked potential signal stimulates one or more of a somatosensory, auditory, or visual evoked response, and optionally wherein said means for stimulating an auditory evoked response signal includes a cochlear microphone.

10. Apparatus according to claim 9 whereby said means for stimulating said auditory evoked response induces a steady state response signal from ½Hz to 100Hz.

11. Apparatus according to any of the preceding claims including means for displaying a functional or operational status of any sensor.

12. Apparatus according to any one of the preceding claims wherein said means for inducing an auditory evoked potential response signal includes means for producing one or more of evoked response paradigms including:

a) at least one type of click stimulus according to an individual patient;
b) at least one response at spaced intervals within the at least one type of click stimulus
c) sounds with characteristics corresponding to white noise or speech
d) oddball sound characteristics
e) unusual sound characteristics
f) masked noise sounds
g) unanticipated noise sounds
h) composite sounds
i) familiar sounds
j) recognisable sounds with reference to said patient

wherein a combination of a sound stimulus is generated according to a predetermined sequence, and optionally wherein said predetermined sequence is determined by determination means incorporated within said apparatus.

13. Apparatus according to any one of the preceding claims including means for alerting an operator or user of a status of at least one sensor.

14. Method for determining a state of consciousness of a sentient subject or living body by obtaining, characterising and classifying physiological signals from said sentient subject or living body, said method comprising the steps of:

a) deriving a first index of consciousness by obtaining at least one continuous physiological signal (step 14);
b) stimulating an evoked potential response signal in said sentient subject or living body (step 12);
c) deriving a second index of consciousness by deriving at least one evoked potential response physiological signal from said evoked potential response signal (step 12); and

deriving an index of consciousness from said continuous physiological signal and said evoked potential response signal (step 13) and classifying said indices as being representative of entering or leaving consciousness according to a weighting process; and outputting the results of said weighting process for monitoring said state of consciousness, and optionally wherein the physiological signal is an EEG signal.

15. Method according to claim 14, further comprising the steps of:

d) transforming said at least one physiological signal according to a weighting calculation based on a mediation process (step 23);
e) transforming said at least one evoked potential response physiological signal according to said weighting calculation (step 23); and
f) calculating an index from said transformed physiological signal and said transformed evoked potential response physiological signal (step 24).

Patentansprüche

1. Gerät zur Bestimmung eines Zustands des Bewusstseins einer empfindenden Testperson oder eines lebenden Körpers durch Erhalten physiologischer Daten von dieser empfindenden Testperson oder dem lebenden Körper, wobei dieses Gerät umfasst:

   Mittel zum Erhalten wenigstens eines kontinuierlichen physiologischen Signals (BLK30);
   Mittel zum Stimulieren wenigstens eines evozierten Potentialsignals in dieser empfindenden Testperson oder dem lebenden Körper (BLK5); und
   Mittel zum Erhalten dieses wenigstens einen evozierten Potentialsignals von diesem wenigstens einen kontinuierlichen physiologischen Signal (BLK33); und
   gekennzeichnet durch:

   Mittel zur Ableitung eines ersten Bewusstseinsindex von dem wenigstens einen physiologischen Signal (BLK30) und eines zweiten Bewusstseinsindex von diesem wenigstens einen evozierten Potentialsignal (BLK17); und
   Mittel für die Klassifizierung dieser Indizes als repräsentativ für das Erlangen oder das Verlieren des Bewusstseins gemäß einem Gewichtungsprozess; und
   Mittel für das Ausgeben der Ergebnisse dieses Gewichtungsprozesses zur Überwachung dieses Bewusstseinszustands.

2. Gerät nach Anspruch 1, bei dem das wenigstens eine physiologische Signal eines oder mehrere EEG-Signale einschließt und wenigstens ein muskuläres Aktivierungssignal.

3. Gerät nach Anspruch 2, bei dem dieses muskuläre Aktivierungssignal die Messung einerAugenlidbewegung einschließt.

4. Gerät nach einem der Ansprüche 2 oder 3, bei dem das EEG-Signal ein kontinuierliches Signal einschließt.

5. Gerät nach Anspruch 2, 3 oder 4, umfassend Mittel zur Ableitung des evozierten Potentialsignals von dem EEG-Signal.

6. Gerät nach einem der vorhergehenden Ansprüche, bei dem die Mittel zum Erhalten des wenigstens einen kontinuierlichen physiologischen Signals oder die Mittel zum Erhalten des wenigstens einen evozierten Potentialsignals wenigstens einen Elektrodensensor einschließen.

7. Gerät nach einem der vorhergehenden Ansprüche, umfassend Mittel zur Überwachung des wenigstens einen Sensors für eine Signalintegrität und/oder umfassend Mittel zur Überwachung des wenigstens einen Sensors für eine Signalqualität.

8. Gerät nach einem der vorhergehenden Ansprüche, bei dem diese Mittel zum Erhalten des wenigstens einen kontinuierlichen physiologischen Signals oder die Mittel zum Erhalten des wenigstens einen evozierten Potentialsignals wenigstens einen verfügbaren oder semi-verfügbaren Sensor umfassen und bei dem gegebenenfalls dieser wenigstens eine verfügbare oder semi-verfügbare Sensor Mittel umfasst zur Aktivierung einer elektrischen Energiequelle und bei dem gegebenenfalls diese Mittel zur Aktivierung dieser Energiequelle eine Verpackung für diese Energiequelle umfassen und bei dem gegebenenfalls diese Mittel zum Erhalten des wenigstens einen physiologischen Signals einen Elektrodensensor einschließen, der aktivierbar ist als Antwort auf Druck von einem Bediener oder Benutzer dieses Geräts.

9. Gerät nach einem der vorhergehenden Ansprüche, bei dem diese Mittel für das Stimulieren wenigstens eines evozierten Potentialsignals eine oder mehrere aus somatosensorisch, auditiv oder visuell evozierten Antworten stimulieren und bei dem gegebenenfalls diese Mittel für das Stimulieren eines auditiv evozierten Signals ein cochleäres Mikrophon umfassen.

10. Gerät nach Anspruch 9, bei dem diese Mittel für das Stimulieren der auditiv evozierten Antwort ein "stabiler Zustand"-Antwortsignal von ½ Hz bis 100 Hz induzieren.

11. Gerät gemäß einem der vorhergehenden Ansprüche umfassend Mittel zum Anzeigen eines Funktionsstatus oder

Operationsstatus irgendeines Sensors.

12. Gerät nach einem der vorhergehenden Ansprüche, bei dem diese Mittel für das Induzieren eines auditiv evozierten Potentialantwortsignals Mittel umfassen für die Erzeugung eines oder mehrerer evozierterAntwort-Paradigmen einschließlich:

a) wenigstens ein Typ eines Klicklautstimulus, welcher einem individuellen Patienten entspricht;
b) wenigstens eine Antwort in beabstandeten Intervallen innerhalb des wenigstens einen Typs von Klicklautstimulus;
c) Geräusche mit Merkmalen, die Weißrauschen oder Sprache entsprechen
d) exzentrische Klangmerkmale
e) ungewöhnliche Klangmerkmale
f) maskierte Lärmgeräusche
g) unerwartete Lärmgeräusche
h) zusammengesetzte Klänge
i) vertraute Klänge
j) erkennbare Klänge mit Bezug auf diesen Patienten

wobei eine Kombination eines Klangstimulus erzeugt wird gemäß einer vorgegebenen Sequenz und wobei gegebenenfalls diese vorgegebene Sequenz durch Bestimmungsmittel bestimmt wird, die zu dem Gerät gehören.

13. Gerät nach einem der vorhergehenden Ansprüche umfassend Mittel zum Alarmieren einer Bedienungsperson oder eines Benutzers über den Status wenigstens eines Sensors.

14. Verfahren zur Bestimmung eines Bewusstseinsstatus eines empfindenden Subjekts oder eines lebenden Körpers durch Erhalten, Charakterisieren und Klassifizieren physiologischer Signale von diesem empfindenden Subjekt oder lebenden Körper, wobei dieses Verfahren die Schritte umfasst:

a) Ableiten eines ersten Bewusstseinsindex durch Erhalten wenigstens eines kontinuierlichen physiologischen Signals (Schritt 14);
b) Stimulieren eines evozierten Potentialantwortsignals in diesem empfindenden Subjekt oder lebenden Körper (Schritt 12);
c) Ableiten eines zweiten Bewusstseinsindex durch Ableiten wenigstens eines evozierten Potentialanwortsignals von diesem evozierten physiologischen Potentialantwortsignal (Schritt 12); und

Ableiten eines Bewusstseinsindex aus diesem kontinuierlichen physiologischen Signal und diesem evozierten Potentialantwortsignal (Schritt 13) und Klassifizieren dieser Indizes als repräsentativ für das Erlangen oder Verlieren des Bewusstseins gemäß einem gewichteten Prozess; und Ausgeben der Ergebnisse dieses gewichteten Prozesses für eine Überwachung dieses Bewusstseinsstatus, und wobei gegebenenfalls dieses physiologische Signal ein EEG-Signal ist.

15. Verfahren nach Anspruch 14, welches weiterhin die Schritte umfasst:

d) Umwandeln dieses wenigstens einen physiologischen Signals gemäß einer Wichtungsberechnung basierend auf einem Vermittlungsprozess (Schritt 23);
e) Umwandeln dieses wenigstens einen evozierten physiologischen Potentialantwortsignals gemäß dieser Wichtungsberechnung (Schritt 23); und
f) Berechnen eines Index aus diesem transformierten physiologischen Signal und diesem transformierten evozierten physiologischen Potentialantwortsignal (Schritt 24).

Revendications

1. Appareil pour déterminer un état de conscience d'un sujet sensible ou d'un corps vivant par obtention de données physiologiques à partir dudit sujet sensible ou dudit corps vivant, ledit appareil comprenant :

- des moyens pour obtenir au moins un signal physiologique continu (BLK30) ;
- des moyens pour stimuler au moins un signal de potentiel évoqué dans ledit sujet sensible ou ledit corps vivant

(BLK5) ; et
- des moyens pour obtenir ledit ou lesdits signaux de potentiel évoqué à partir dudit ou desdits signaux physiologiques continus (BLK33) ; et

caractérisé par :

- des moyen pour déduire un premier indice de conscience à partir du ou des signaux physiologiques continus (BLK30) et un second indice de conscience à partir du ou desdits signaux de potentiel évoqué (BLK17) ; et
- des moyens pour classifier lesdits indices comme étant représentatifs d'une entrée ou d'une sortie de conscience selon un traitement de pondération ; et
- des moyens pour délivrer en sortie les résultats dudit traitement de pondération pour surveiller ledit état de conscience.

2. Appareil selon la revendication 1, dans lequel le ou les signaux physiologiques comprennent un ou plusieurs d'un signal d'EEG et d'au moins un signal d'activation musculaire.

3. Appareil selon la revendication 2, dans lequel ledit signal d'activation musculaire comprend une mesure de mouvement de paupière.

4. Appareil selon l'une des revendications 2 ou 3, dans lequel le signal d'EEG comprend un signal continu.

5. Appareil selon l'une des revendications 2, 3 ou 4, comprenant des moyens pour déduire ledit signal de potentiel évoqué à partir du signal d'EEG.

6. Appareil selon l'une quelconque des revendications précédentes, dans lequel lesdits moyens pour obtenir le ou les signaux physiologiques continus ou les moyens pour obtenir le ou les signaux de potentiel évoqué comprennent au moins un capteur à électrode.

7. Appareil selon l'une quelconque des revendications précédentes, comprenant des moyens pour surveiller le ou les capteurs pour une intégrité de signal ; et/ou comprenant des moyens pour surveiller le ou les capteurs pour une qualité de signal.

8. Appareil selon l'une quelconque des revendications précédentes, dans lequel lesdits moyens pour obtenir le ou les signaux physiologiques continus ou les moyens pour obtenir le ou les signaux de potentiel évoqué comprennent au moins un capteur jetable ou semi-jetable, et ledit ou lesdits capteurs jetables ou semi-jetables comprenant facultativement des moyens pour activer une source d'énergie électrique, et lesdits moyens pour activer ladite source d'énergie comprenant facultativement un conditionnement de ladite source d'énergie électrique, et lesdits moyens pour obtenir le ou les signaux physiologiques comprenant facultativement un capteur à électrode apte à être activé en réponse à une pression provenant d'un opérateur ou d'un utilisateur dudit appareil.

9. Appareil selon l'une quelconque des revendications précédentes, dans lequel lesdits moyens pour stimuler le ou les signaux de potentiel évoqué stimulent une ou plusieurs d'une réponse évoquée somatosensorielle, auditive ou visuelle, et lesdits moyens pour stimuler un signal de réponse évoquée auditive comprenant facultativement un microphone cochléaire.

10. Appareil selon la revendication 9, par lequel lesdits moyens pour stimuler ladite réponse évoquée auditive induisent un signal de réponse à l'état stable de 1/2 Hz à 100 Hz.

11. Appareil selon l'une quelconque des revendications précédentes, comprenant des moyens pour afficher un statut fonctionnel ou opérationnel d'un quelconque capteur.

12. Appareil selon l'une quelconque des revendications précédentes, dans lequel lesdits moyens pour induire un signal de réponse de potentiel évoqué auditive comprennent des moyens pour produire un ou plusieurs de paradigmes de réponse évoquée comprenant :

a) au moins un type de stimulus de clic selon un patient individuel ;
b) au moins une réponse à des intervalles espacés à l'intérieur du ou des types de stimulus de clic
c) des sons ayant des caractéristiques correspondant à un bruit blanc ou une parole

d) des caractéristiques sonores excentriques
e) des caractéristiques sonores inhabituelles
f) des sons de bruit masqués
g) des sons de bruit non anticipés
h) des sons composites
i) des sons familiers
j) des sons reconnaissables en référence audit patient une combinaison d'un stimulus sonore étant générée selon une séquence prédéterminée, et ladite séquence prédéterminée étant facultativement déterminée par des moyens de détermination incorporés à l'intérieur dudit appareil.

13. Appareil selon l'une quelconque des revendications précédentes, comprenant des moyens pour alerter un opérateur ou un utilisateur d'un statut d'au moins un capteur.

14. Procédé pour déterminer un état de conscience d'un sujet sensible ou d'un corps vivant par obtention, caractérisation et classification de signaux physiologiques provenant dudit sujet sensible ou corps vivant, ledit procédé comprenant les étapes de :

a) déduction d'un premier indice de conscience par obtention d'au moins un signal physiologique continu (étape 14) ;
b) stimulation d'un signal de réponse de potentiel évoqué dans ledit sujet sensible ou corps vivant (étape 12) ;
c) déduction d'un second indice de conscience par déduction d'au moins un signal physiologique de réponse de potentiel évoqué à partir dudit signal de réponse de potentiel évoqué (étape 12) ; et

déduction d'un indice de conscience à partir dudit signal physiologique continu et dudit signal de réponse de potentiel évoqué (étape 13) et classification desdits indices comme étant représentatifs d'une entrée ou d'une sortie de conscience selon un traitement de pondération ; et délivrance en sortie des résultats dudit traitement de pondération pour surveiller ledit état de conscience, et le signal physiologique étant facultativement un signal d'EEG.

15. Procédé selon la revendication 14, comprenant en outre les étapes de :

d) transformation dudit ou desdits signaux physiologiques selon un calcul de pondération fondé sur un traitement de médiation (étape 23) ;
e) transformation dudit ou desdits signaux physiologiques de réponse de potentiel évoqué selon ledit calcul de pondération (étape 23) ; et
f) calcul d'un indice à partir dudit signal physiologique transformé et dudit signal physiologique de réponse de potentiel évoqué transformé (étape 24).

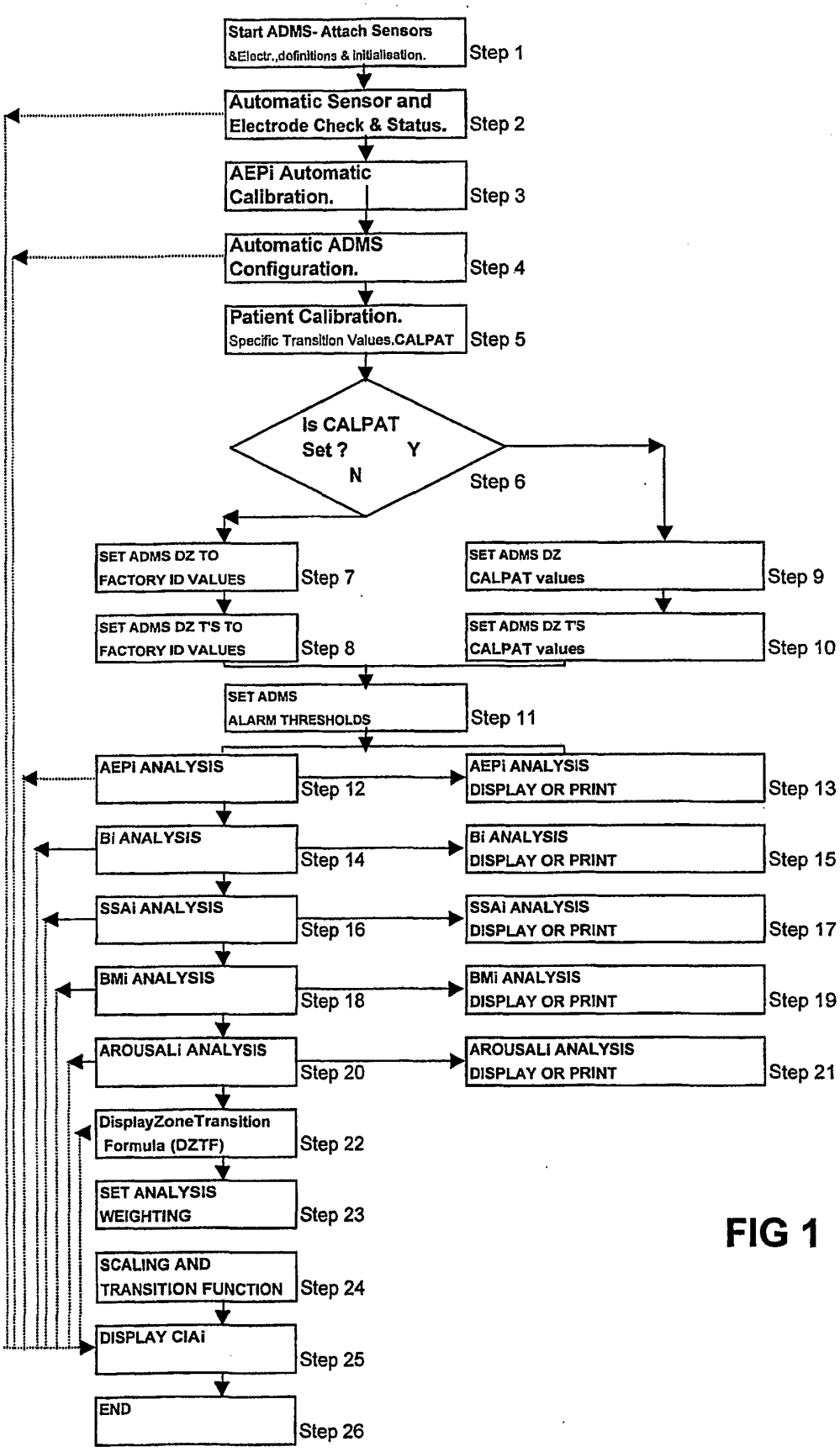

Start ADMS- Attach Sensors
&Electr.,definitions & initialisation.
Step 1
Automatic Sensor and
Electrode Check & Status.
Step 2
AEPi Automatic
Calibration.
Step 3
Automatic ADMS
Configuration.
Step 4
Patient Calibration.
Specific Transition Values.CALPAT
Step 5
Is CALPAT
Set ?
Y
N
Step 6
SET ADMS DZ TO
FACTORY ID VALUES
Step 7
SET ADMS DZ T'S TO
FACTORY ID VALUES
Step 8
SET ADMS DZ
CALPAT values
Step 9
SET ADMS DZ T'S
CALPAT values
Step 10
SET ADMS
ALARM THRESHOLDS
Step 11
AEPi ANALYSIS
Step 12
AEPi ANALYSIS
DISPLAY OR PRINT
Step 13
Bi ANALYSIS
Step 14
Bi ANALYSIS
DISPLAY OR PRINT
Step 15
SSAi ANALYSIS
Step 16
SSAi ANALYSIS
DISPLAY OR PRINT
Step 17
BMi ANALYSIS
Step 18
BMi ANALYSIS
DISPLAY OR PRINT
Step 19
AROUSALi ANALYSIS
Step 20
AROUSALi ANALYSIS
DISPLAY OR PRINT
Step 21
DisplayZoneTransition
Formula (DZTF)
Step 22
SET ANALYSIS
WEIGHTING
Step 23
SCALING AND
TRANSITION FUNCTION
Step 24
DISPLAY CIAi
Step 25
END
Step 26

FIG 1

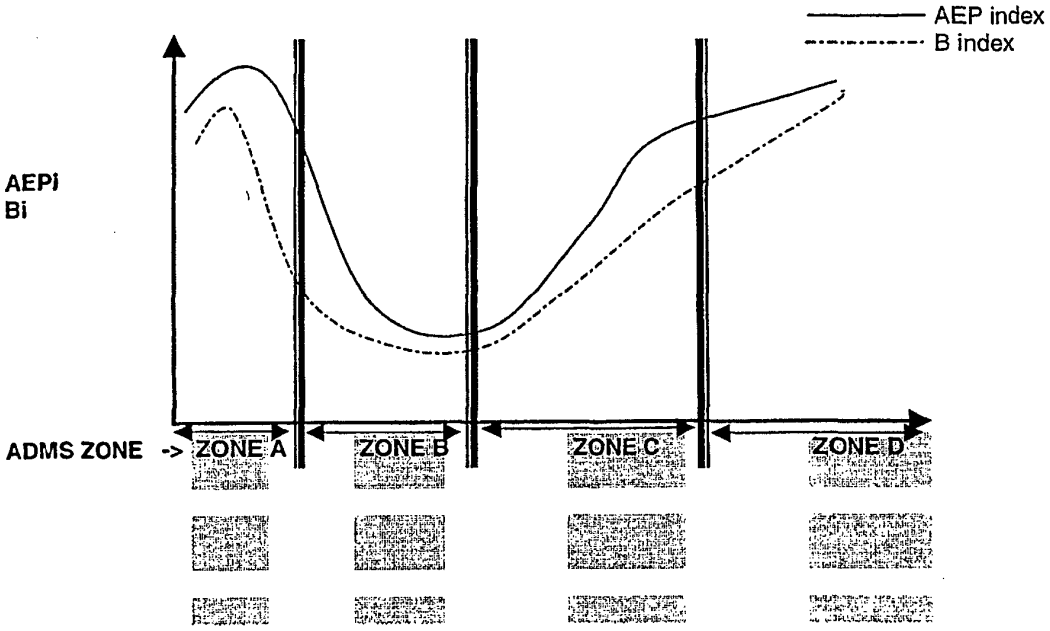


FIG 2

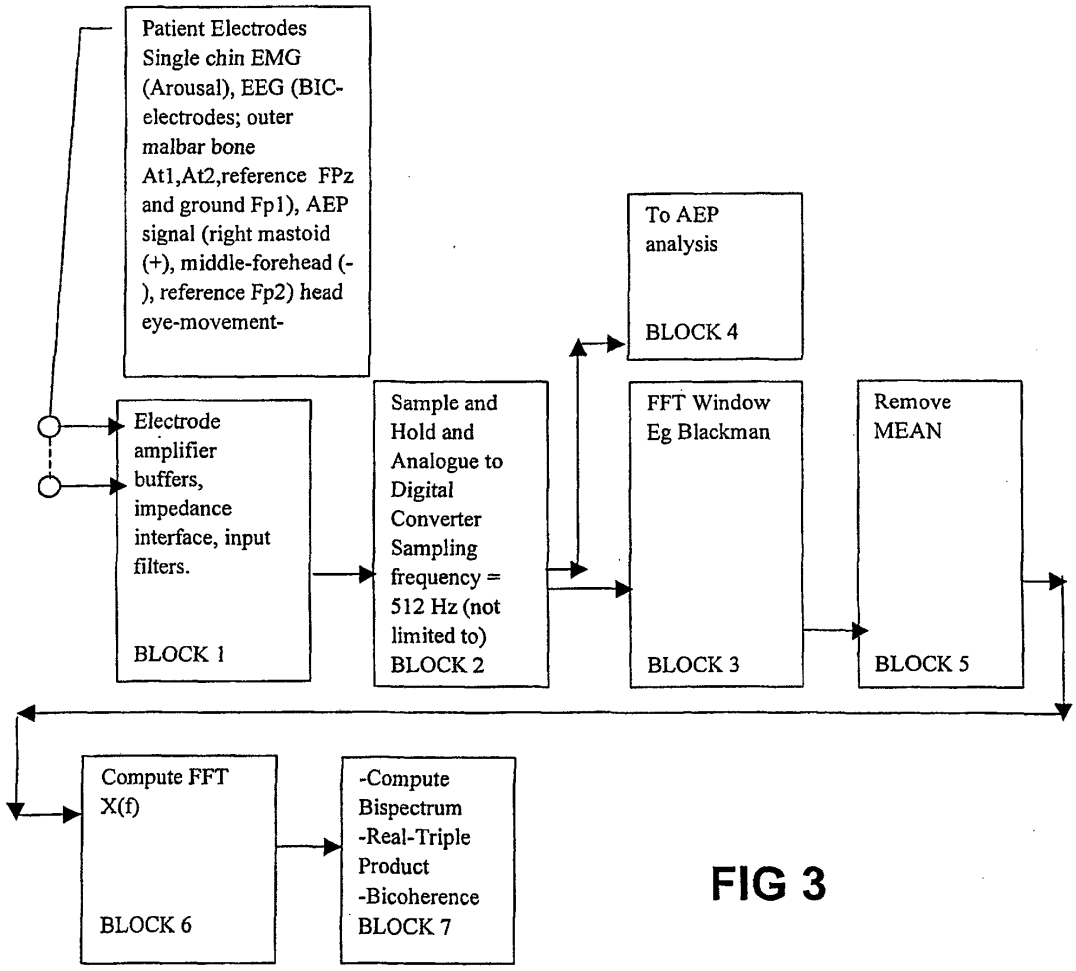

Patient Electrodes Single chin EMG (Arousal), EEG (BIC-electrodes; outer malbar bone At1,At2,reference FPz and ground Fp1), AEP signal (right mastoid (+), middle-forehead (-), reference Fp2) head eye-movement-
To AEP analysis
BLOCK 4
Electrode amplifier buffers, impedance interface, input filters.
BLOCK 1
Sample and Hold and Analogue to Digital Converter Sampling frequency = 512 Hz (not limited to)
BLOCK 2
FFT Window Eg Blackman
BLOCK 3
Remove MEAN
BLOCK 5
Compute FFT X(f)
BLOCK 6
-Compute Bispectrum
-Real-Triple Product
-Bicoherence
BLOCK 7

FIG 3

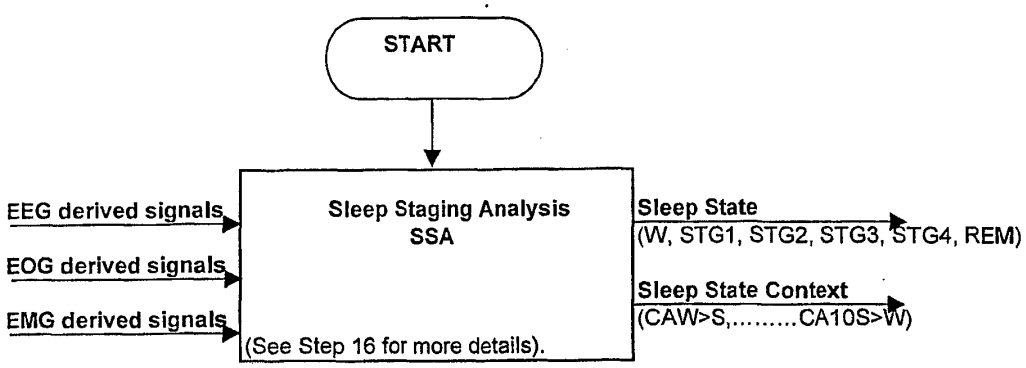

START
EEG derived signals
EOG derived signals
EMG derived signals
Sleep Staging Analysis
SSA
(See Step 16 for more details).
Sleep State
(W, STG1, STG2, STG3, STG4, REM)
Sleep State Context
(CAW>S,.....CA10S>W)

FIG 4

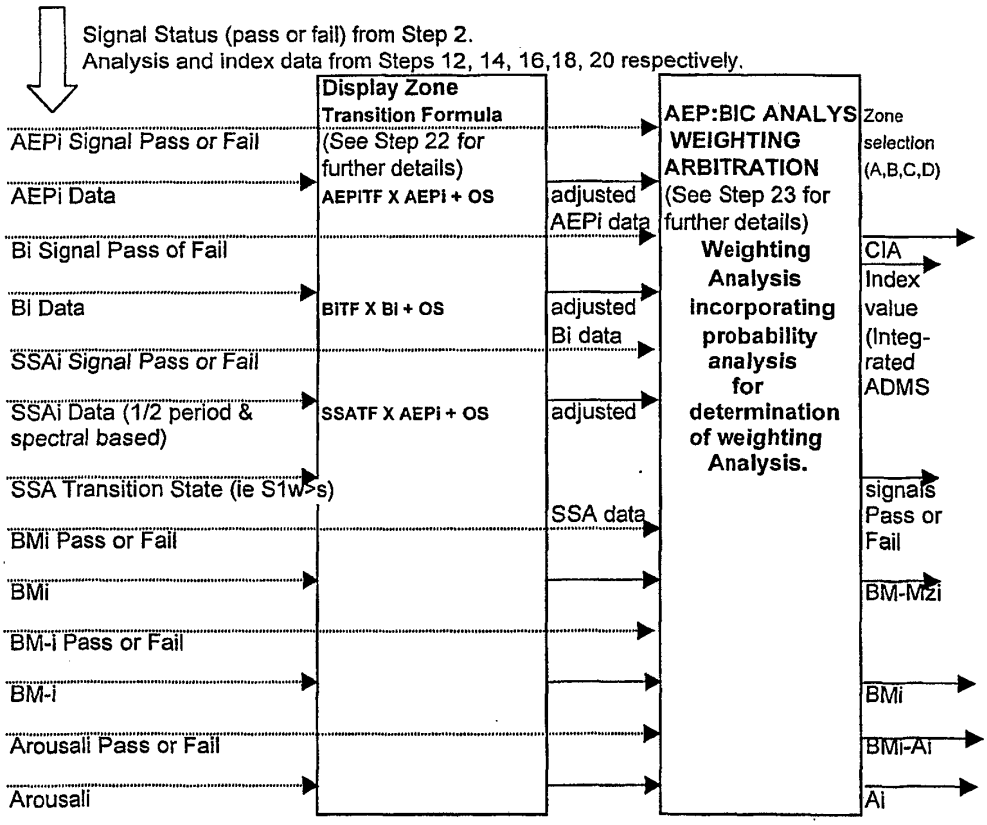

Signal Status (pass or fail) from Step 2.
Analysis and index data from Steps 12, 14, 16,18, 20 respectively.
Display Zone Transition Formula
(See Step 22 for further details)
AEPi Signal Pass or Fail
AEPi Data
Bi Signal Pass of Fail
Bi Data
SSAi Signal Pass or Fail
SSAi Data (1/2 period & spectral based)
SSA Transition State (ie S1w>s)
BMi Pass or Fail
BMi
BM-i Pass or Fail
BM-i
Arousali Pass or Fail
Arousali
AEPITF X AEPi + OS
BITF X Bi + OS
SSATF X AEPi + OS
adjusted AEPi data
adjusted Bi data
adjusted
SSA data
AEP:BIC ANALYS
WEIGHTING
ARBITRATION
(See Step 23 for further details)
Weighting Analysis incorporating probability analysis for determination of weighting Analysis.
Zone selection (A,B,C,D)
CIA Index value (Integ-rated ADMS
signals Pass or Fail
BM-Mzi
BMi
BMi-Ai
Ai

FIG 5

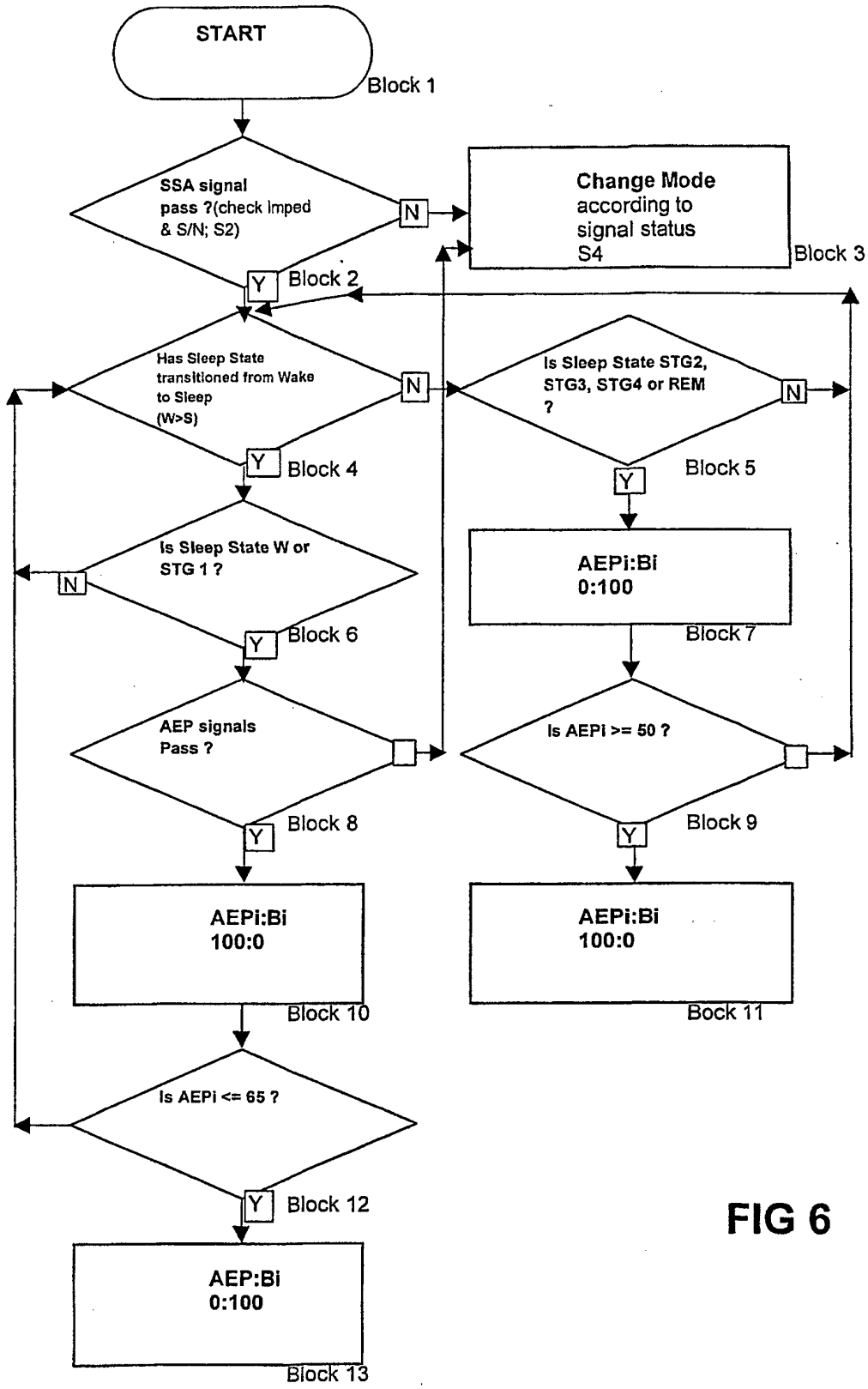

START
Block 1
SSA signal pass ?(check Imped & S/N; S2)
N
Change Mode according to signal status S4
Block 3
Y
Block 2
Has Sleep State transitioned from Wake to Sleep (W>S)
N
Is Sleep State STG2, STG3, STG4 or REM ?
N
Y
Block 4
Y
Block 5
Is Sleep State W or STG 1 ?
AEPi:Bi 0:100
N
Block 7
Y
Block 6
AEP signals Pass ?
Is AEPi >= 50 ?
Y
Block 8
Y
Block 9
AEPi:Bi 100:0
AEPi:Bi 100:0
Block 10
Bock 11
Is AEPi <= 65 ?
Y
Block 12
AEP:Bi 0:100
Block 13

FIG 6

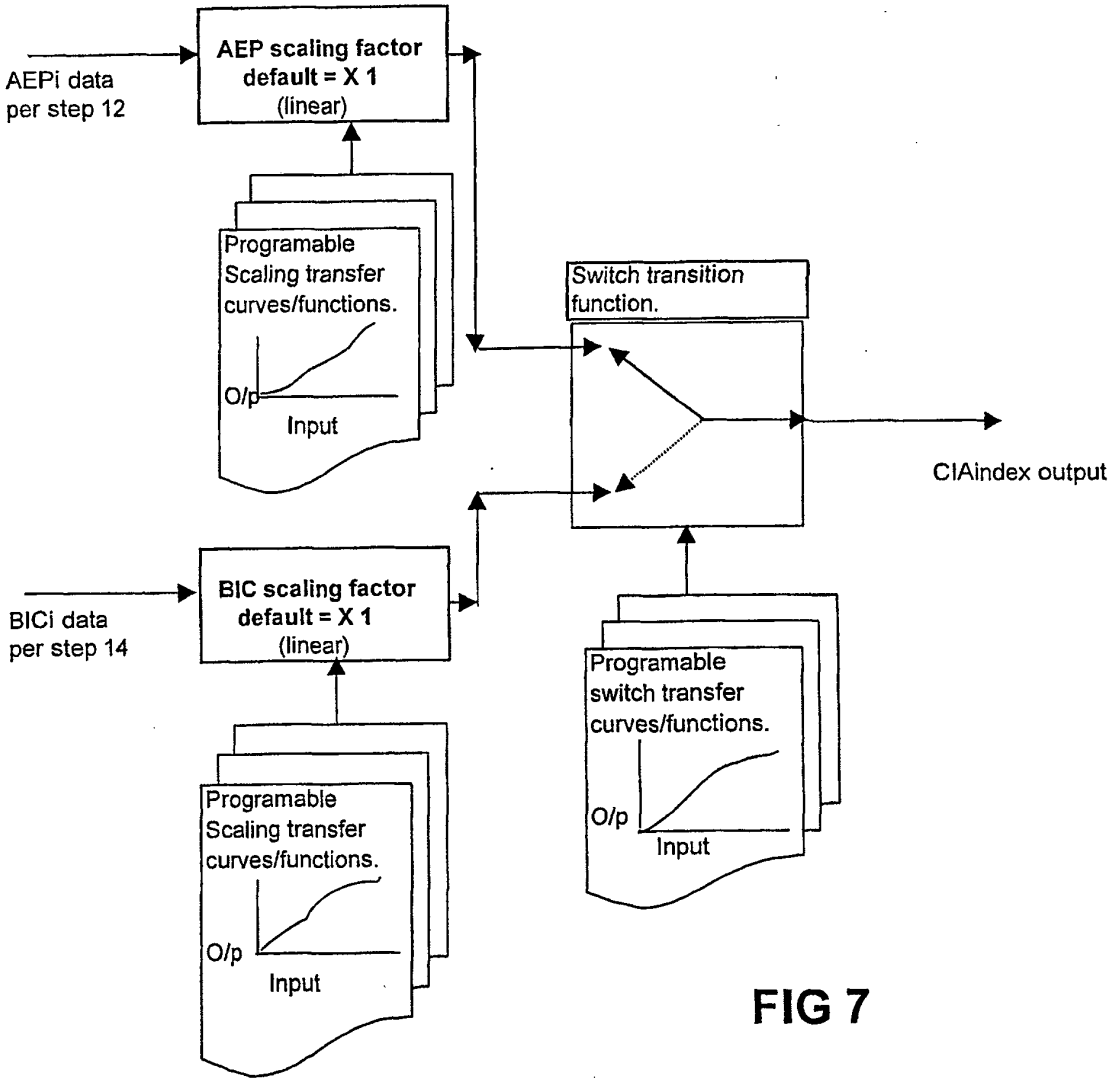

AEPi data
per step 12
AEP scaling factor
default = X 1
(linear)
Programable
Scaling transfer
curves/functions.
O/p
Input
Switch transition
function.
CIAindex output
BICi data
per step 14
BIC scaling factor
default = X 1
(linear)
Programable
Scaling transfer
curves/functions.
O/p
Input
Programable
switch transfer
curves/functions.
O/p
Input

FIG 7

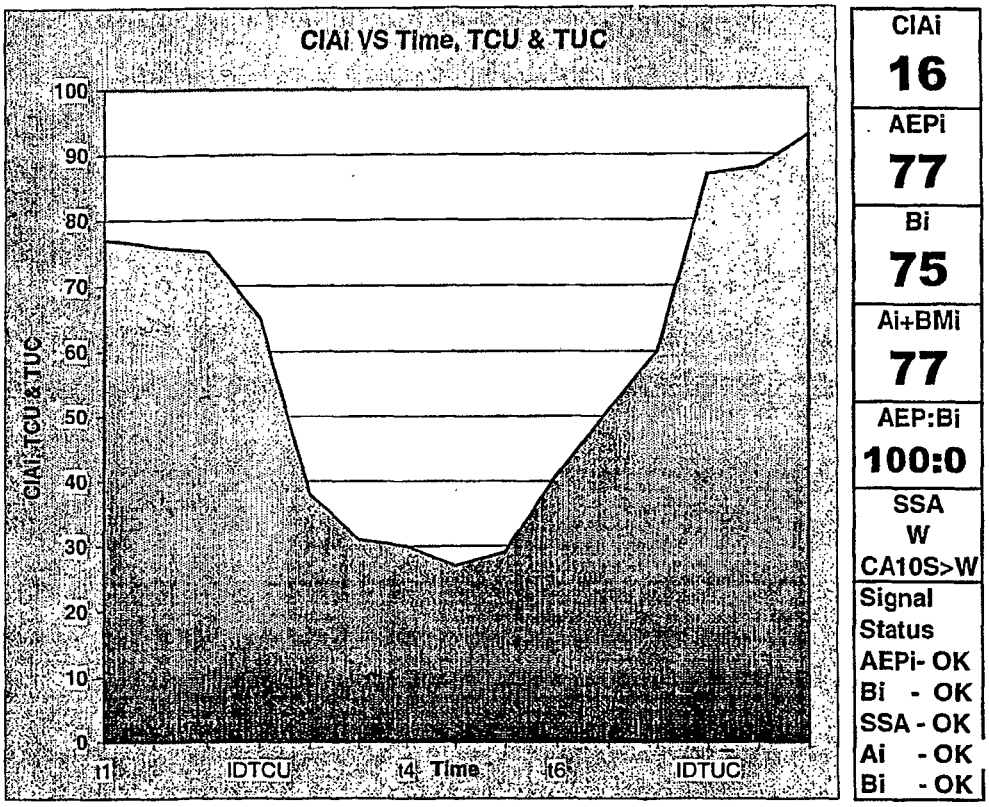

CIAi VS Time, TCU & TUC
CIAi;TCU &TUC
100
90
80
70
60
50
40
30
20
10
0
t1
IDTCU
t4
Time
t6
IDTUC
CIAi
16
AEPi
77
Bi
75
Ai+BMi
77
AEP:Bi
100:0
SSA
W
CA10S>W
Signal
Status
AEPi- OK
Bi - OK
SSA - OK
Ai - OK
Bi - OK

FIG 8

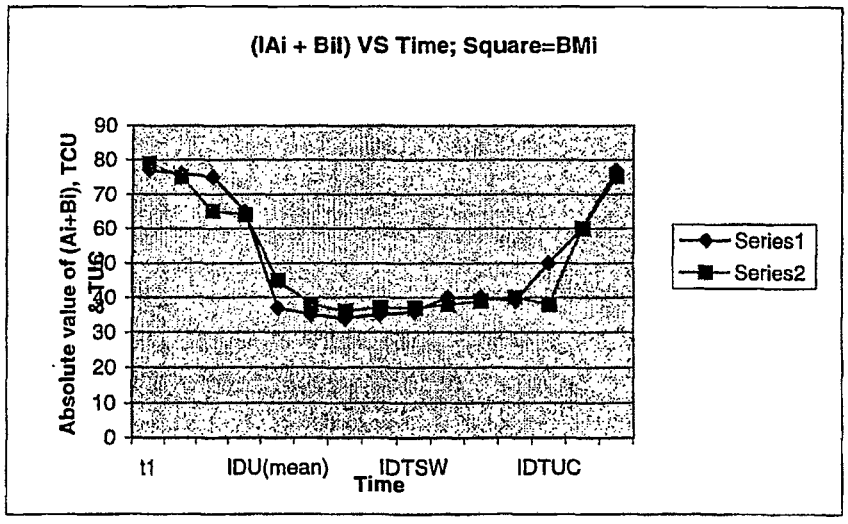

(IAi + Bii) VS Time; Square=BMi
Absolute value of (Ai+Bi), TCU &TUC
90
80
70
60
50
40
30
20
10
0
t1
IDU(mean)
IDTSW
IDTUC
Time
Series1
Series2

FIG 9

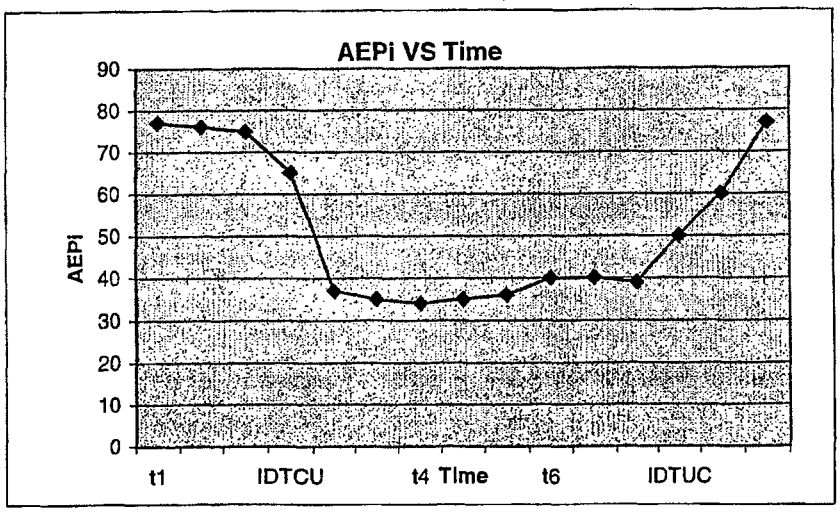

AEPi VS Time
AEPi
90
80
70
60
50
40
30
20
10
0
t1
IDTCU
t4 TIme
t6
IDTUC

FIG 10

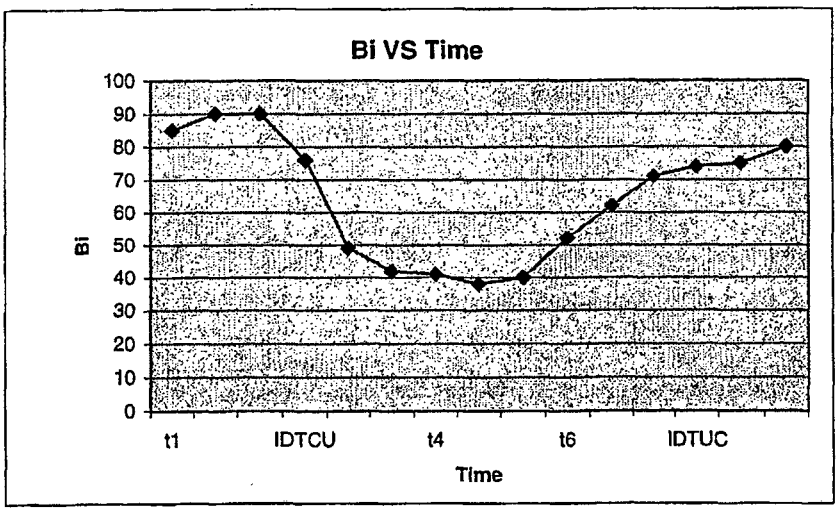

Bi VS Time
Bi
100
90
80
70
60
50
40
30
20
10
0
t1
IDTCU
t4
t6
IDTUC
TIme

FIG 11

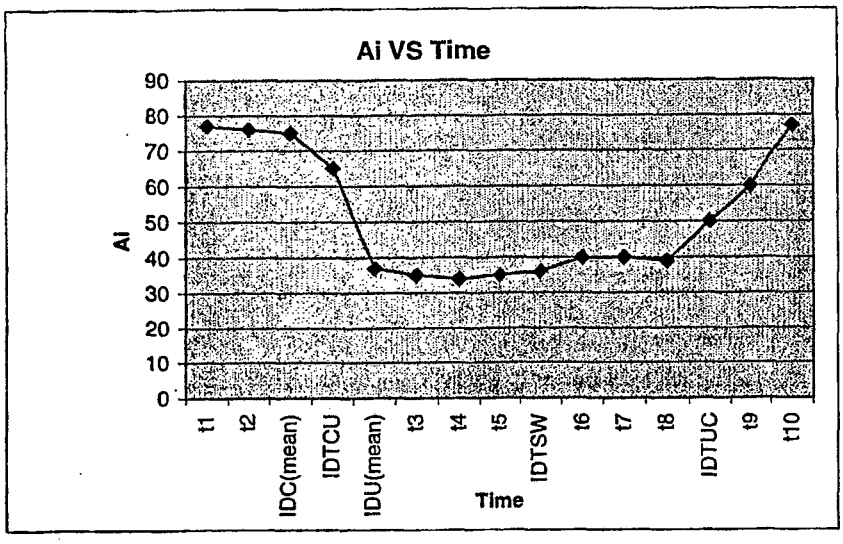

Ai VS Time
Ai
90
80
70
60
50
40
30
20
10
0
t1
t2
IDC(mean)
IDTCU
IDU(mean)
t3
t4
t5
IDTSW
t6
t7
t8
IDTUC
t9
t10
Time

FIG 12

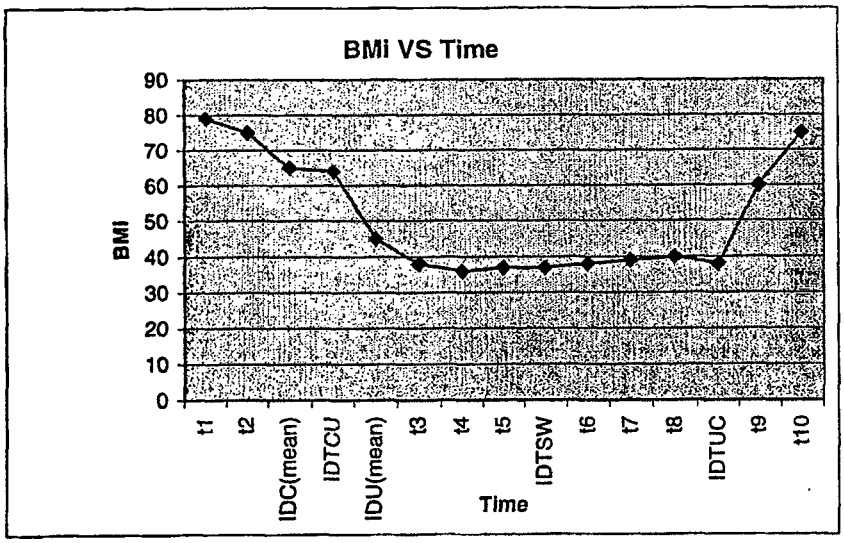

BMi VS Time
BMi
90
80
70
60
50
40
30
20
10
0
t1
t2
IDC(mean)
IDTCU
IDU(mean)
t3
t4
t5
IDTSW
t6
t7
t8
IDTUC
t9
t10
Time

FIG 13

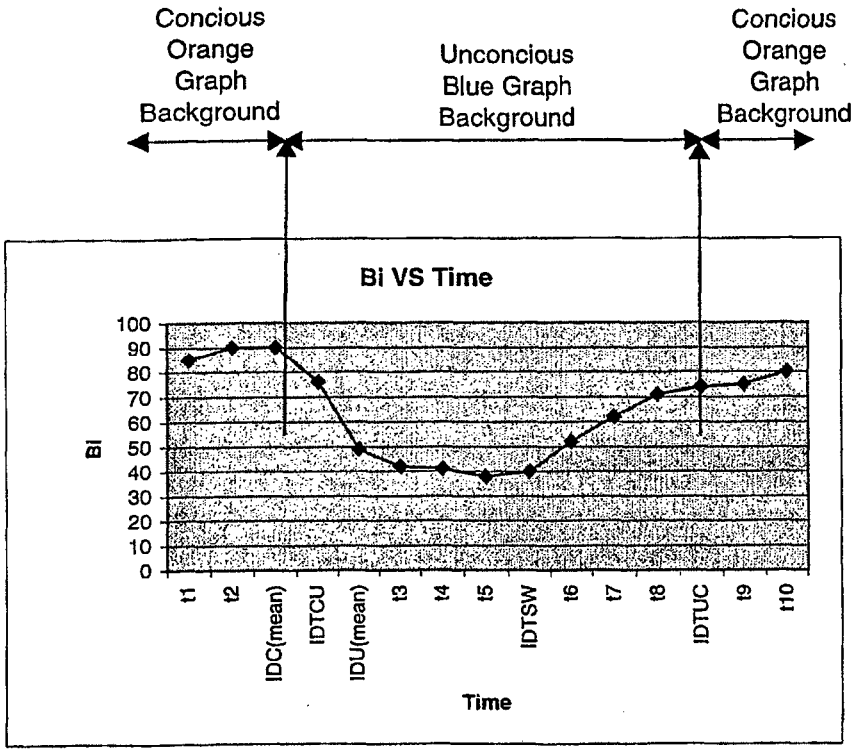

Concious
Orange
Graph
Background
Unconcious
Blue Graph
Background
Concious
Orange
Graph
Background
Bi VS Time
Bi
100
90
80
70
60
50
40
30
20
10
0
t1
t2
IDC(mean)
IDTCU
IDU(mean)
t3
t4
t5
IDTSW
t6
t7
t8
IDTUC
t9
t10
Time

FIG 14

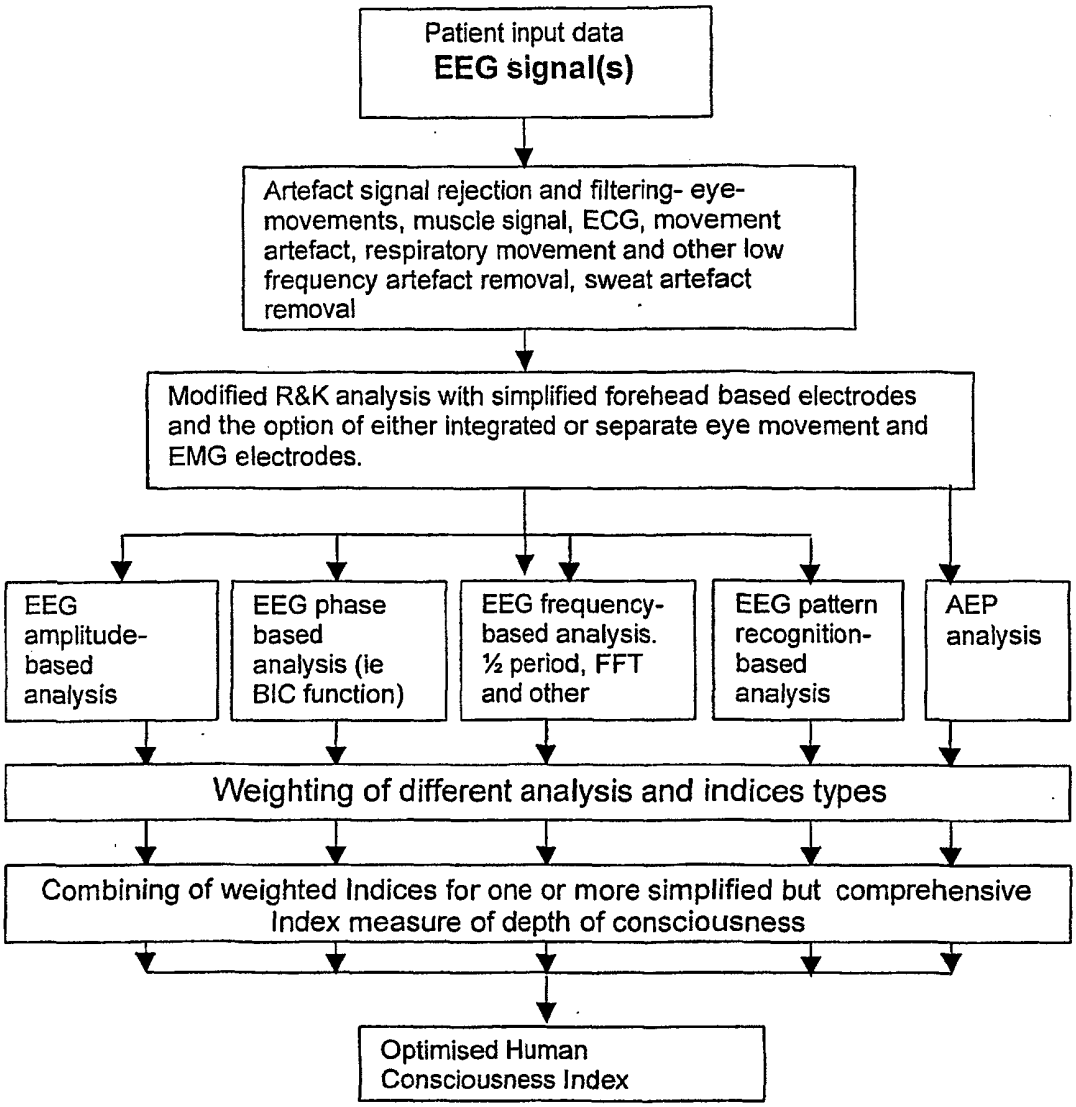

Patient input data
EEG signal(s)
Artefact signal rejection and filtering- eye-movements, muscle signal, ECG, movement artefact, respiratory movement and other low frequency artefact removal, sweat artefact removal
Modified R&K analysis with simplified forehead based electrodes and the option of either integrated or separate eye movement and EMG electrodes.
EEG amplitude-based analysis
EEG phase based analysis (ie BIC function)
EEG frequency-based analysis. ½ period, FFT and other
EEG pattern recognition-based analysis
AEP analysis
Weighting of different analysis and indices types
Combining of weighted Indices for one or more simplified but comprehensive Index measure of depth of consciousness
Optimised Human Consciousness Index

FIG 15

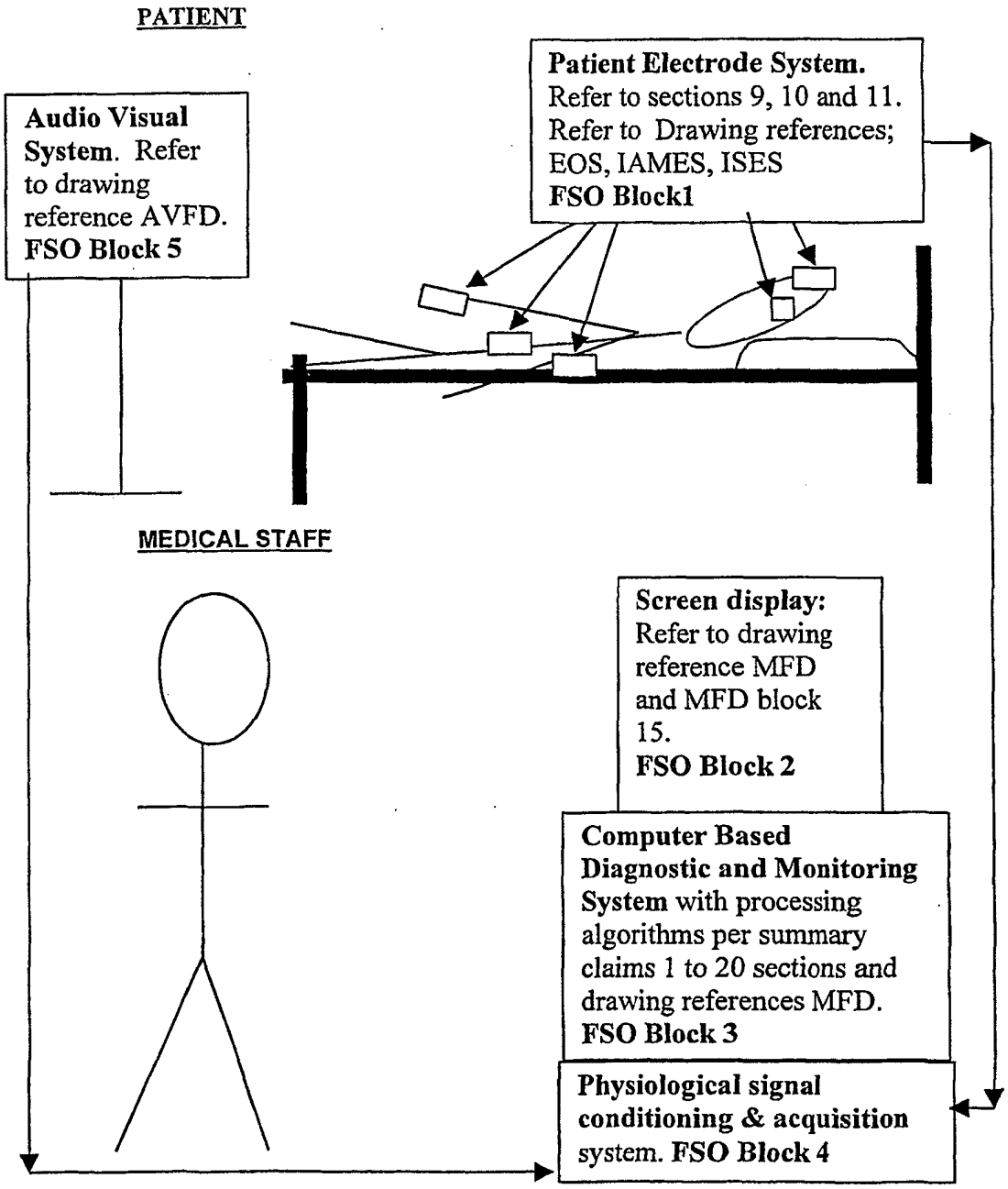

PATIENT
Audio Visual System. Refer to drawing reference AVFD. FSO Block 5
Patient Electrode System. Refer to sections 9, 10 and 11. Refer to Drawing references; EOS, IAMES, ISES FSO Block1
MEDICAL STAFF
Screen display: Refer to drawing reference MFD and MFD block 15. FSO Block 2
Computer Based Diagnostic and Monitoring System with processing algorithms per summary claims 1 to 20 sections and drawing references MFD. FSO Block 3
Physiological signal conditioning & acquisition system. FSO Block 4

FIG 16

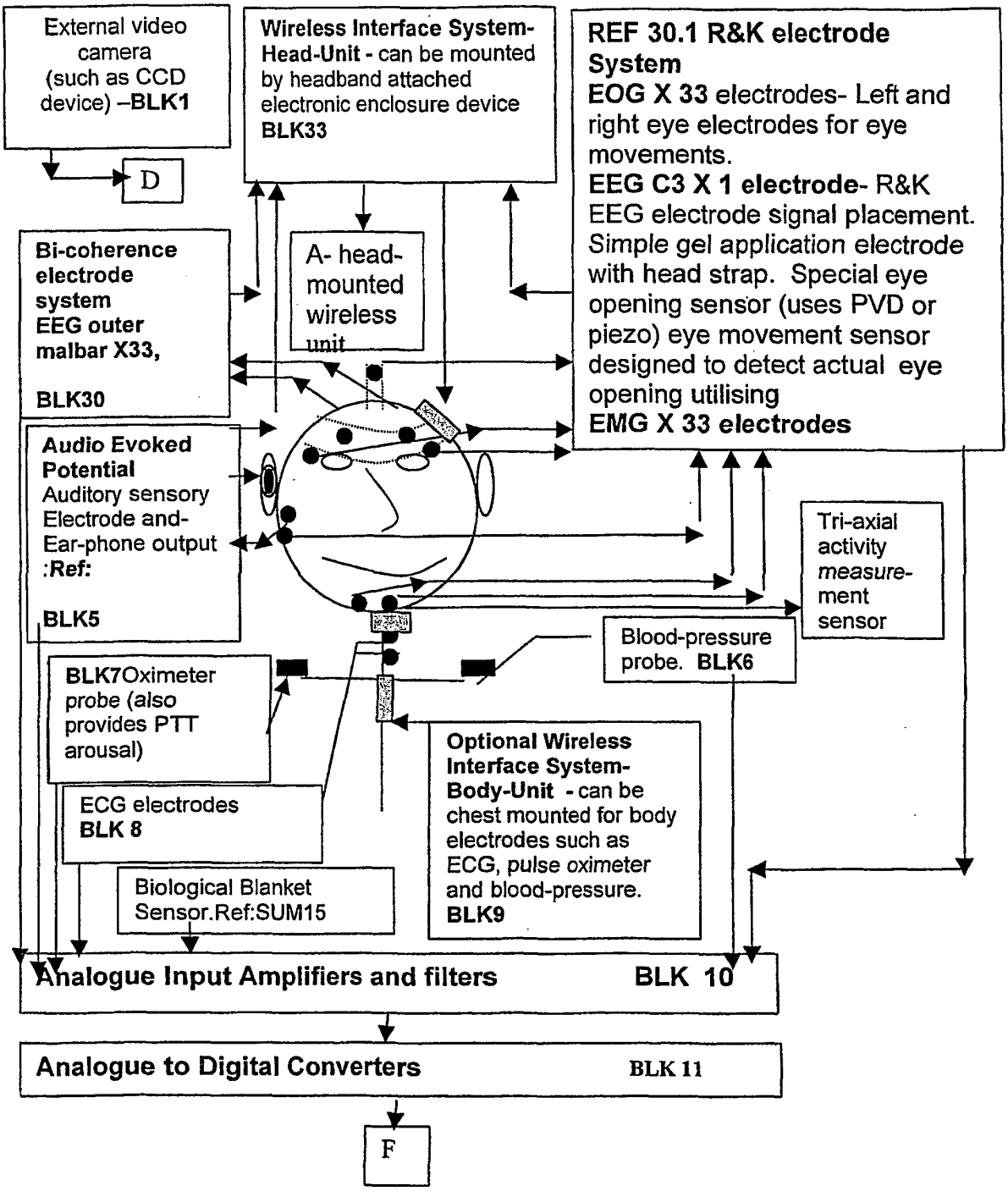

External video camera (such as CCD device) –BLK1
D
Wireless Interface System-Head-Unit - can be mounted by headband attached electronic enclosure device BLK33
REF 30.1 R&K electrode System
EOG X 33 electrodes- Left and right eye electrodes for eye movements.
EEG C3 X 1 electrode- R&K EEG electrode signal placement. Simple gel application electrode with head strap. Special eye opening sensor (uses PVD or piezo) eye movement sensor designed to detect actual eye opening utilising
EMG X 33 electrodes
Bi-coherence electrode system EEG outer malbar X33, BLK30
A- head-mounted wireless unit
Audio Evoked Potential Auditory sensory Electrode and-Ear-phone output :Ref: BLK5
Tri-axial activity measure-ment sensor
Blood-pressure probe. BLK6
BLK7Oximeter probe (also provides PTT arousal)
Optional Wireless Interface System-Body-Unit - can be chest mounted for body electrodes such as ECG, pulse oximeter and blood-pressure. BLK9
ECG electrodes BLK 8
Biological Blanket Sensor.Ref:SUM15
Analogue Input Amplifiers and filters BLK 10
Analogue to Digital Converters BLK 11
F

FIG 17

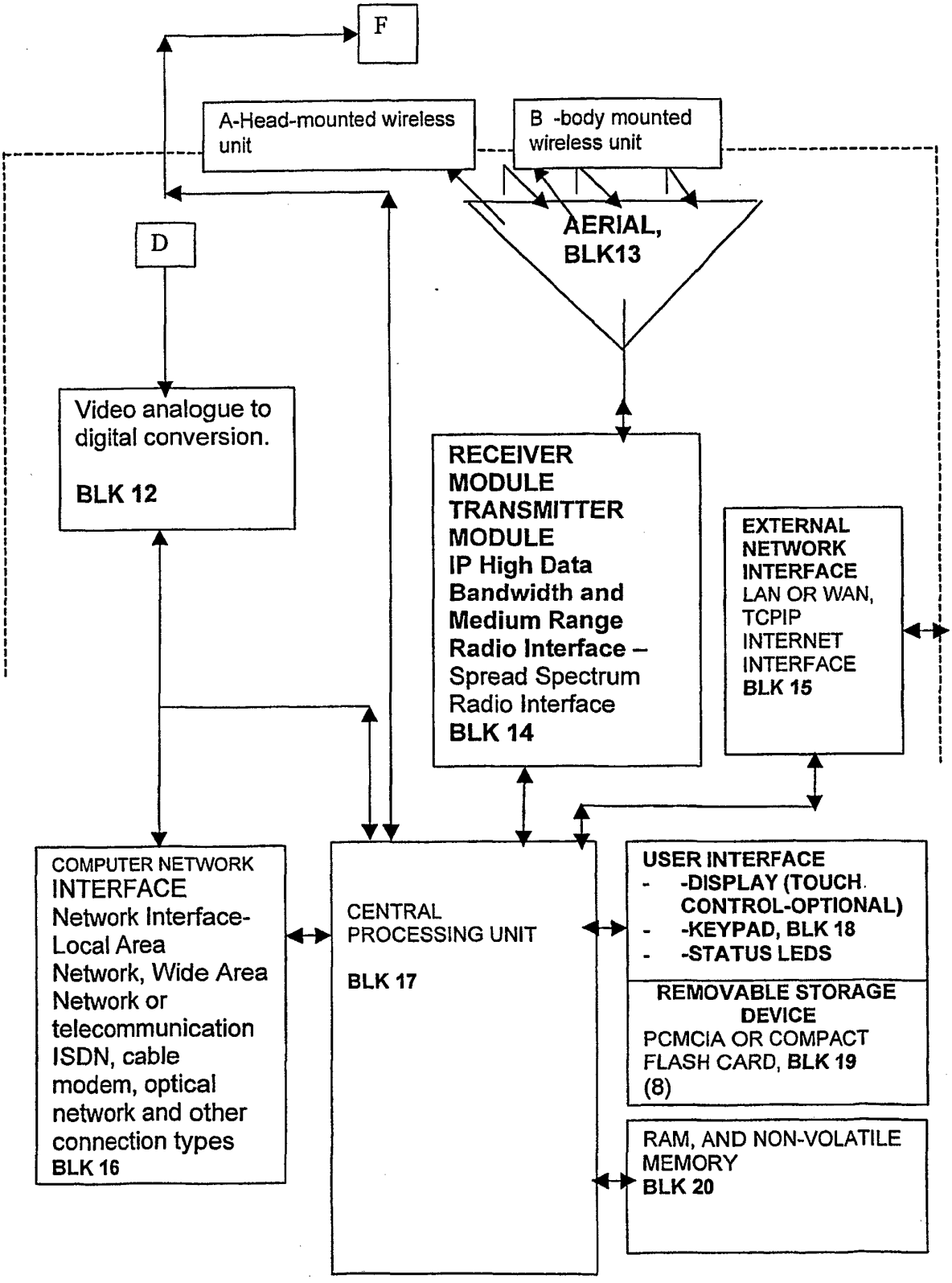

F
A-Head-mounted wireless unit
B -body mounted wireless unit
AERIAL, BLK13
D
Video analogue to digital conversion.
BLK 12
RECEIVER MODULE TRANSMITTER MODULE IP High Data Bandwidth and Medium Range Radio Interface – Spread Spectrum Radio Interface BLK 14
EXTERNAL NETWORK INTERFACE LAN OR WAN, TCPIP INTERNET INTERFACE BLK 15
COMPUTER NETWORK INTERFACE Network Interface-Local Area Network, Wide Area Network or telecommunication ISDN, cable modem, optical network and other connection types BLK 16
CENTRAL PROCESSING UNIT
BLK 17
USER INTERFACE
- -DISPLAY (TOUCH CONTROL-OPTIONAL)
- -KEYPAD, BLK 18
- -STATUS LEDS
REMOVABLE STORAGE DEVICE
PCMCIA OR COMPACT FLASH CARD, BLK 19 (8)
RAM, AND NON-VOLATILE MEMORY
BLK 20

FIG 17 (cont)

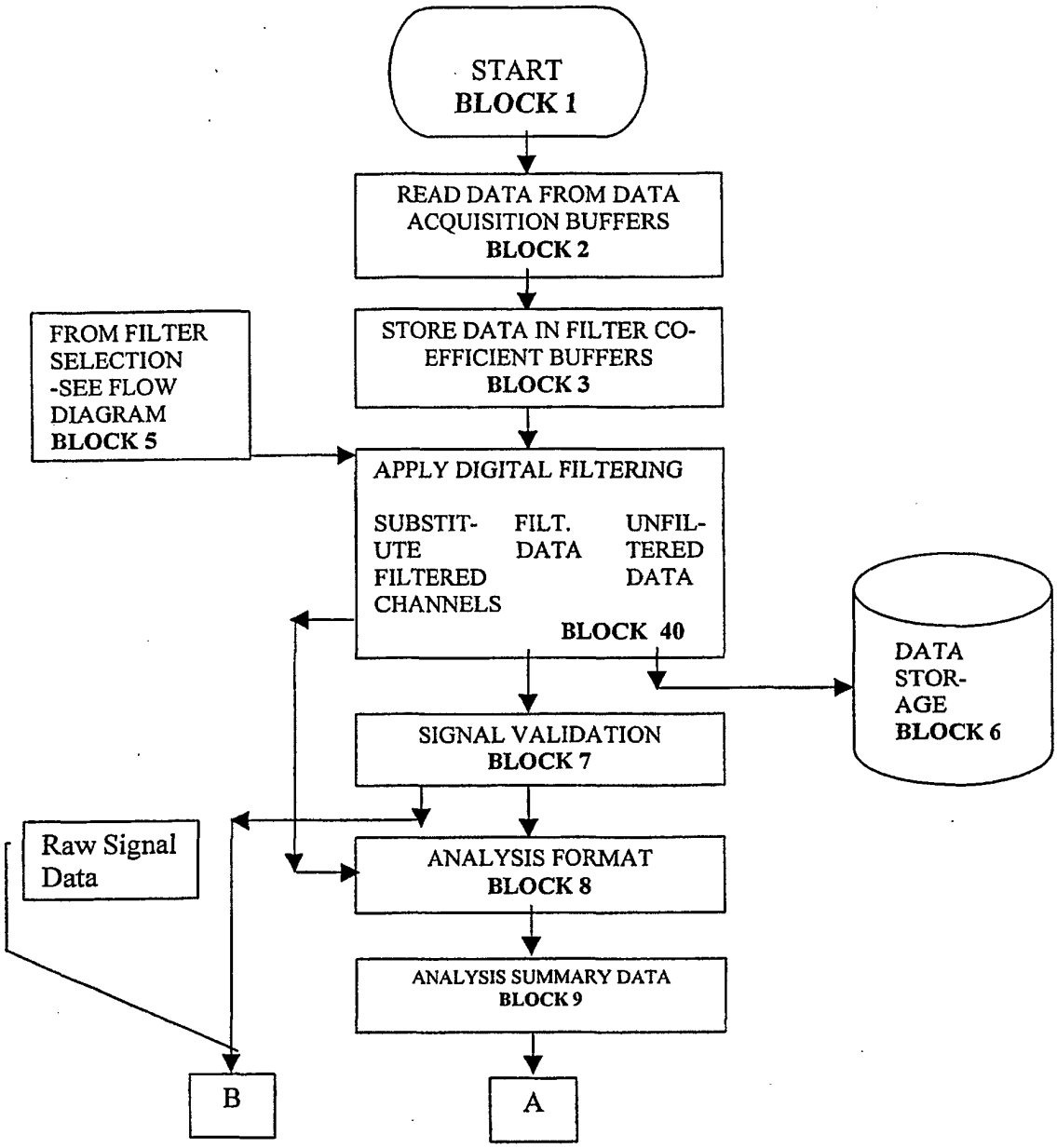

START
BLOCK 1
READ DATA FROM DATA ACQUISITION BUFFERS
BLOCK 2
STORE DATA IN FILTER CO-EFFICIENT BUFFERS
BLOCK 3
FROM FILTER SELECTION -SEE FLOW DIAGRAM
BLOCK 5
APPLY DIGITAL FILTERING
SUBSTIT-UTE FILTERED CHANNELS
FILT. DATA
UNFIL-TERED DATA
BLOCK 40
DATA STOR-AGE
BLOCK 6
SIGNAL VALIDATION
BLOCK 7
Raw Signal Data
ANALYSIS FORMAT
BLOCK 8
ANALYSIS SUMMARY DATA
BLOCK 9
B
A

FIG 18

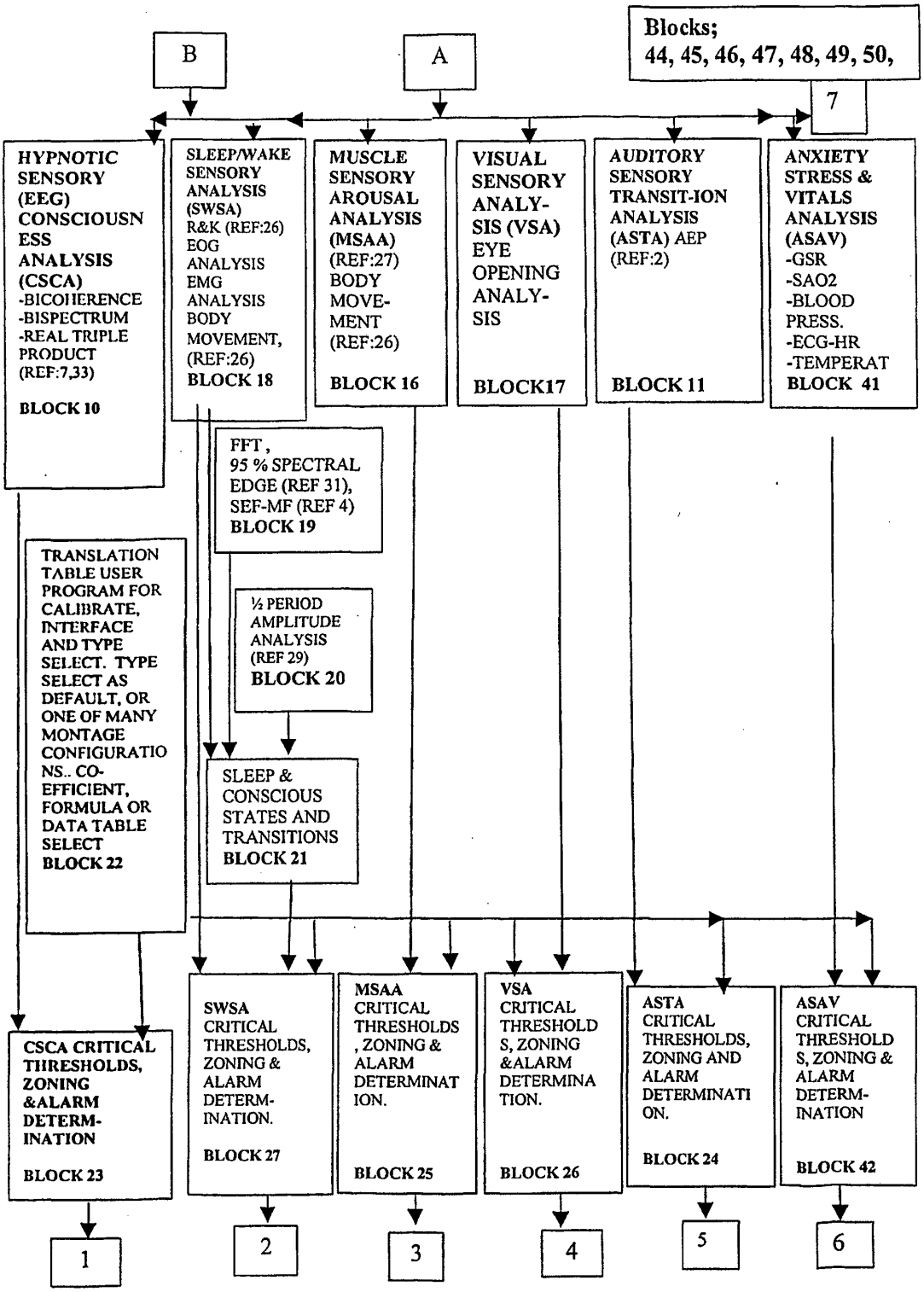

B
A
Blocks;
44, 45, 46, 47, 48, 49, 50,
7
HYPNOTIC SENSORY (EEG) CONSCIOUSNESS ANALYSIS (CSCA) -BICOHERENCE -BISPECTRUM -REAL TRIPLE PRODUCT (REF:7,33) BLOCK 10
SLEEP/WAKE SENSORY ANALYSIS (SWSA) R&K (REF:26) EOG ANALYSIS EMG ANALYSIS BODY MOVEMENT, (REF:26) BLOCK 18
MUSCLE SENSORY AROUSAL ANALYSIS (MSAA) (REF:27) BODY MOVEMENT (REF:26) BLOCK 16
VISUAL SENSORY ANALYSIS (VSA) EYE OPENING ANALYSIS BLOCK17
AUDITORY SENSORY TRANSIT-ION ANALYSIS (ASTA) AEP (REF:2) BLOCK 11
ANXIETY STRESS & VITALS ANALYSIS (ASAV) -GSR -SAO2 -BLOOD PRESS. -ECG-HR -TEMPERAT BLOCK 41
FFT, 95 % SPECTRAL EDGE (REF 31), SEF-MF (REF 4) BLOCK 19
TRANSLATION TABLE USER PROGRAM FOR CALIBRATE, INTERFACE AND TYPE SELECT. TYPE SELECT AS DEFAULT, OR ONE OF MANY MONTAGE CONFIGURATIONS.. CO-EFFICIENT, FORMULA OR DATA TABLE SELECT BLOCK 22
½ PERIOD AMPLITUDE ANALYSIS (REF 29) BLOCK 20
SLEEP & CONSCIOUS STATES AND TRANSITIONS BLOCK 21
CSCA CRITICAL THRESHOLDS, ZONING &ALARM DETERM-INATION BLOCK 23
SWSA CRITICAL THRESHOLDS, ZONING & ALARM DETERM-INATION. BLOCK 27
MSAA CRITICAL THRESHOLDS, ZONING & ALARM DETERMINATION. BLOCK 25
VSA CRITICAL THRESHOLDS, ZONING &ALARM DETERMINATION. BLOCK 26
ASTA CRITICAL THRESHOLDS, ZONING AND ALARM DETERMINATION. BLOCK 24
ASAV CRITICAL THRESHOLDS, ZONING & ALARM DETERM-INATION BLOCK 42
1
2
3
4
5
6

FIG 18 (cont)(i)

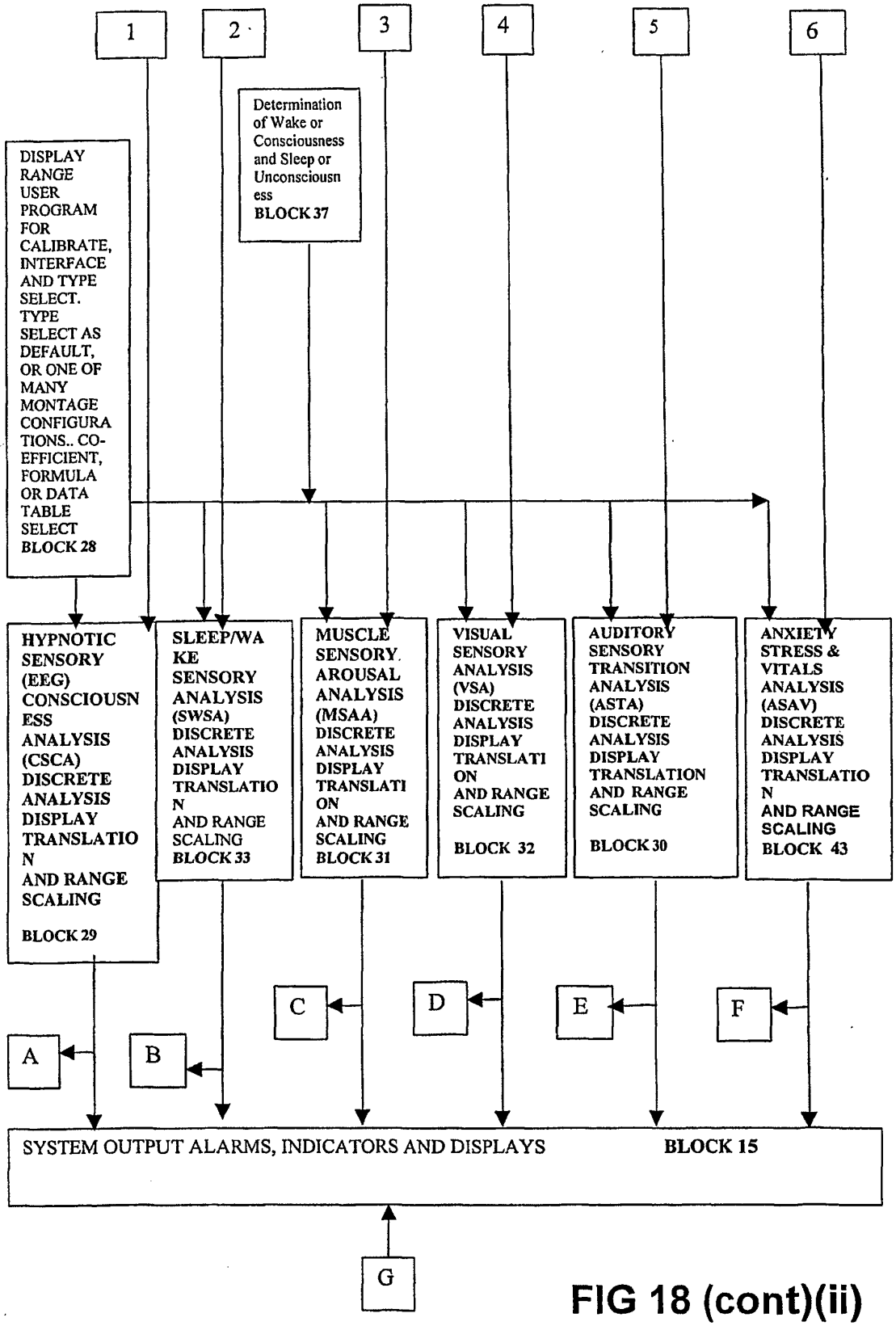


FIG 18 (cont)(ii)

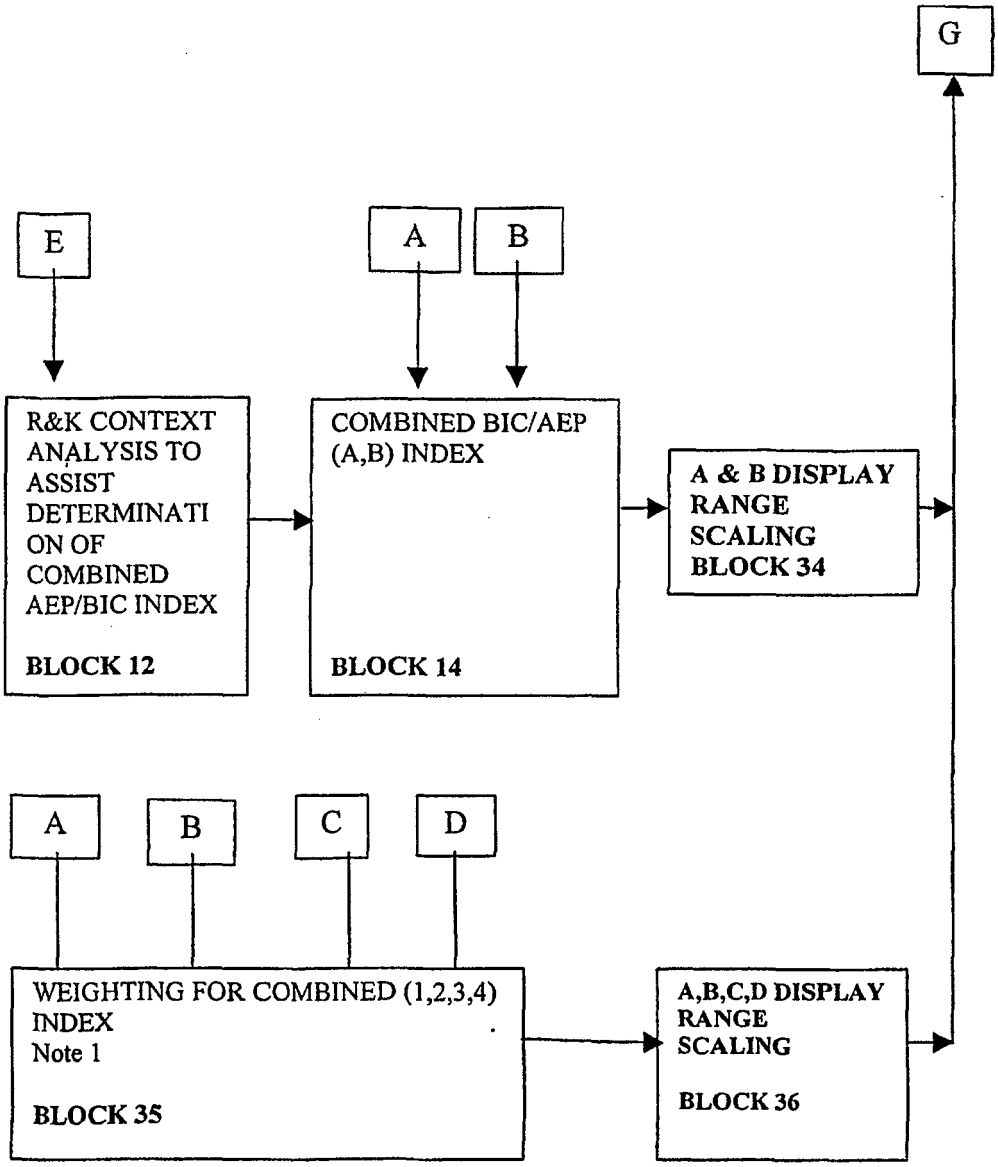


FIG 18 (cont)(iii)

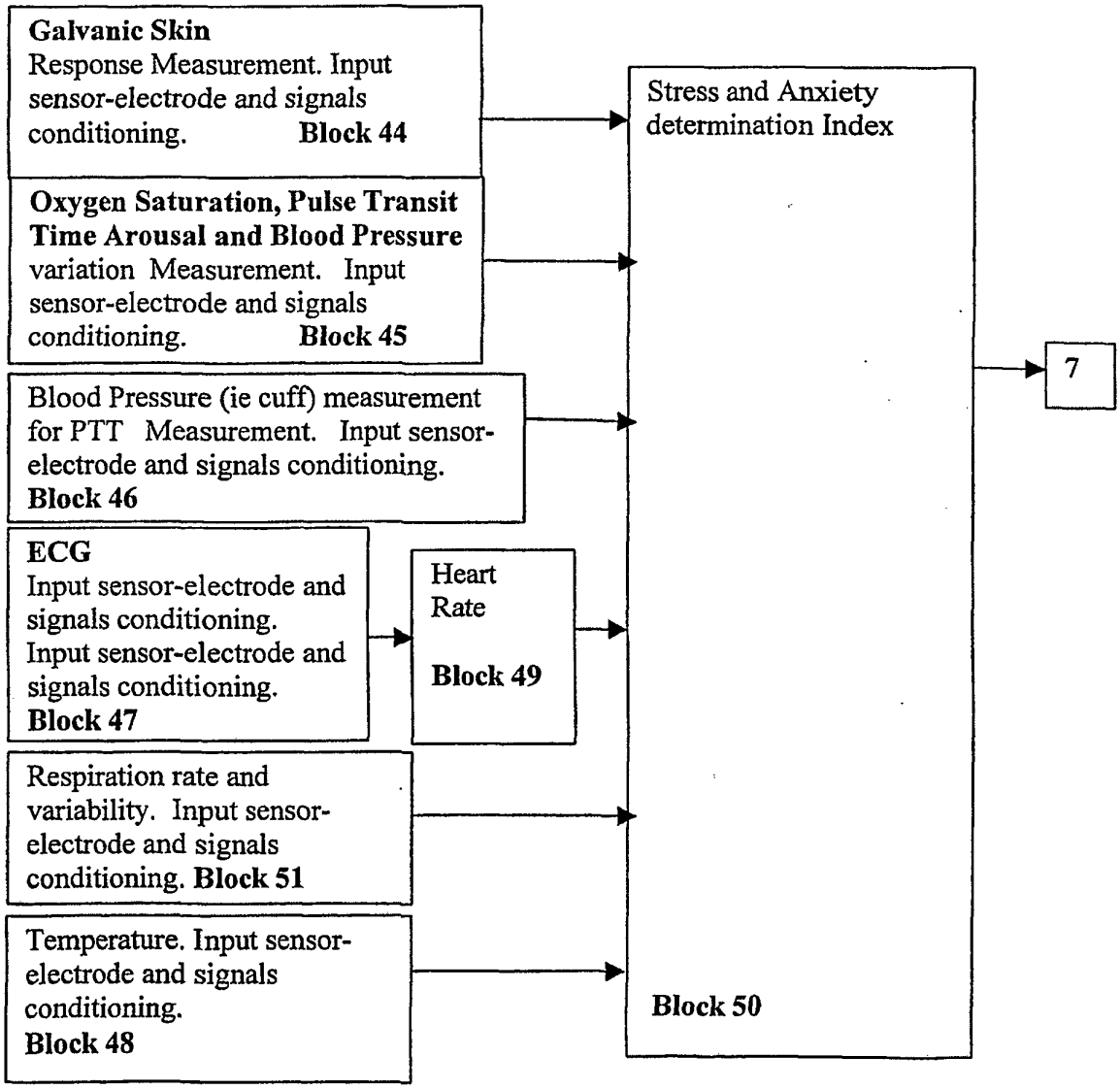


FIG 18 (cont)(iv)

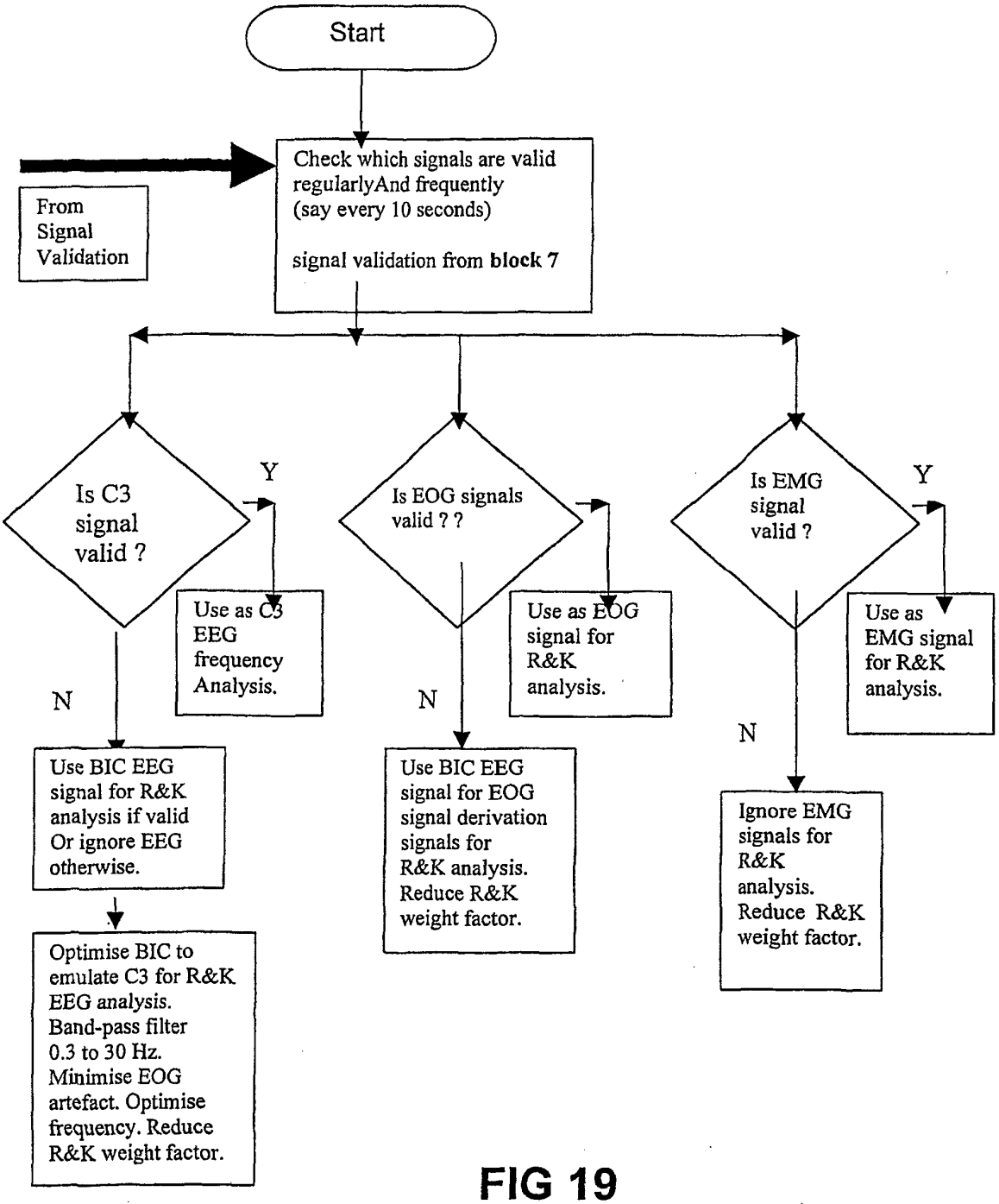

Start
From Signal Validation
Check which signals are valid regularlyAnd frequently (say every 10 seconds)
signal validation from block 7
Is C3 signal valid ?
Y
Use as C3 EEG frequency Analysis.
N
Use BIC EEG signal for R&K analysis if valid Or ignore EEG otherwise.
Optimise BIC to emulate C3 for R&K EEG analysis. Band-pass filter 0.3 to 30 Hz. Minimise EOG artefact. Optimise frequency. Reduce R&K weight factor.
Is EOG signals valid ? ?
Use as EOG signal for R&K analysis.
N
Use BIC EEG signal for EOG signal derivation signals for R&K analysis. Reduce R&K weight factor.
Is EMG signal valid ?
Y
Use as EMG signal for R&K analysis.
N
Ignore EMG signals for R&K analysis. Reduce R&K weight factor.

FIG 19

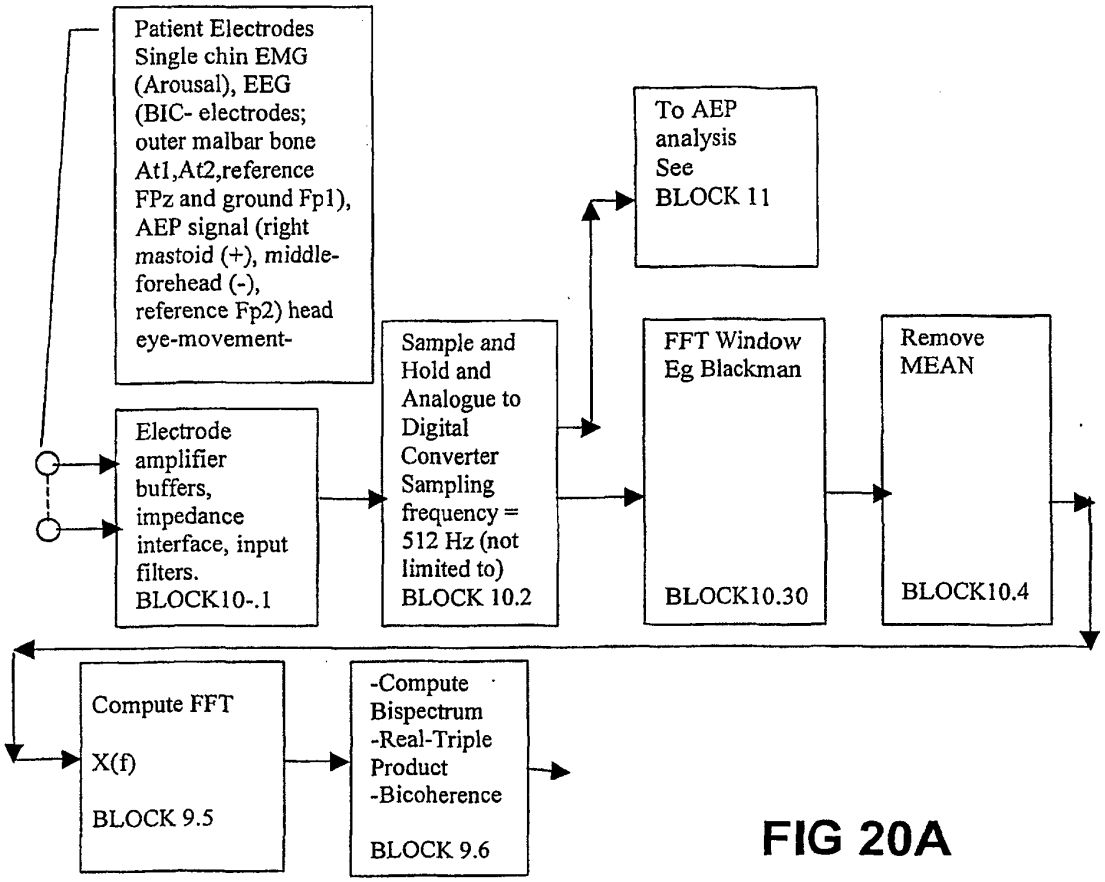


FIG 20A

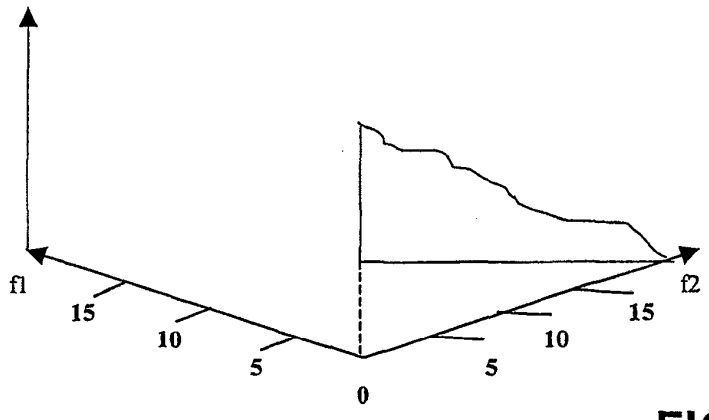


FIG 20B

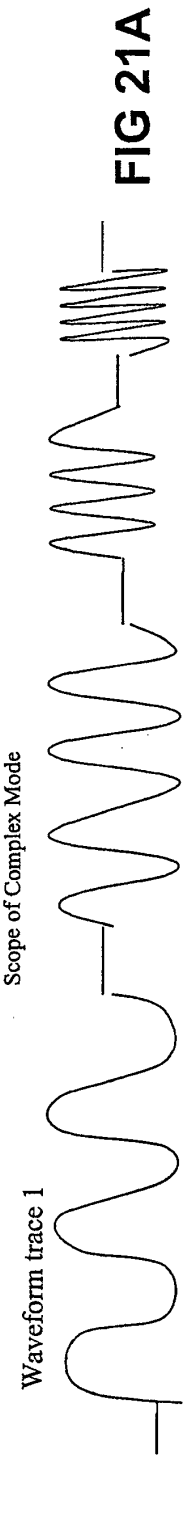


FIG 21A

FIG 21B

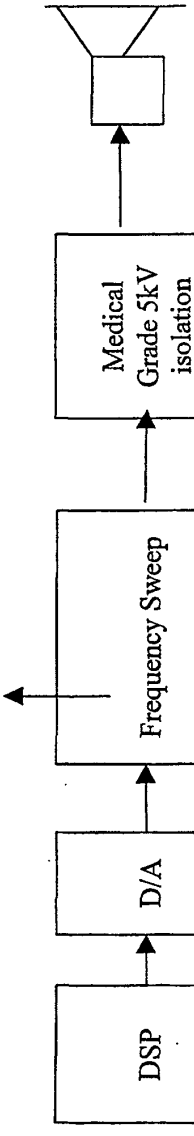


FIG 21C

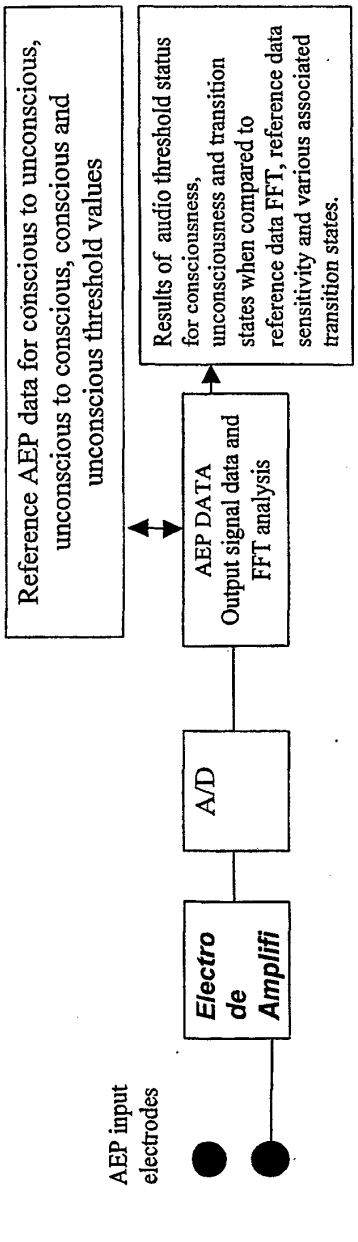


FIG 21D

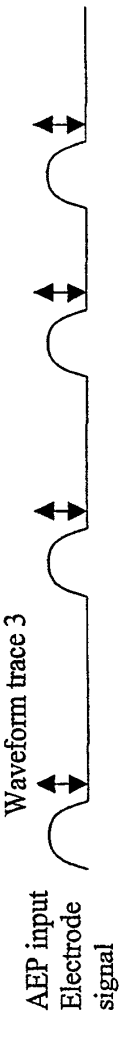


FIG 21E

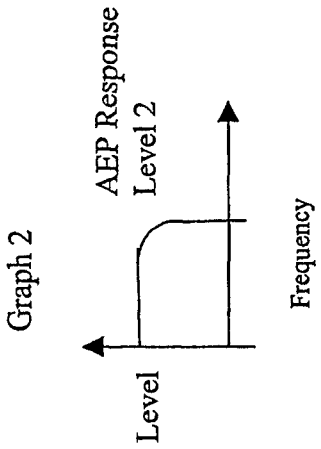


FIG 21G

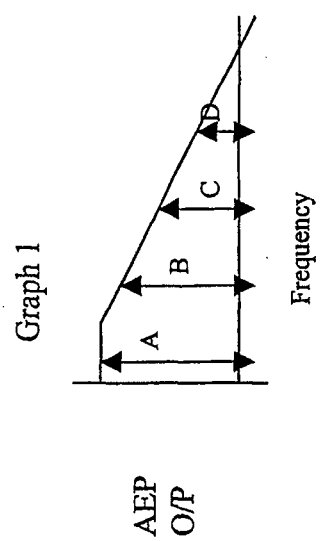


FIG 21F

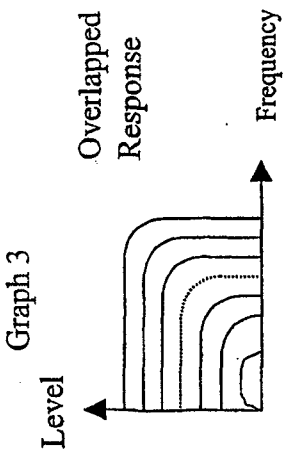


FIG 21H

Context Analysis Method

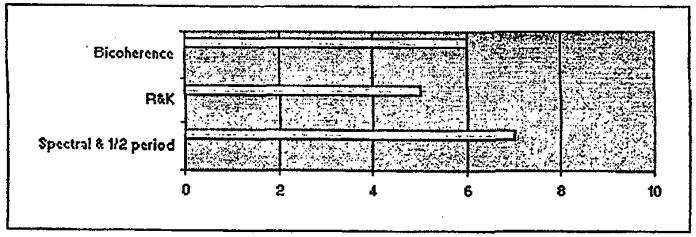


FIG 22A

Context Analysis Probability

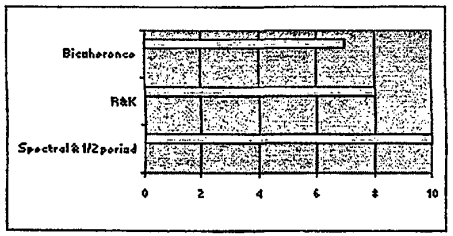


FIG 22B

Validate

FIG 22a

Validate

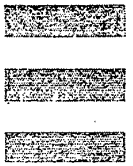


FIG 22b

Transition Analysis Method

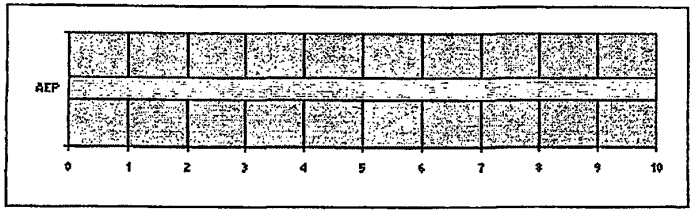


FIG 22C

Transition Analysis Probability

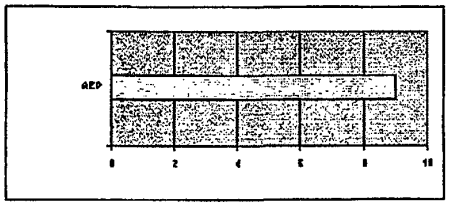


FIG 22D

FIG 22c

FIG 22d

Movement Analysis Method

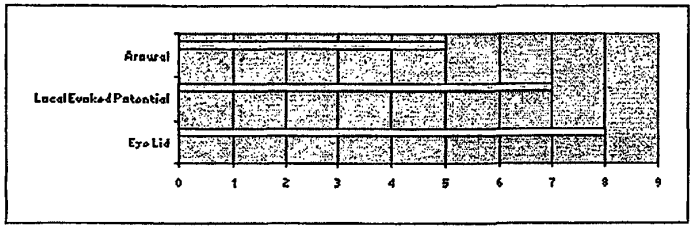


FIG 22E

Movement Analysis Probability

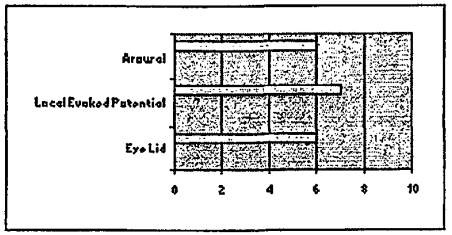


FIG 22F

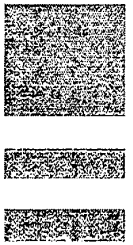
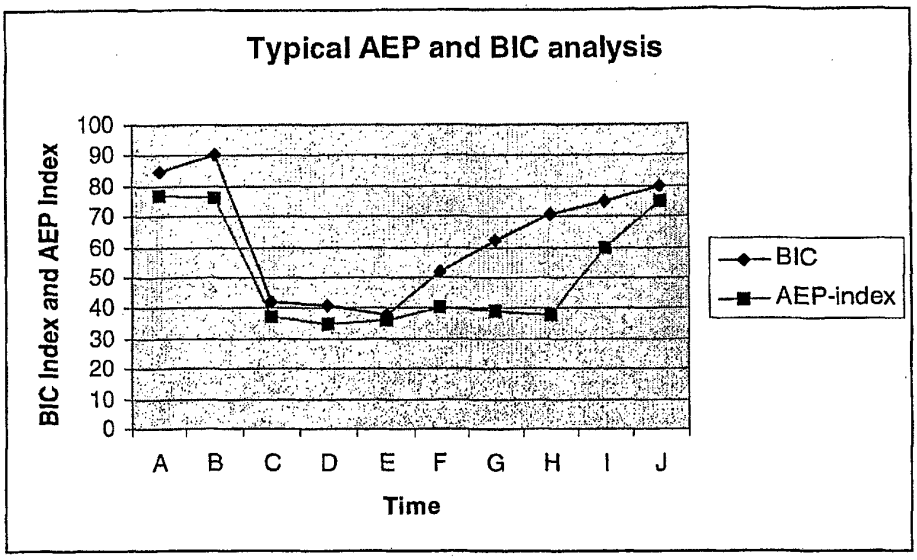
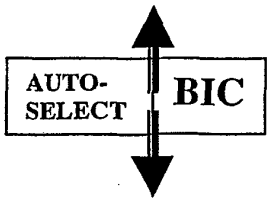
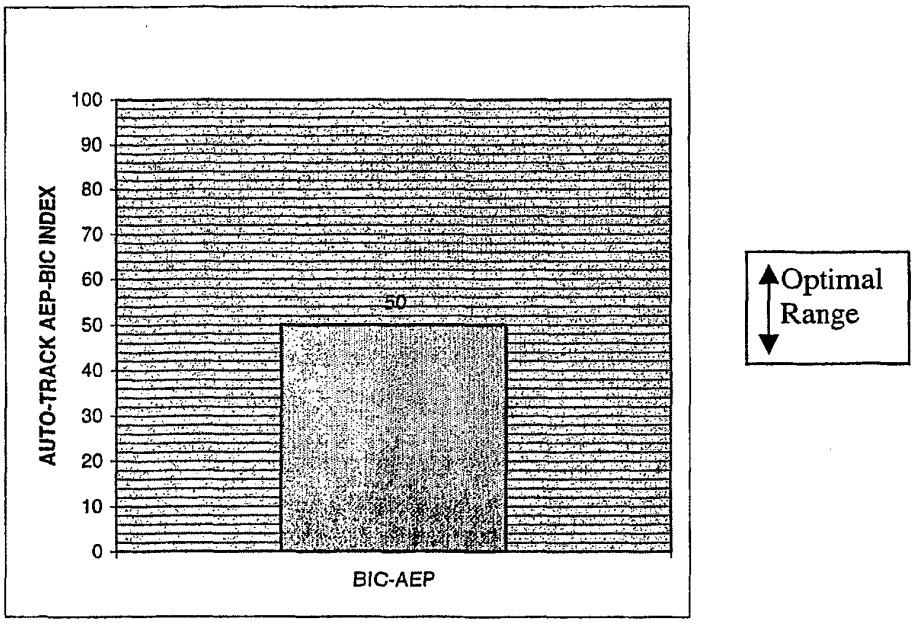


FIG 22e

FIG 22f



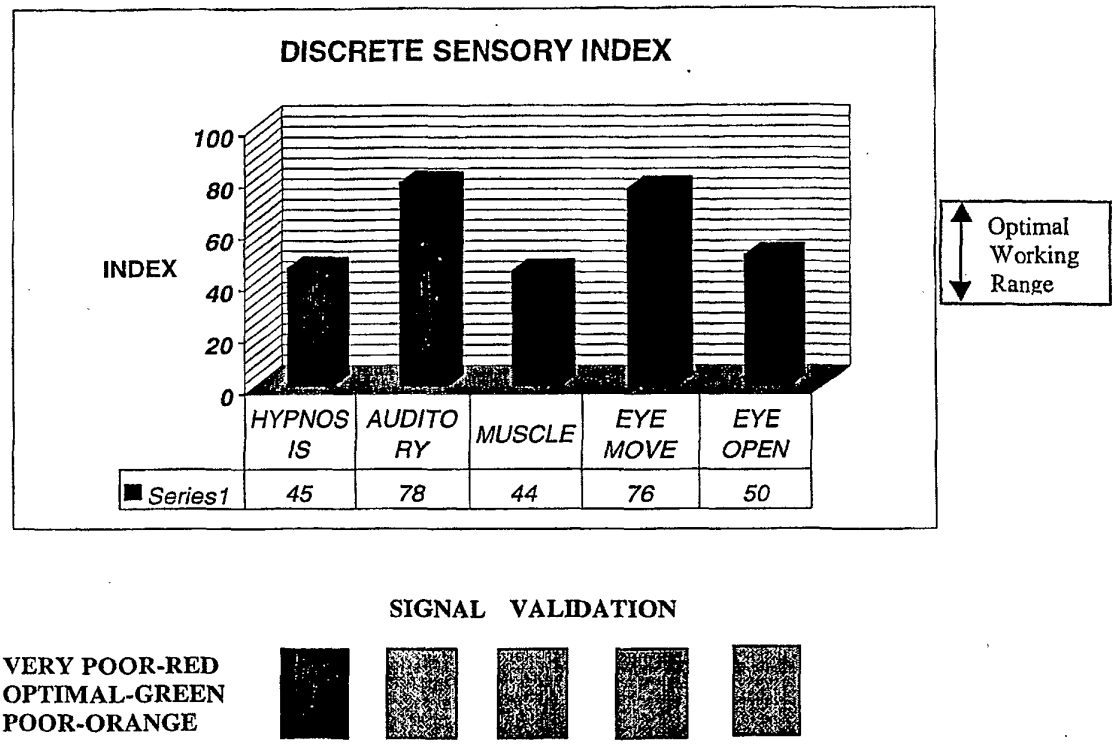




VALUE

HIGH-RED
OPTIMAL-GREEN
LOW-ORANGE

FIG 23A



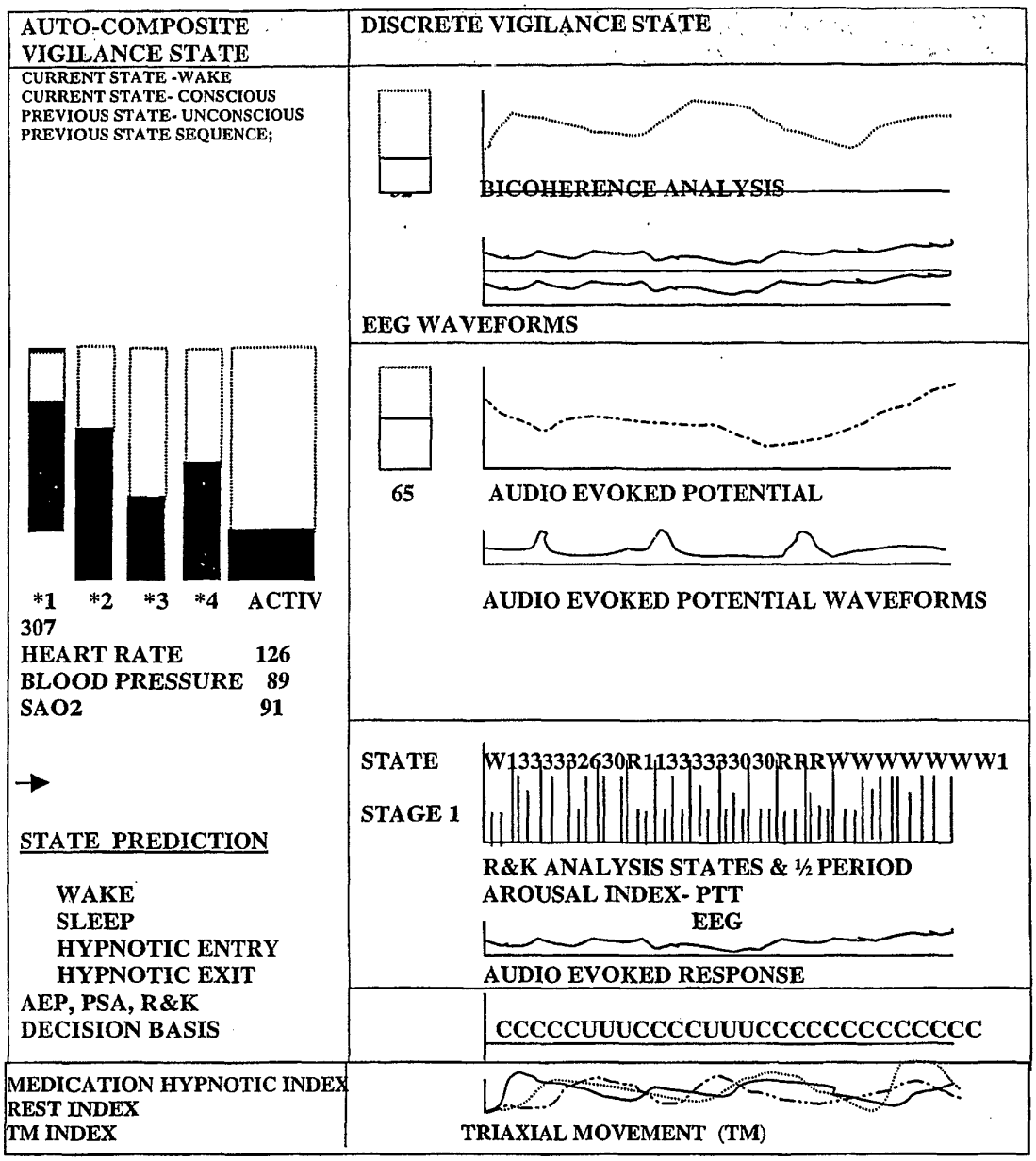
SIGNAL VALIDATION

VERY POOR-RED
OPTIMAL-GREEN
POOR-ORANGE

CURRENTCONSCIOUS STATE-	CONSCIOUS
TRANSITION STATUS-	CONSCIOUS TO UNCONSCIOUS

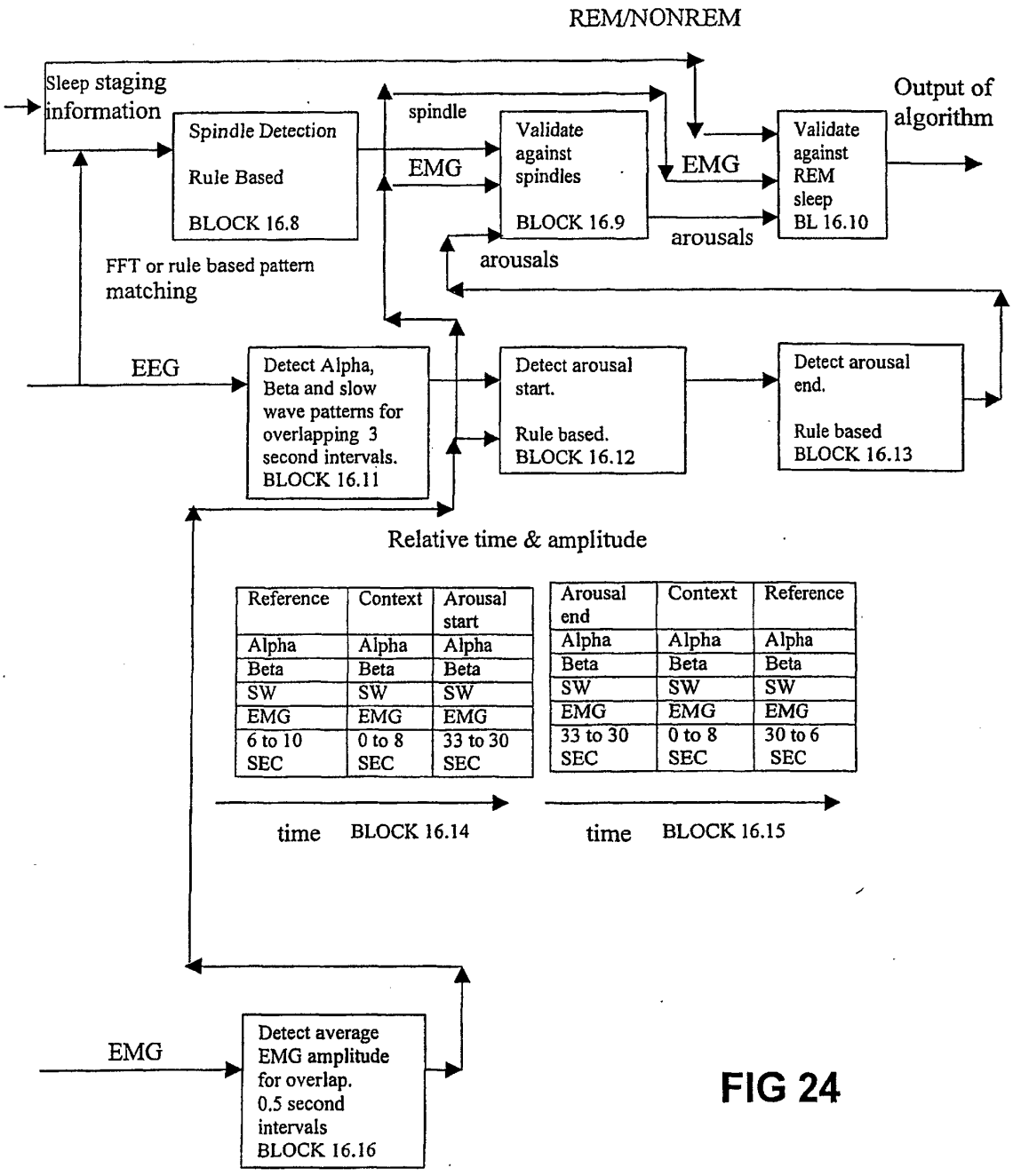
SIGNAL VALIDATION HINT	: CHECK BIC + ELECTRODE
ANALYSIS VALIDATION HINT	: BIC ANALYSIS LOW QUALITY

FIG 23B



KEY;
1 = STAGE 1
2 = STAGE 2
3 = STAGE 3
4 = STAGE 4, R = REM
W = WAKE
C = CONSCIOUS, U= UNCONSCOIOUS

FIG 23C

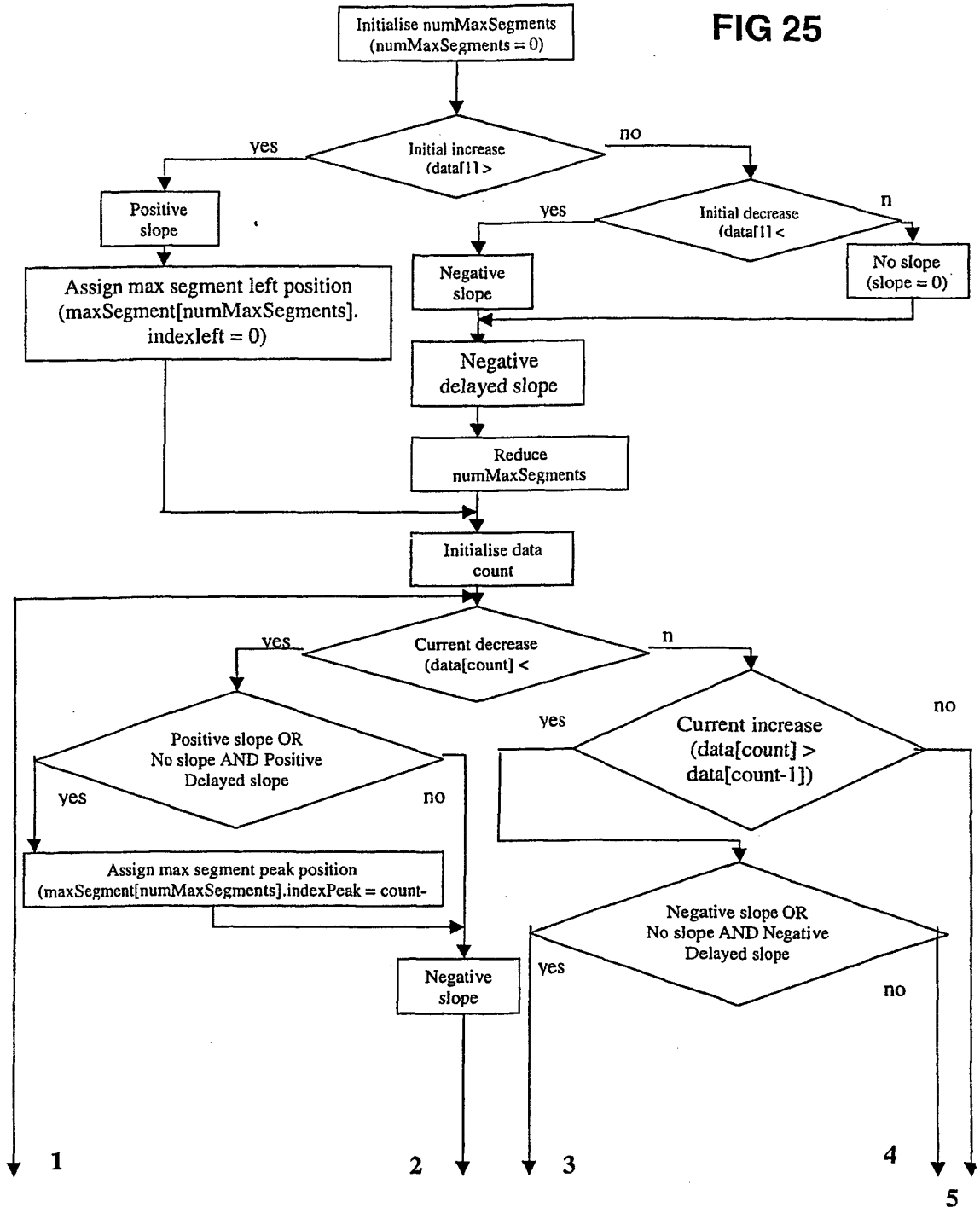


Reference	Context	Arousal start
Alpha	Alpha	Alpha
Beta	Beta	Beta
SW	SW	SW
EMG	EMG	EMG
6 to 10 SEC	0 to 8 SEC	33 to 30 SEC

Arousal end	Context	Reference
Alpha	Alpha	Alpha
Beta	Beta	Beta
SW	SW	SW
EMG	EMG	EMG
33 to 30 SEC	0 to 8 SEC	30 to 6 SEC

FIG 24

FIG 25


Initialise numMaxSegments (numMaxSegments = 0)
Initial increase (data[1] >
yes
no
Positive slope
Initial decrease (data[1] <
yes
n
Negative slope
No slope (slope = 0)
Assign max segment left position (maxSegment[numMaxSegments]. indexleft = 0)
Negative delayed slope
Reduce numMaxSegments
Initialise data count
Current decrease (data[count] <
yes
n
Positive slope OR No slope AND Positive Delayed slope
yes
no
Current increase (data[count] > data[count-1])
yes
no
Assign max segment peak position (maxSegment[numMaxSegments].indexPeak = count-
Negative slope OR No slope AND Negative Delayed slope
yes
no
Negative slope
1
2
3
4
5

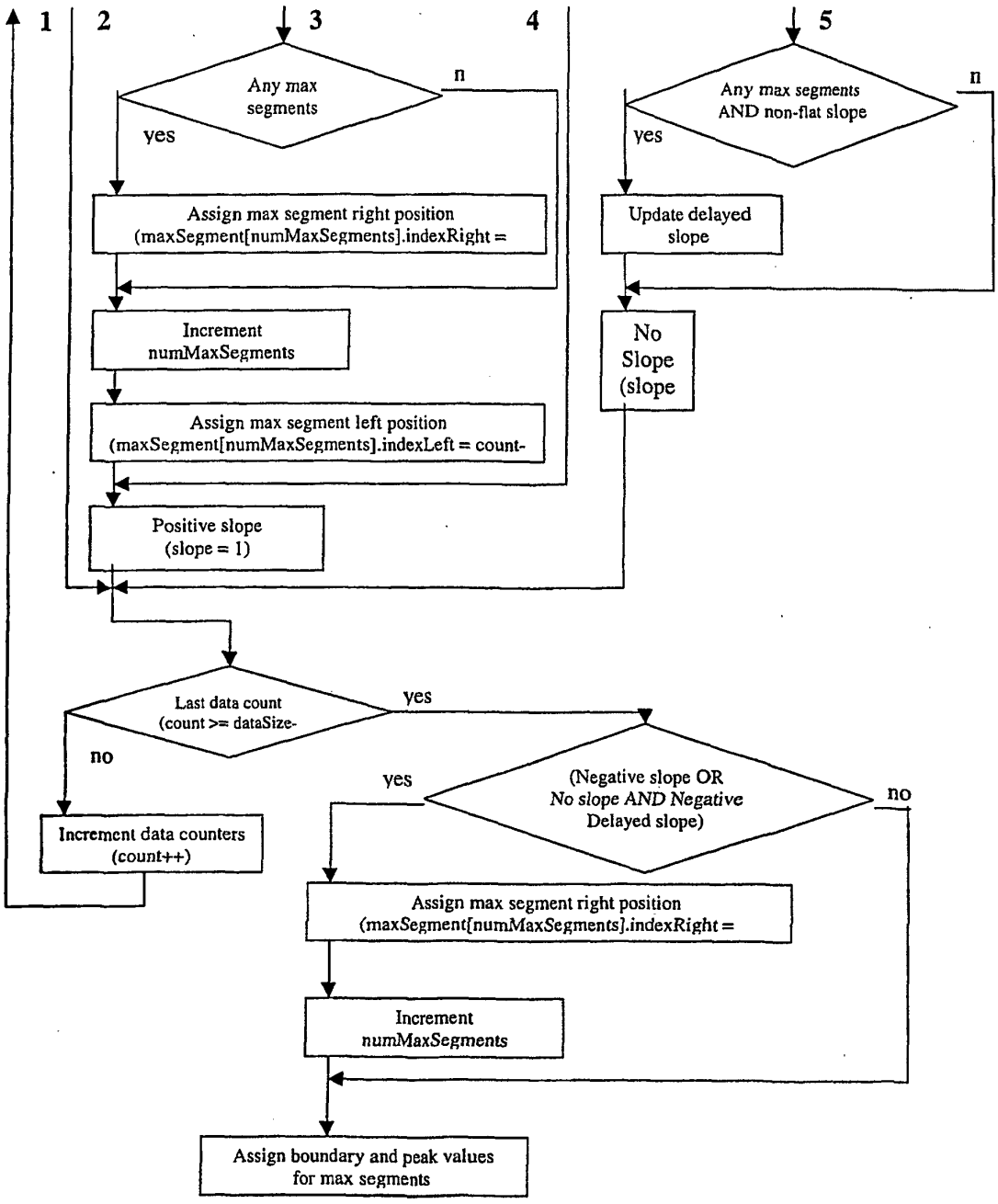
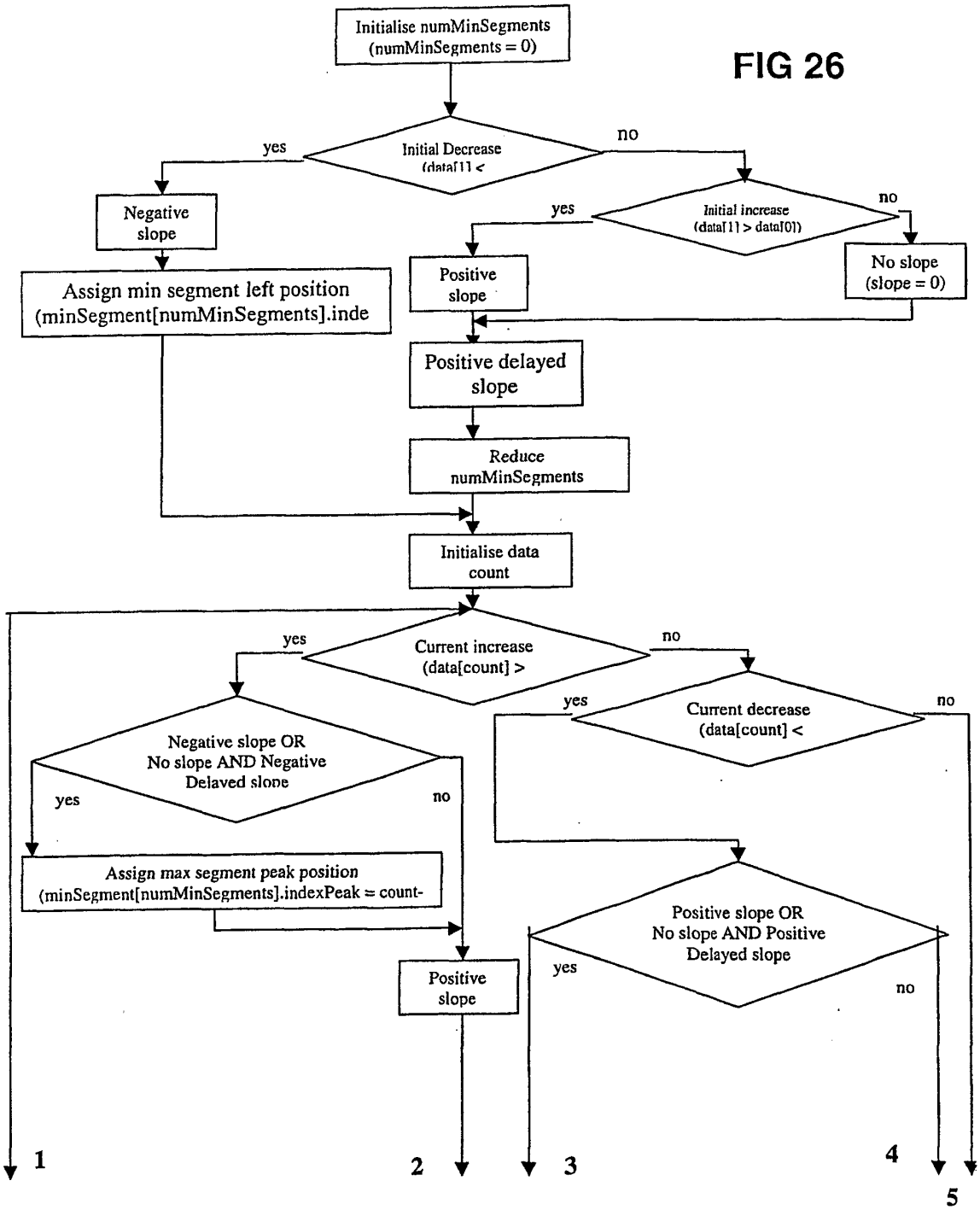

1
2
3
4
5
Any max segments
n
yes
Assign max segment right position (maxSegment[numMaxSegments].indexRight =
Increment numMaxSegments
Assign max segment left position (maxSegment[numMaxSegments].indexLeft = count-
Positive slope (slope = 1)
Any max segments AND non-flat slope
n
yes
Update delayed slope
No Slope (slope
Last data count (count >= dataSize-
yes
no
Increment data counters (count++)
yes
(Negative slope OR No slope AND Negative Delayed slope)
no
Assign max segment right position (maxSegment[numMaxSegments].indexRight =
Increment numMaxSegments
Assign boundary and peak values for max segments

FIG 25 (cont)

FIG 26


Initialise numMinSegments
(numMinSegments = 0)
Initial Decrease
(data[1] <
yes
no
Negative
slope
Initial increase
(data[1] > data[0])
yes
no
Positive
slope
No slope
(slope = 0)
Assign min segment left position
(minSegment[numMinSegments].inde
Positive delayed
slope
Reduce
numMinSegments
Initialise data
count
Current increase
(data[count] >
yes
no
Negative slope OR
No slope AND Negative
Delaved slope
yes
no
Current decrease
(data[count] <
yes
no
Assign max segment peak position
(minSegment[numMinSegments].indexPeak = count-
Positive slope OR
No slope AND Positive
Delayed slope
yes
no
Positive
slope
1
2
3
4
5

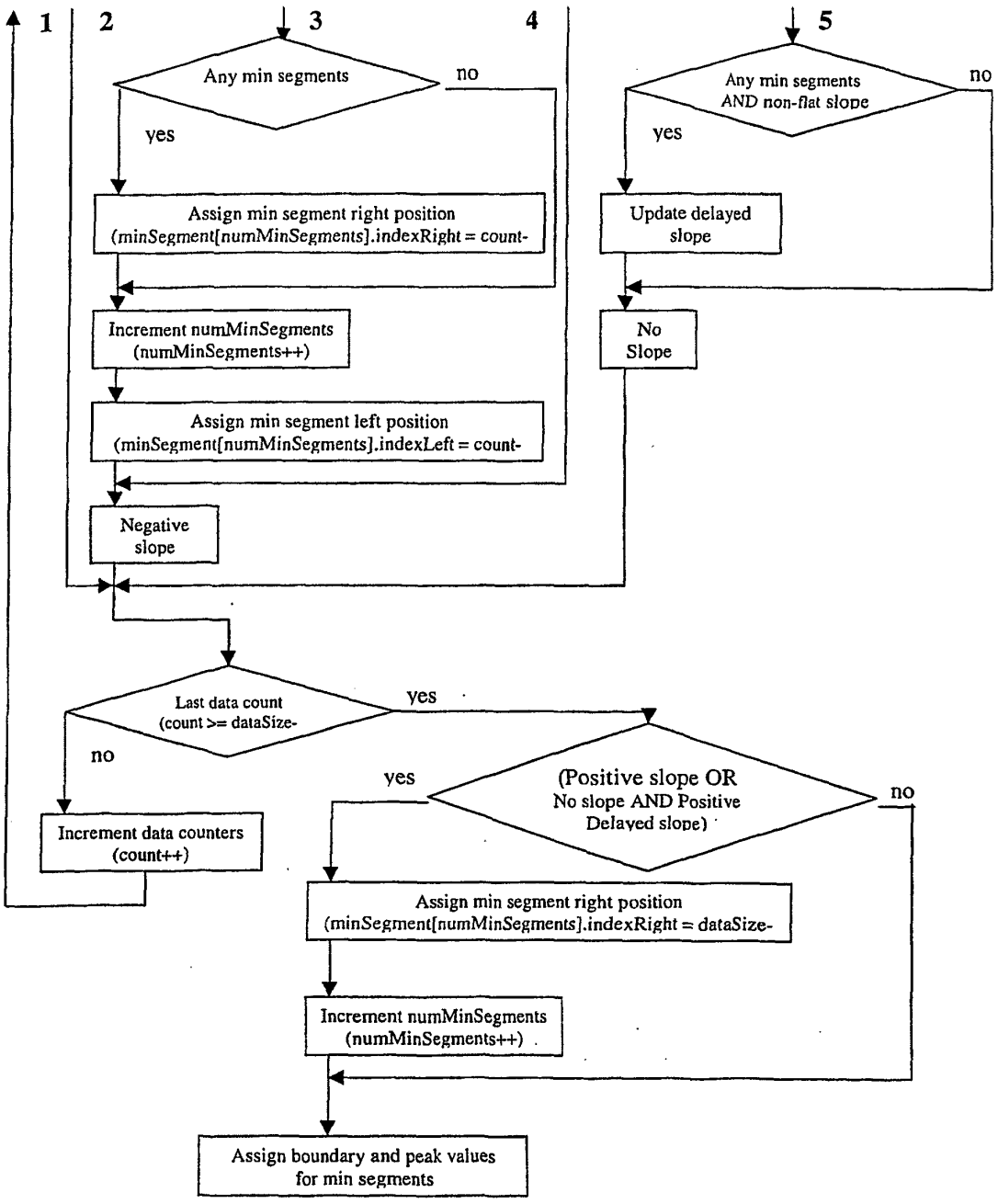

1
2
3
4
5
Any min segments
no
yes
Assign min segment right position
(minSegment[numMinSegments].indexRight = count-
Increment numMinSegments
(numMinSegments++)
Assign min segment left position
(minSegment[numMinSegments].indexLeft = count-
Negative
slope
Any min segments
AND non-flat slope
no
yes
Update delayed
slope
No
Slope
Last data count
(count >= dataSize-
yes
no
Increment data counters
(count++)
yes
(Positive slope OR
No slope AND Positive
Delayed slope)
no
Assign min segment right position
(minSegment[numMinSegments].indexRight = dataSize-
Increment numMinSegments
(numMinSegments++)
Assign boundary and peak values
for min segments

FIG 26 (cont)

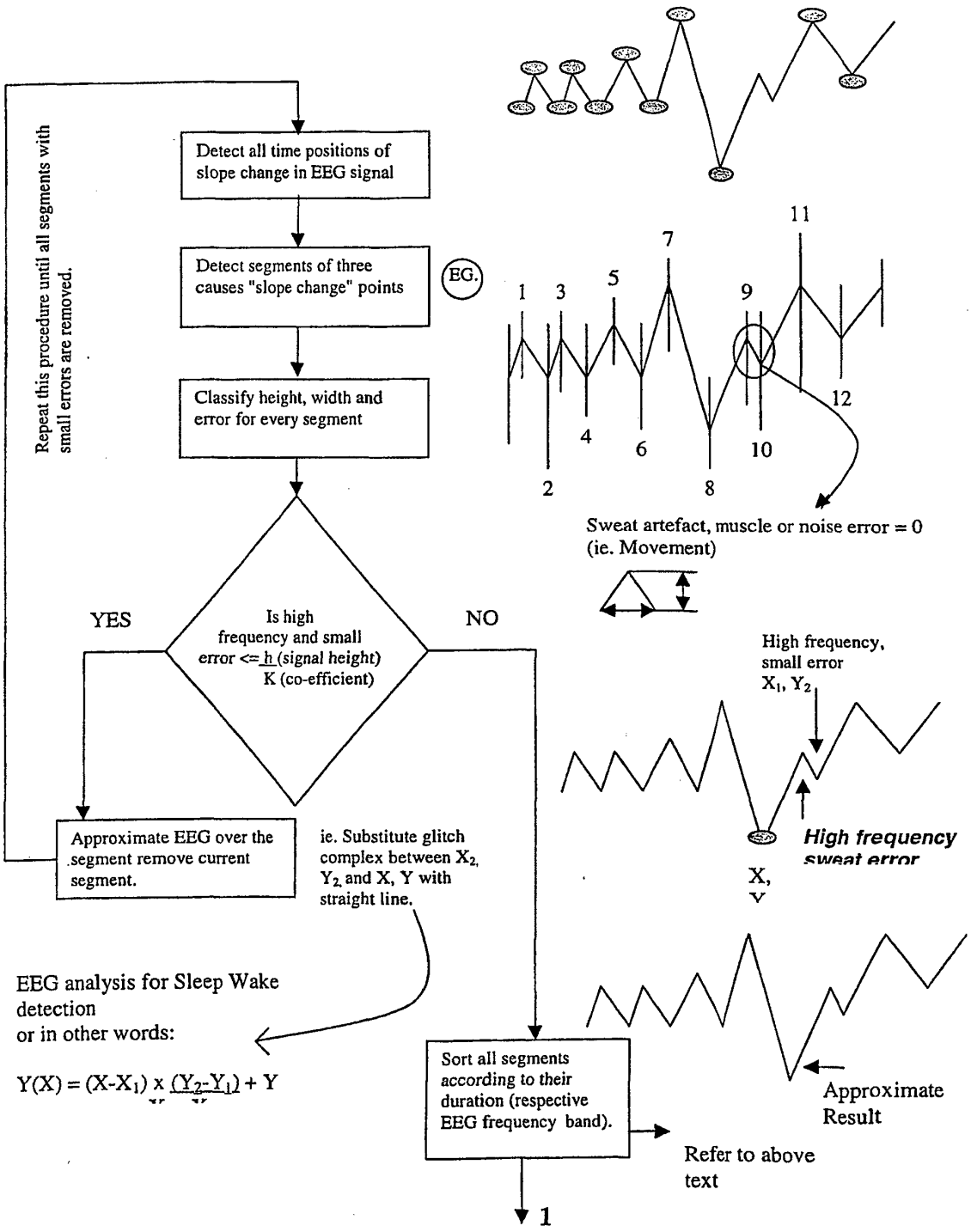
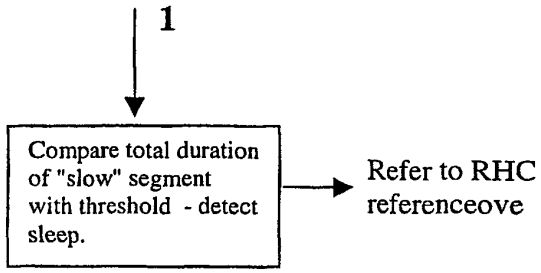

Repeat this procedure until all segments with small errors are removed.
Detect all time positions of slope change in EEG signal
Detect segments of three causes "slope change" points
EG.
Classify height, width and error for every segment
Is high frequency and small error <= h (signal height) K (co-efficient)
YES
NO
Approximate EEG over the segment remove current segment.
ie. Substitute glitch complex between X2, Y2, and X, Y with straight line.
EEG analysis for Sleep Wake detection
or in other words:
Y(X) = (X-X1) x (Y2-Y1) + Y
Sort all segments according to their duration (respective EEG frequency band).
1
1 3 5 7 9 11
2 4 6 8 10 12
Sweat artefact, muscle or noise error = 0
(ie. Movement)
High frequency, small error
X1, Y2
High frequency sweat error
X, Y
Approximate Result
Refer to above text

FIG 27



EG. Note 1. we do not apply glitch element sleep analysis is corrupted due to excessive fast frequency noise or artefact signal corruption (this fast frequency artefact can be created by generation of muscle movement)

Note 2.

IE. Instead of this example being interpreted as alpha it may (due to glitch) be interpreted as beta and generate errors in sleep state assessment.

FIG 27 (cont)

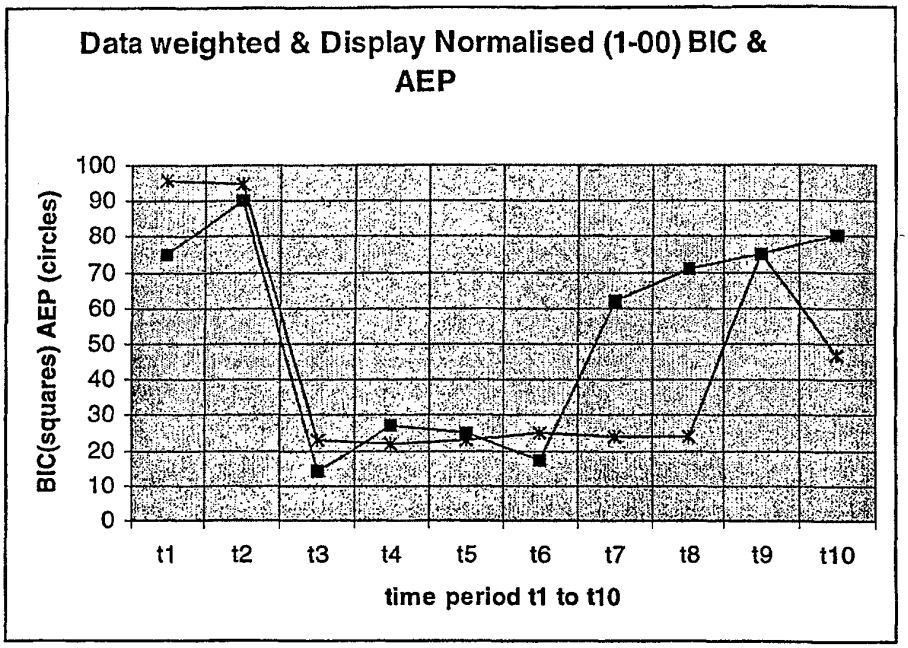

Data weighted & Display Normalised (1-00) BIC & AEP
BIC(squares) AEP (circles)
100
90
80
70
60
50
40
30
20
10
0
t1
t2
t3
t4
t5
t6
t7
t8
t9
t10
time period t1 to t10

FIG 28

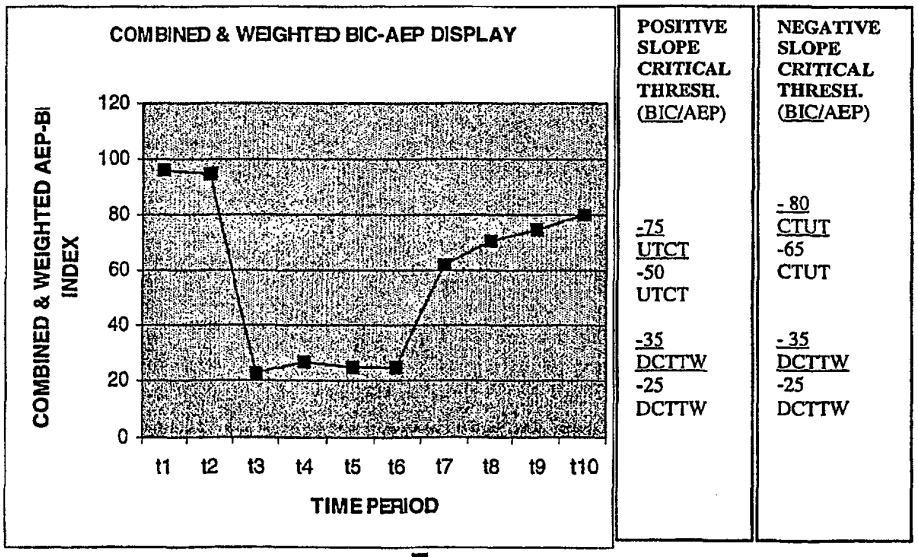

COMBINED & WEIGHTED BIC-AEP DISPLAY
COMBINED & WEIGHTED AEP-BI INDEX
120
100
80
60
40
20
0
t1
t2
t3
t4
t5
t6
t7
t8
t9
t10
TIME PERIOD
POSITIVE SLOPE CRITICAL THRESH. (BIC/AEP)
-75 UTCT
-50 UTCT
-35 DCTTW
-25 DCTTW
NEGATIVE SLOPE CRITICAL THRESH. (BIC/AEP)
- 80 CTUT
-65 CTUT
- 35 DCTTW
-25 DCTTW
STATE- UNCONSCIOUS
WARNINGS- NONE

FIG 29

Input data for S=1, S=2, S=3 .....S=n-1, S=n

Input Analysis Type	S=1 input data
1	26
2	79
3	89
4	56
5	33

Output Data

89

FIG 30A

Input Analysis Type	S=1 input data
1	26
2	33
3	78
4	57
5	30

78

Where S = data sample
S1= data sample 1
Where n= total number of data samples

FIG 30B

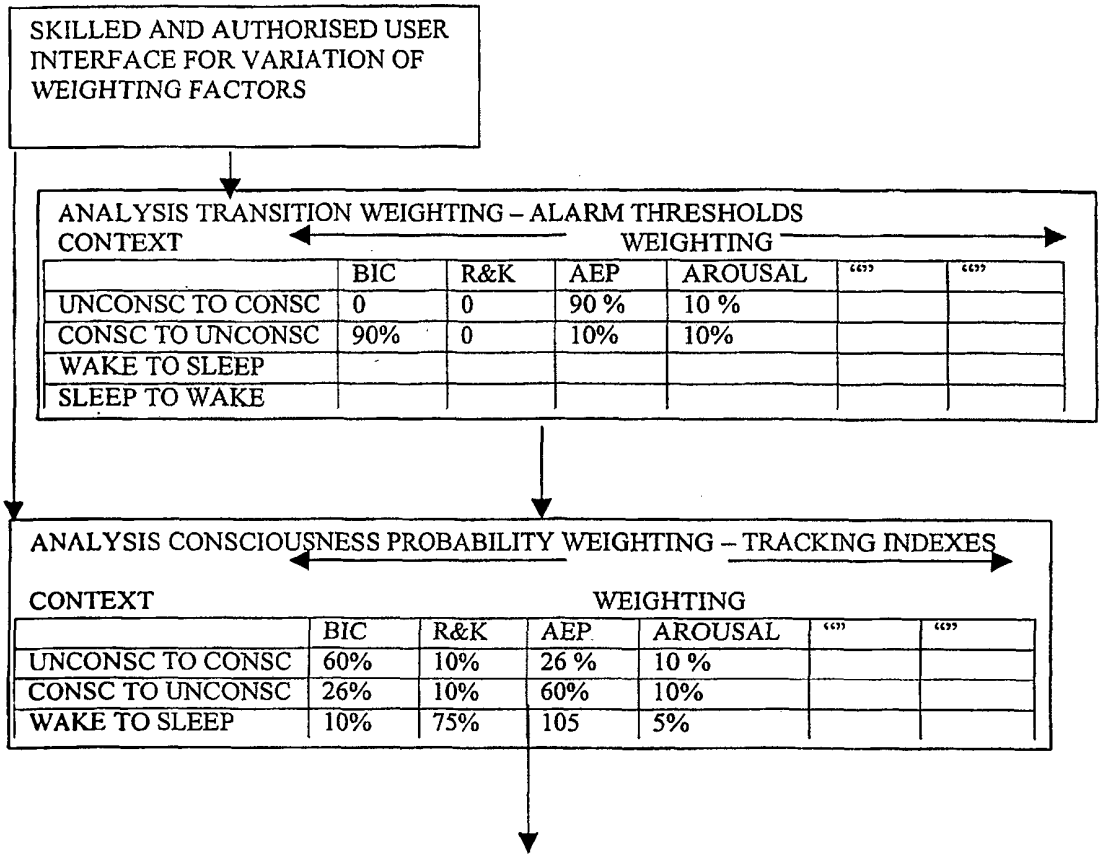

SKILLED AND AUTHORISED USER INTERFACE FOR VARIATION OF WEIGHTING FACTORS
ANALYSIS TRANSITION WEIGHTING – ALARM THRESHOLDS
CONTEXT
WEIGHTING
BIC R&K AEP AROUSAL "" ""
UNCONSC TO CONSC 0 0 90 % 10 %
CONSC TO UNCONSC 90% 0 10% 10%
WAKE TO SLEEP
SLEEP TO WAKE
ANALYSIS CONSCIOUSNESS PROBABILITY WEIGHTING – TRACKING INDEXES
CONTEXT
WEIGHTING
BIC R&K AEP AROUSAL "" ""
UNCONSC TO CONSC 60% 10% 26 % 10 %
CONSC TO UNCONSC 26% 10% 60% 10%
WAKE TO SLEEP 10% 75% 105 5%

FIG 31

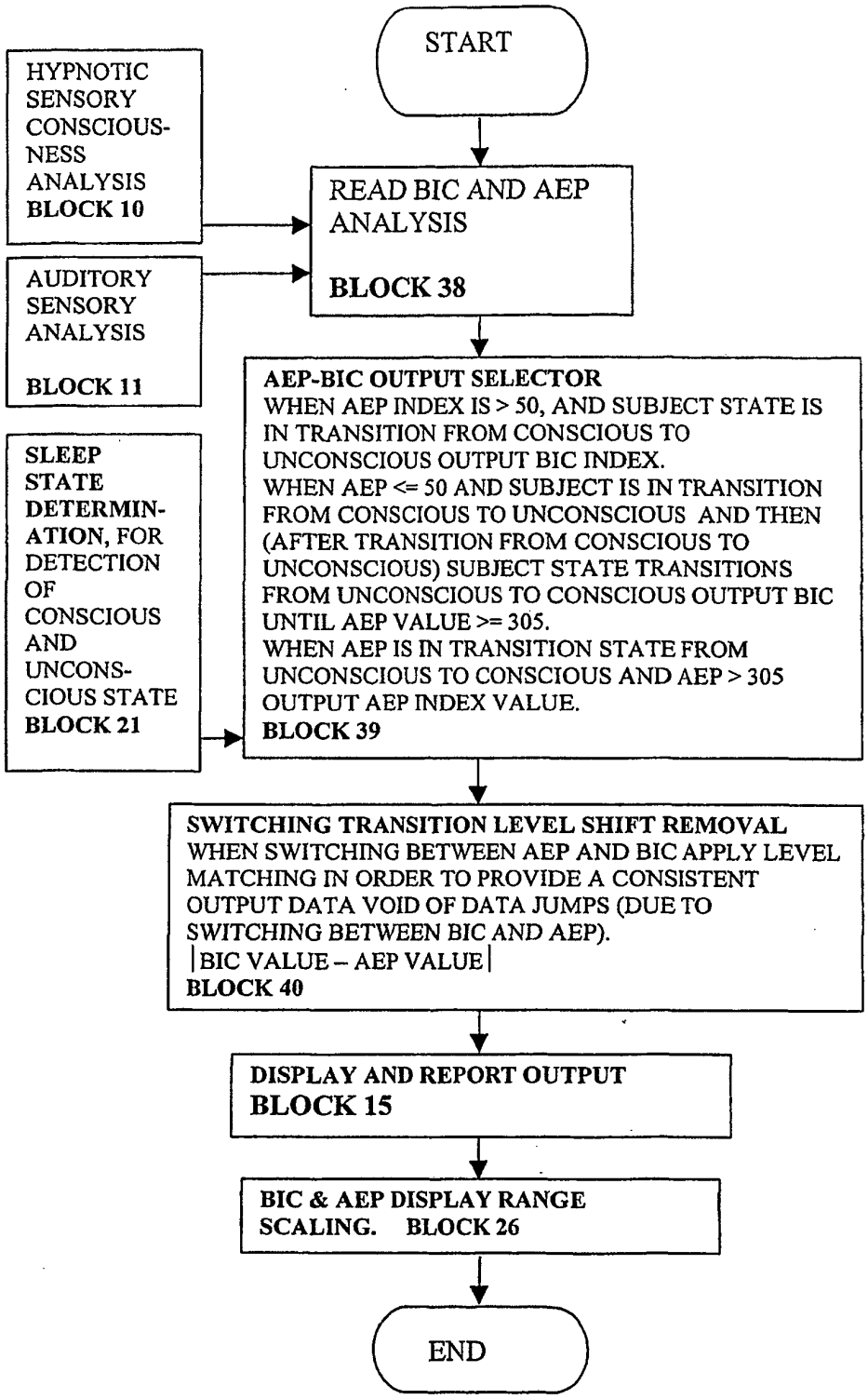

START
HYPNOTIC SENSORY CONSCIOUS-NESS ANALYSIS BLOCK 10
AUDITORY SENSORY ANALYSIS BLOCK 11
SLEEP STATE DETERMIN-ATION, FOR DETECTION OF CONSCIOUS AND UNCONS-CIOUS STATE BLOCK 21
READ BIC AND AEP ANALYSIS BLOCK 38
AEP-BIC OUTPUT SELECTOR
WHEN AEP INDEX IS > 50, AND SUBJECT STATE IS IN TRANSITION FROM CONSCIOUS TO UNCONSCIOUS OUTPUT BIC INDEX.
WHEN AEP <= 50 AND SUBJECT IS IN TRANSITION FROM CONSCIOUS TO UNCONSCIOUS AND THEN (AFTER TRANSITION FROM CONSCIOUS TO UNCONSCIOUS) SUBJECT STATE TRANSITIONS FROM UNCONSCIOUS TO CONSCIOUS OUTPUT BIC UNTIL AEP VALUE >= 305.
WHEN AEP IS IN TRANSITION STATE FROM UNCONSCIOUS TO CONSCIOUS AND AEP > 305 OUTPUT AEP INDEX VALUE.
BLOCK 39
SWITCHING TRANSITION LEVEL SHIFT REMOVAL
WHEN SWITCHING BETWEEN AEP AND BIC APPLY LEVEL MATCHING IN ORDER TO PROVIDE A CONSISTENT OUTPUT DATA VOID OF DATA JUMPS (DUE TO SWITCHING BETWEEN BIC AND AEP).
|BIC VALUE – AEP VALUE|
BLOCK 40
DISPLAY AND REPORT OUTPUT BLOCK 15
BIC & AEP DISPLAY RANGE SCALING. BLOCK 26
END

FIG 32

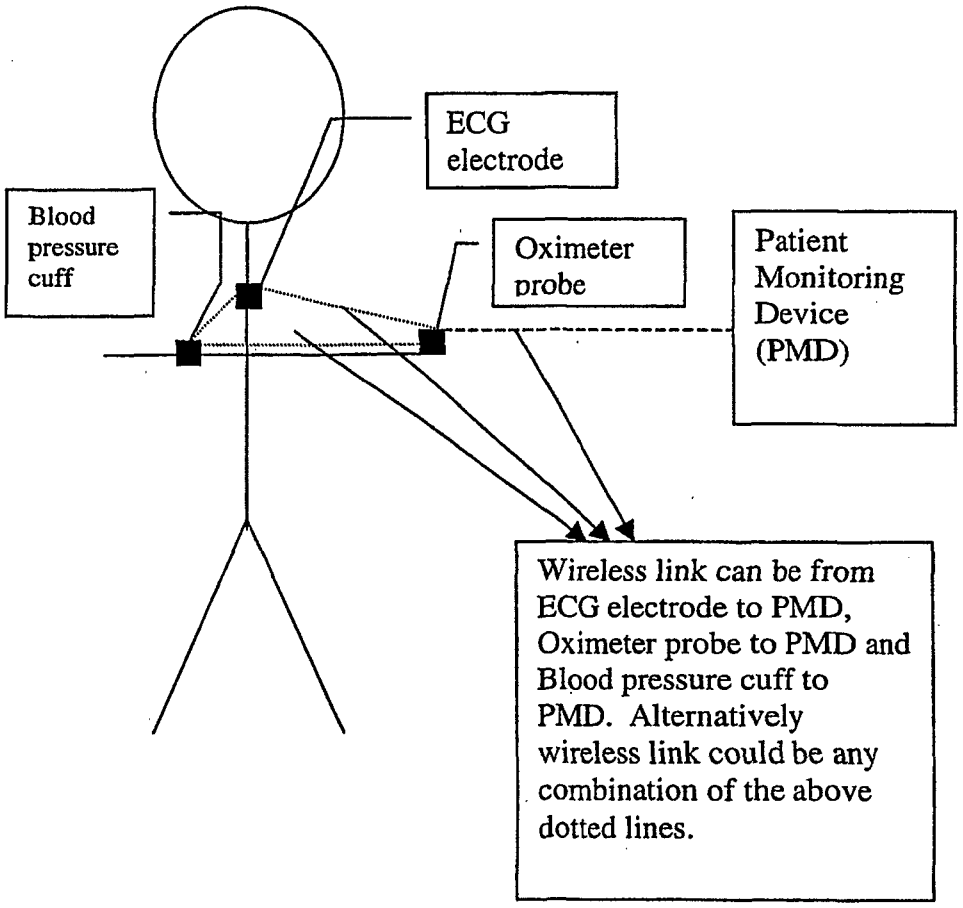

ECG electrode
Blood pressure cuff
Oximeter probe
Patient Monitoring Device (PMD)
Wireless link can be from ECG electrode to PMD, Oximeter probe to PMD and Blood pressure cuff to PMD. Alternatively wireless link could be any combination of the above dotted lines.

FIG 33

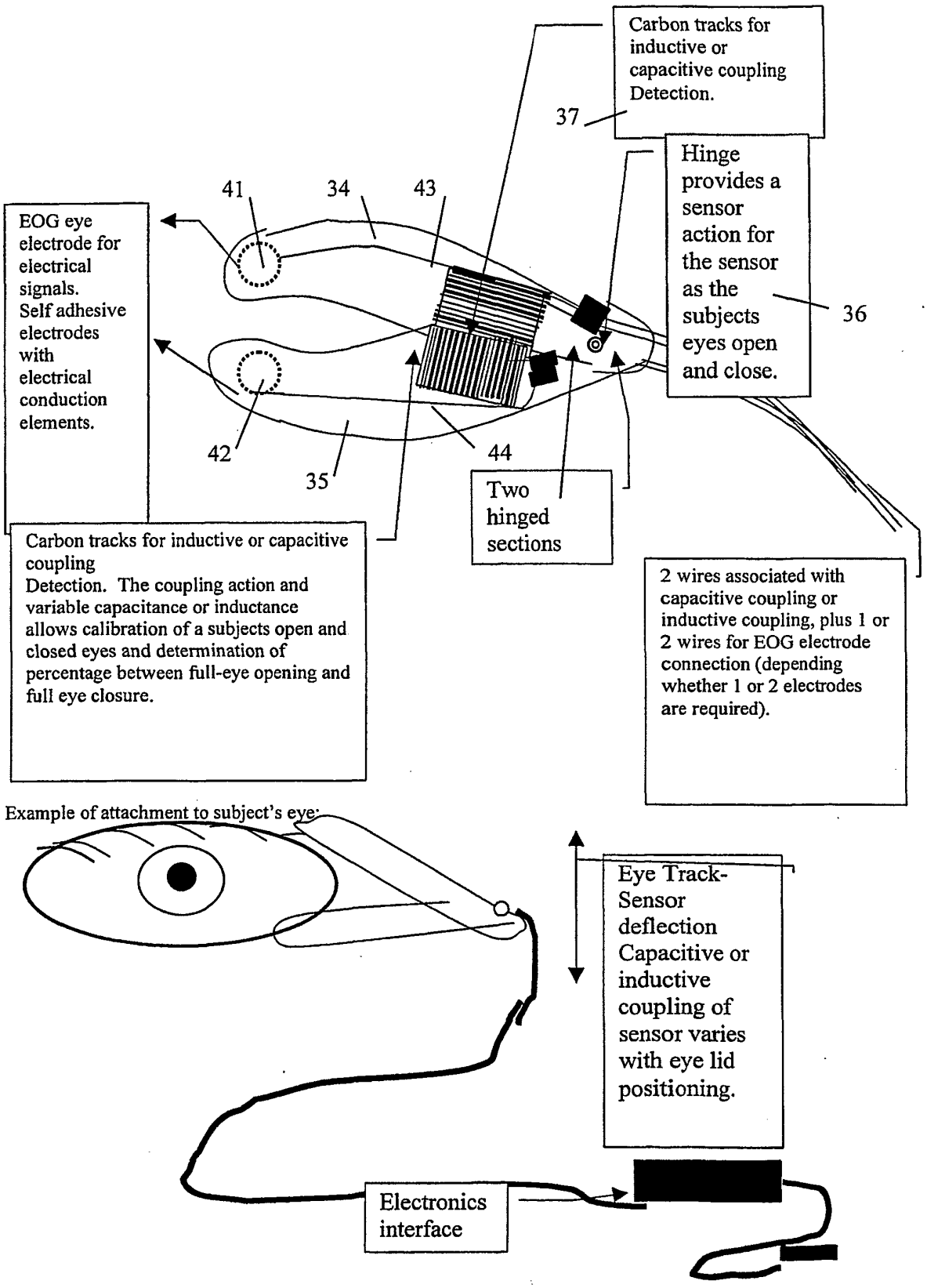

Carbon tracks for inductive or capacitive coupling Detection.
37
Hinge provides a sensor action for the sensor as the subjects eyes open and close.
36
41
34
43
EOG eye electrode for electrical signals. Self adhesive electrodes with electrical conduction elements.
42
35
44
Two hinged sections
Carbon tracks for inductive or capacitive coupling
Detection. The coupling action and variable capacitance or inductance allows calibration of a subjects open and closed eyes and determination of percentage between full-eye opening and full eye closure.
2 wires associated with capacitive coupling or inductive coupling, plus 1 or 2 wires for EOG electrode connection (depending whether 1 or 2 electrodes are required).
Example of attachment to subject's eye
Eye Track-Sensor deflection Capacitive or inductive coupling of sensor varies with eye lid positioning.
Electronics interface

FIG 34A

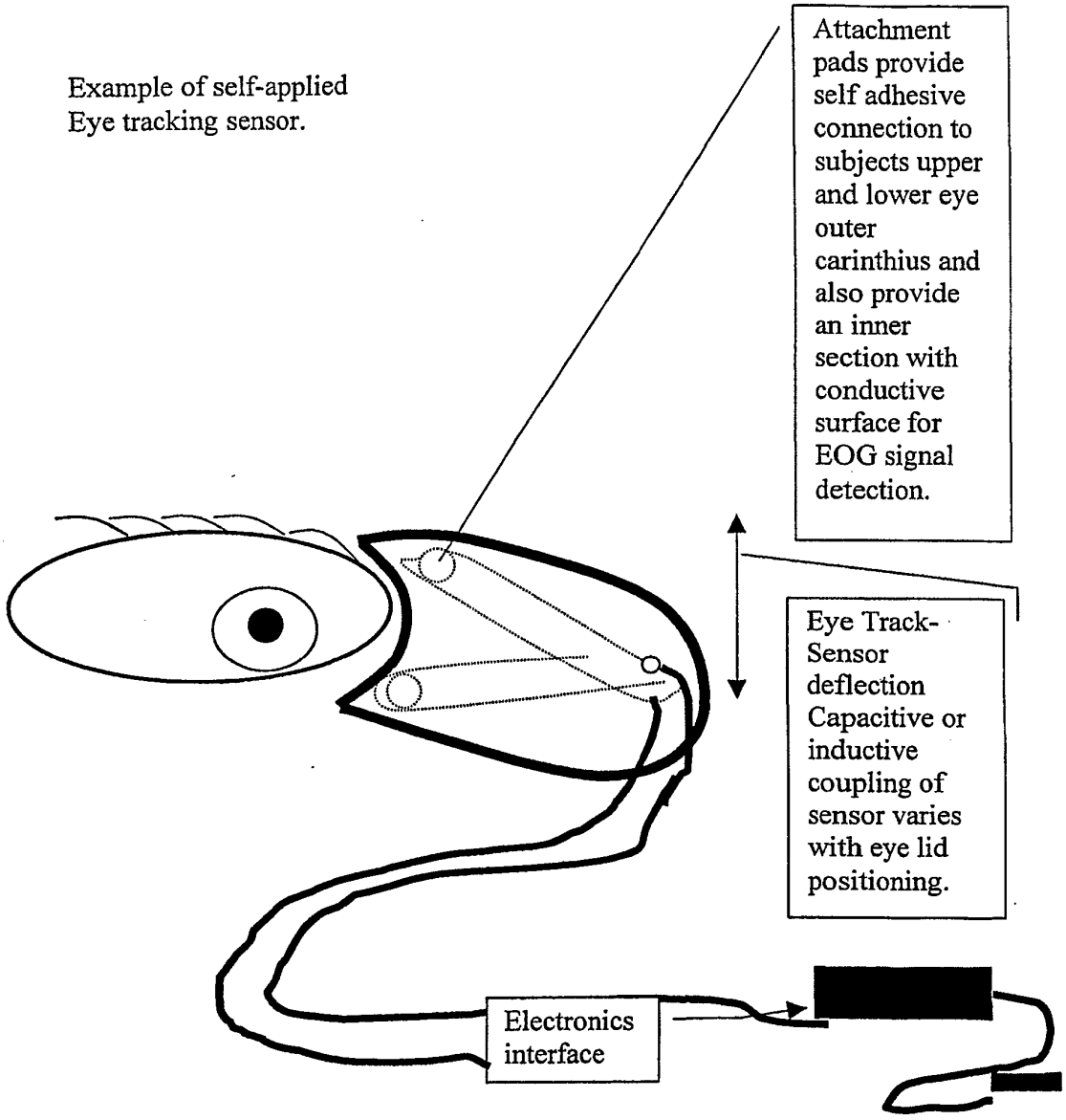

Example of self-applied
Eye tracking sensor.
Attachment pads provide self adhesive connection to subjects upper and lower eye outer carinthius and also provide an inner section with conductive surface for EOG signal detection.
Eye Track-Sensor deflection Capacitive or inductive coupling of sensor varies with eye lid positioning.
Electronics interface

FIG 34A (cont)

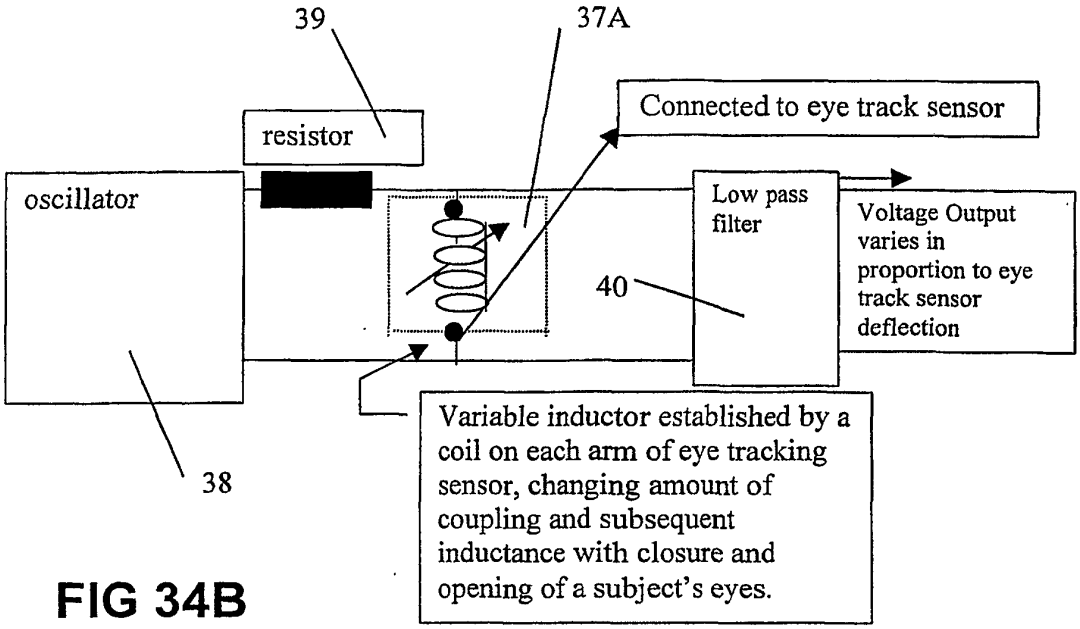


FIG 34B

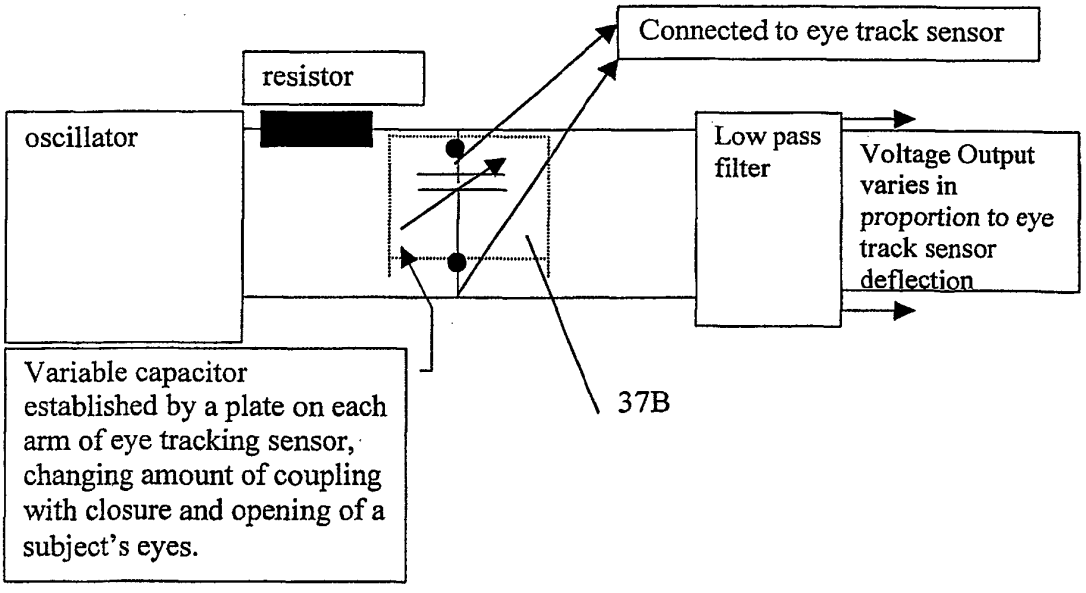


FIG 34C

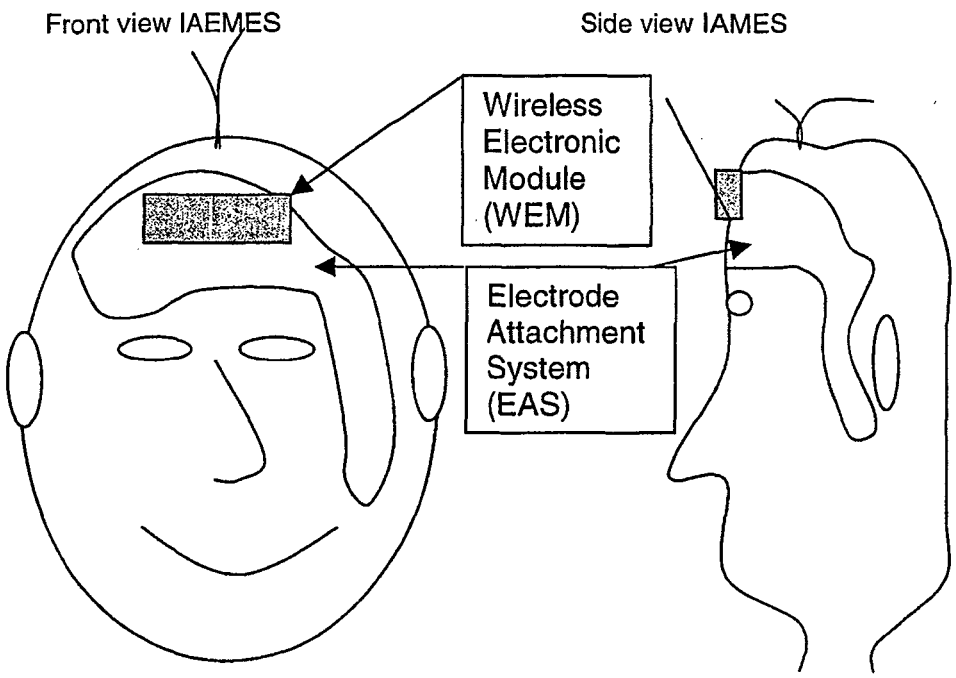

Front view IAEMES
Side view IAMES
Wireless Electronic Module (WEM)
Electrode Attachment System (EAS)

FIG 35

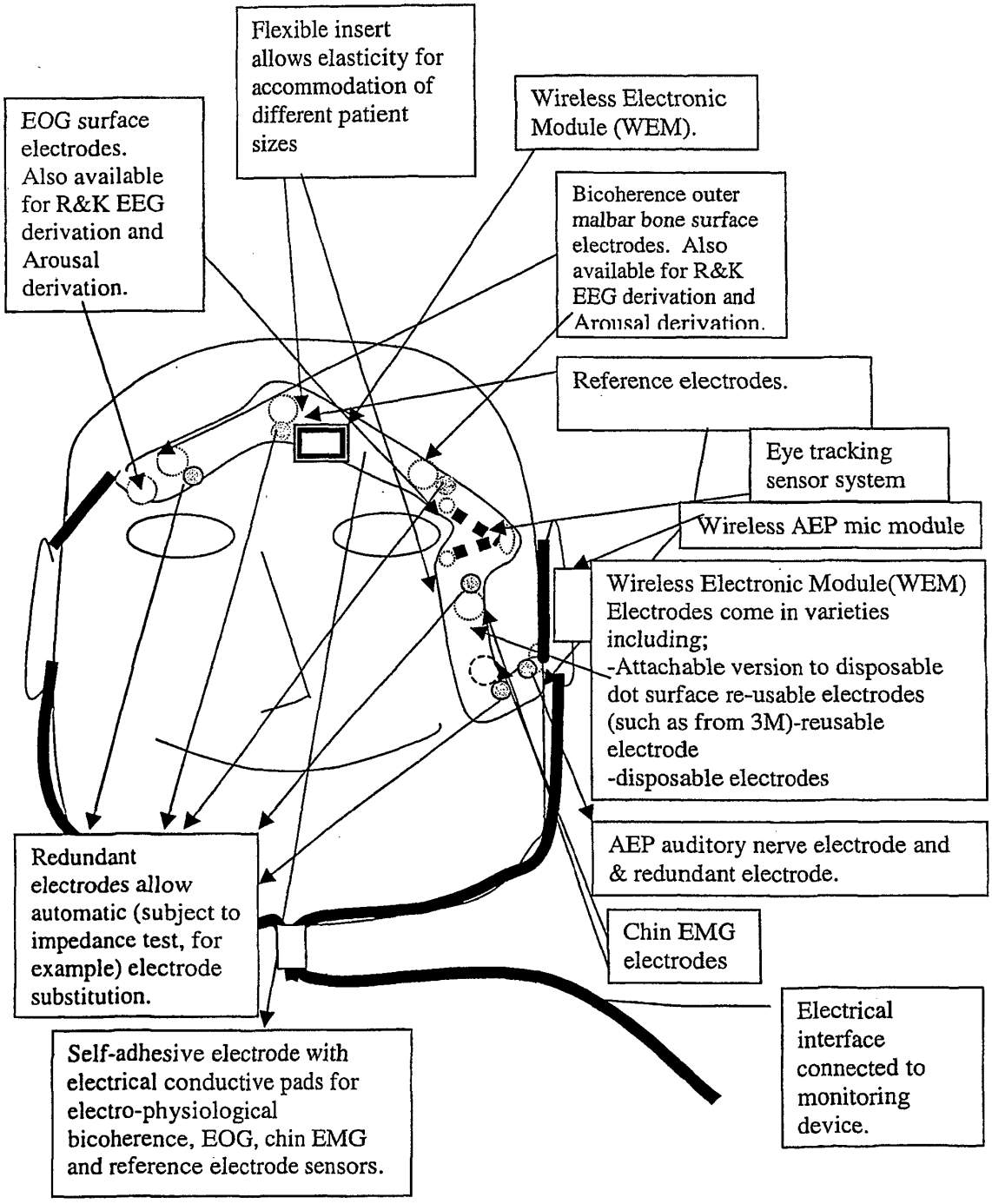

Flexible insert allows elasticity for accommodation of different patient sizes
Wireless Electronic Module (WEM).
EOG surface electrodes. Also available for R&K EEG derivation and Arousal derivation.
Bicoherence outer malbar bone surface electrodes. Also available for R&K EEG derivation and Arousal derivation.
Reference electrodes.
Eye tracking sensor system
Wireless AEP mic module
Wireless Electronic Module(WEM) Electrodes come in varieties including;
-Attachable version to disposable dot surface re-usable electrodes (such as from 3M)-reusable electrode
-disposable electrodes
AEP auditory nerve electrode and & redundant electrode.
Chin EMG electrodes
Electrical interface connected to monitoring device.
Redundant electrodes allow automatic (subject to impedance test, for example) electrode substitution.
Self-adhesive electrode with electrical conductive pads for electro-physiological bicoherence, EOG, chin EMG and reference electrode sensors.

FIG 36

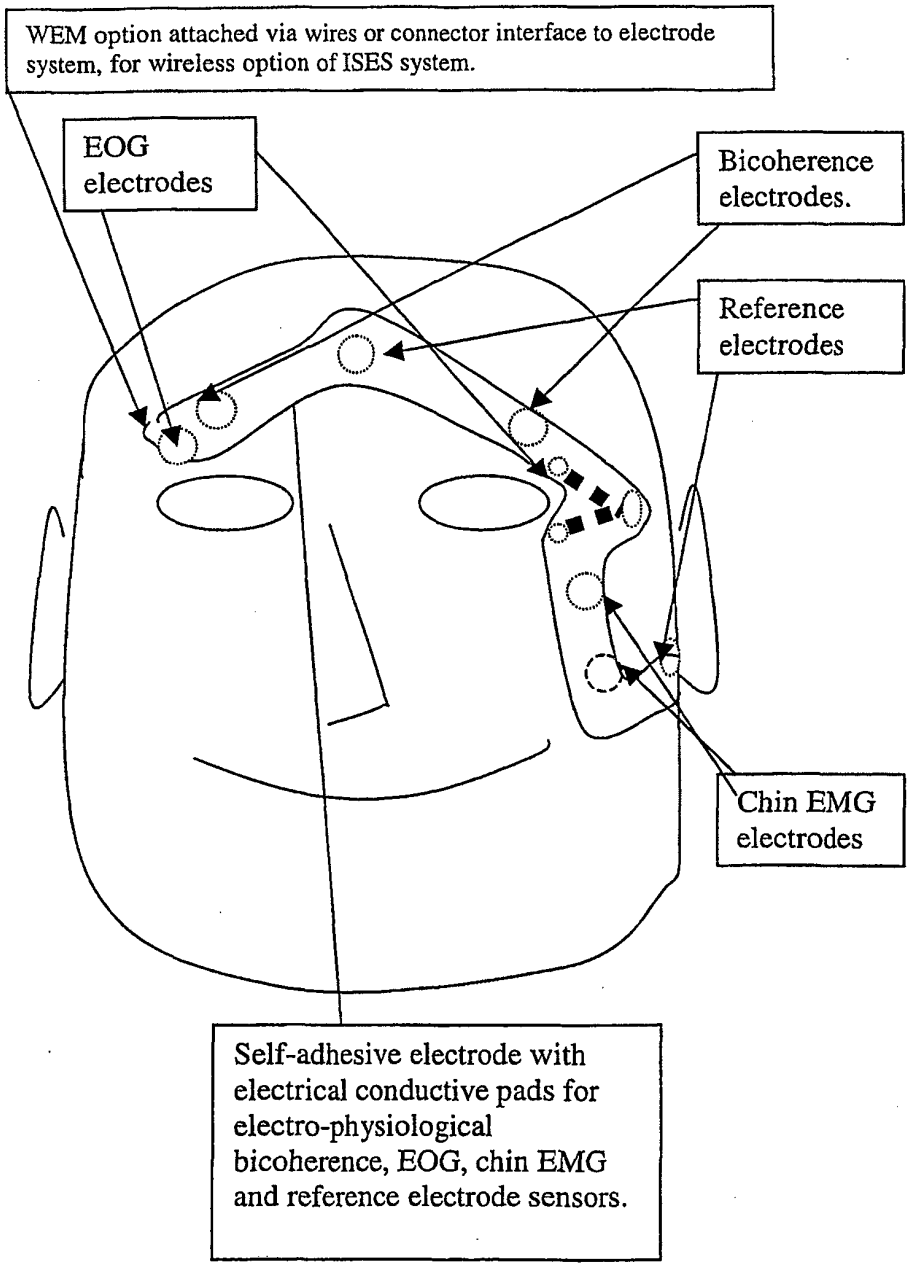

WEM option attached via wires or connector interface to electrode system, for wireless option of ISES system.
EOG electrodes
Bicoherence electrodes.
Reference electrodes
Chin EMG electrodes
Self-adhesive electrode with electrical conductive pads for electro-physiological bicoherence, EOG, chin EMG and reference electrode sensors.

FIG 37

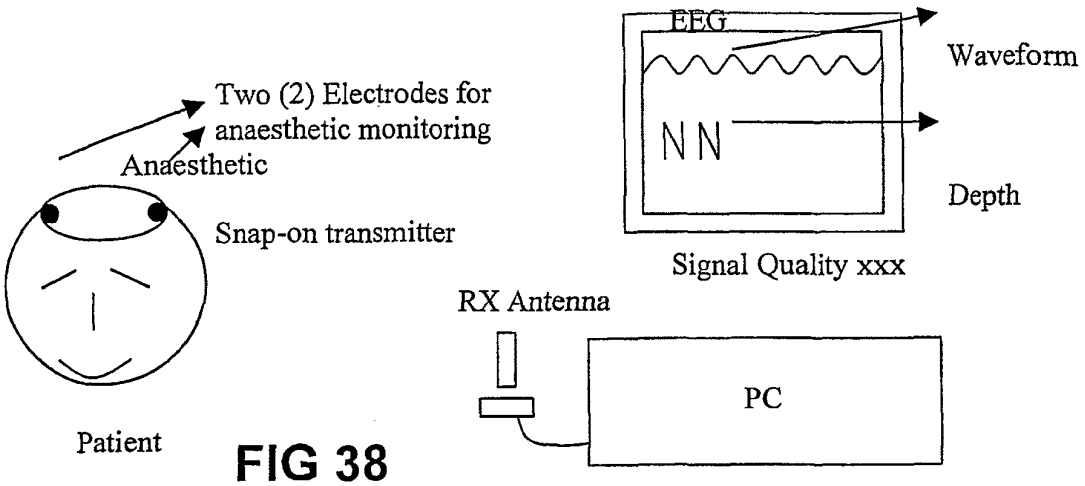

Two (2) Electrodes for anaesthetic monitoring
Anaesthetic
Snap-on transmitter
Patient
EEG
Waveform
NN
Depth
Signal Quality xxx
RX Antenna
PC

FIG 38

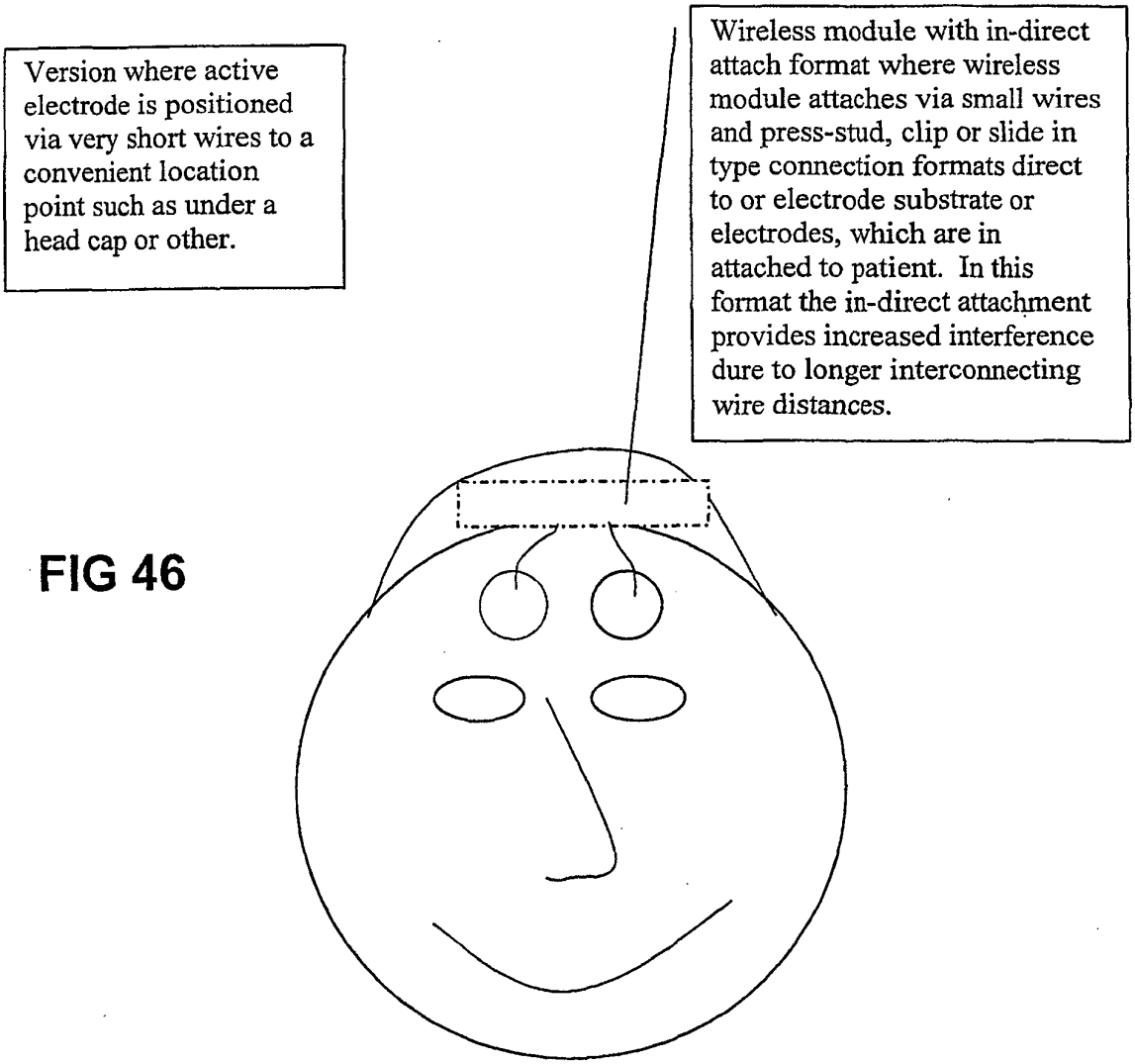

Version where active electrode is positioned via very short wires to a convenient location point such as under a head cap or other.
Wireless module with in-direct attach format where wireless module attaches via small wires and press-stud, clip or slide in type connection formats direct to or electrode substrate or electrodes, which are in attached to patient. In this format the in-direct attachment provides increased interference dure to longer interconnecting wire distances.

FIG 46

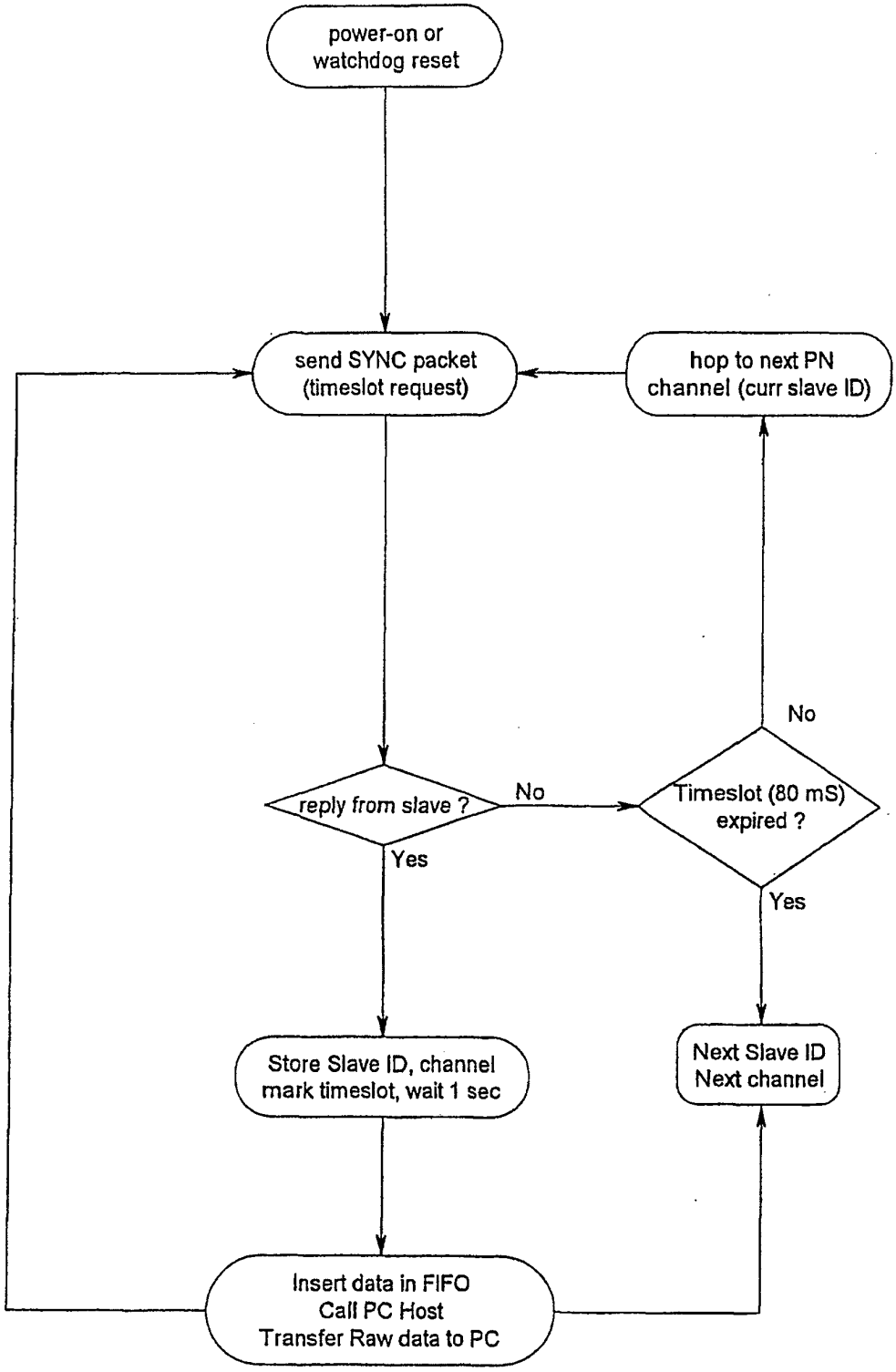

power-on or watchdog reset
send SYNC packet (timeslot request)
hop to next PN channel (curr slave ID)
reply from slave ?
No
Timeslot (80 mS) expired ?
No
Yes
Yes
Store Slave ID, channel mark timeslot, wait 1 sec
Next Slave ID Next channel
Insert data in FIFO Call PC Host Transfer Raw data to PC

FIG 39

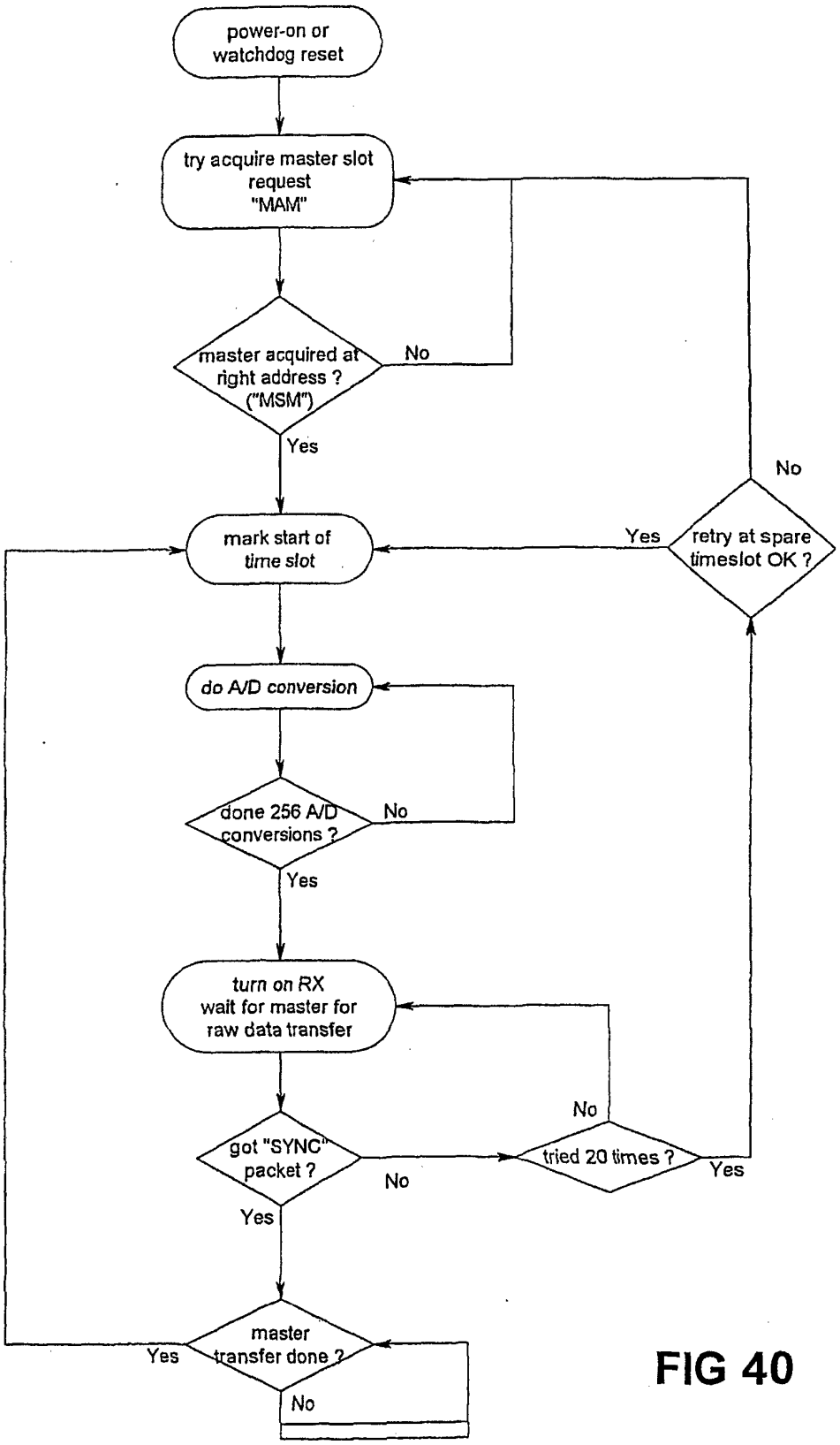

power-on or watchdog reset
try acquire master slot request "MAM"
master acquired at right address ? ("MSM")
No
Yes
mark start of time slot
Yes
retry at spare timeslot OK ?
No
do A/D conversion
done 256 A/D conversions ?
No
Yes
turn on RX wait for master for raw data transfer
got "SYNC" packet ?
No
tried 20 times ?
No
Yes
Yes
master transfer done ?
Yes
No

FIG 40

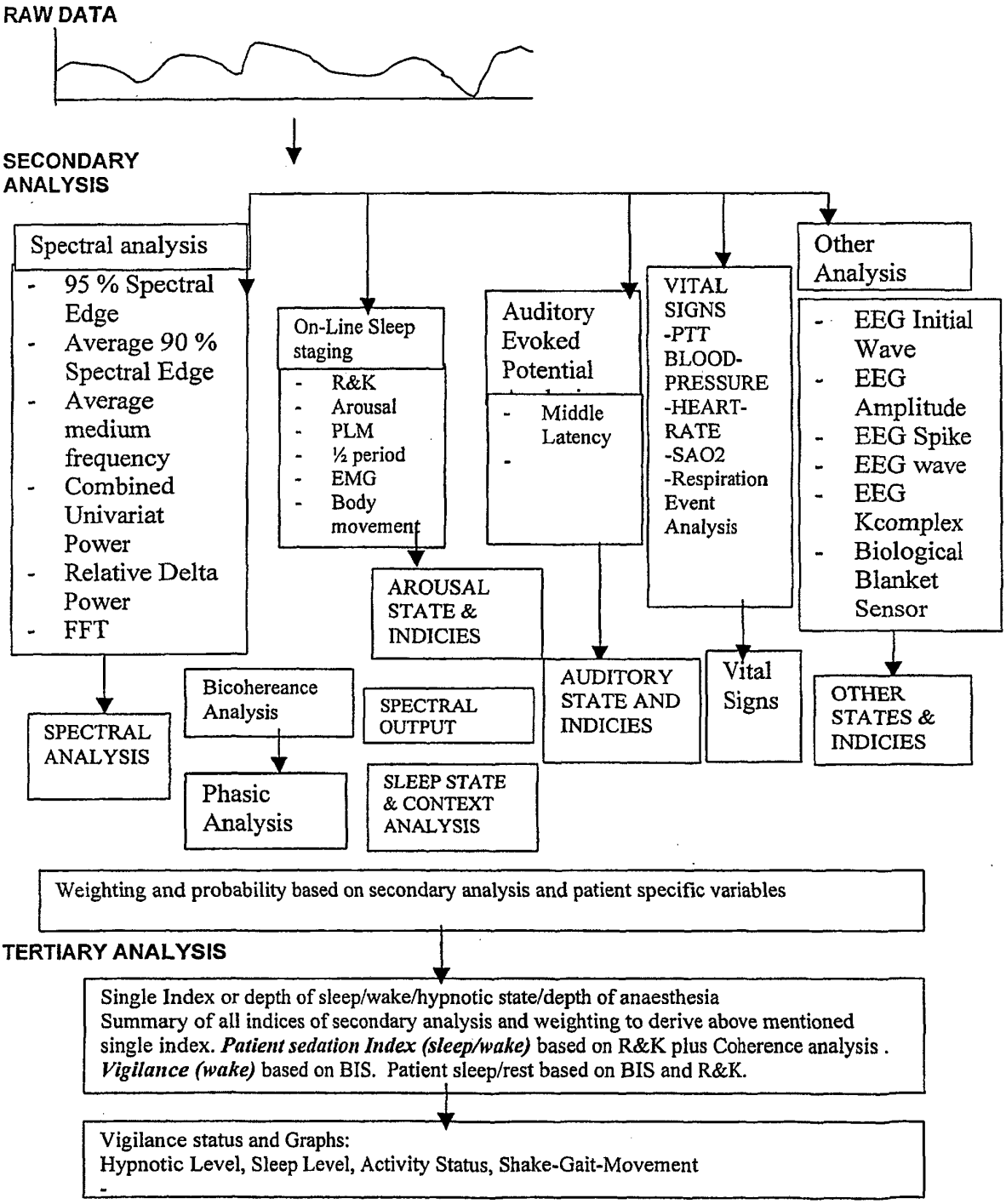

RAW DATA
SECONDARY ANALYSIS
Spectral analysis
- 95 % Spectral Edge
- Average 90 % Spectral Edge
- Average medium frequency
- Combined Univariat Power
- Relative Delta Power
- FFT
On-Line Sleep staging
- R&K
- Arousal
- PLM
- ½ period
- EMG
- Body movement
Auditory Evoked Potential
- Middle Latency
-
VITAL SIGNS -PTT BLOOD-PRESSURE -HEART-RATE -SAO2 -Respiration Event Analysis
Other Analysis
- EEG Initial Wave
- EEG Amplitude
- EEG Spike
- EEG wave
- EEG Kcomplex
- Biological Blanket Sensor
AROUSAL STATE & INDICIES
SPECTRAL ANALYSIS
Bicohereance Analysis
SPECTRAL OUTPUT
AUDITORY STATE AND INDICIES
Vital Signs
OTHER STATES & INDICIES
Phasic Analysis
SLEEP STATE & CONTEXT ANALYSIS
Weighting and probability based on secondary analysis and patient specific variables
TERTIARY ANALYSIS
Single Index or depth of sleep/wake/hypnotic state/depth of anaesthesia
Summary of all indices of secondary analysis and weighting to derive above mentioned single index. Patient sedation Index (sleep/wake) based on R&K plus Coherence analysis . Vigilance (wake) based on BIS. Patient sleep/rest based on BIS and R&K.
Vigilance status and Graphs:
Hypnotic Level, Sleep Level, Activity Status, Shake-Gait-Movement
-

FIG 41

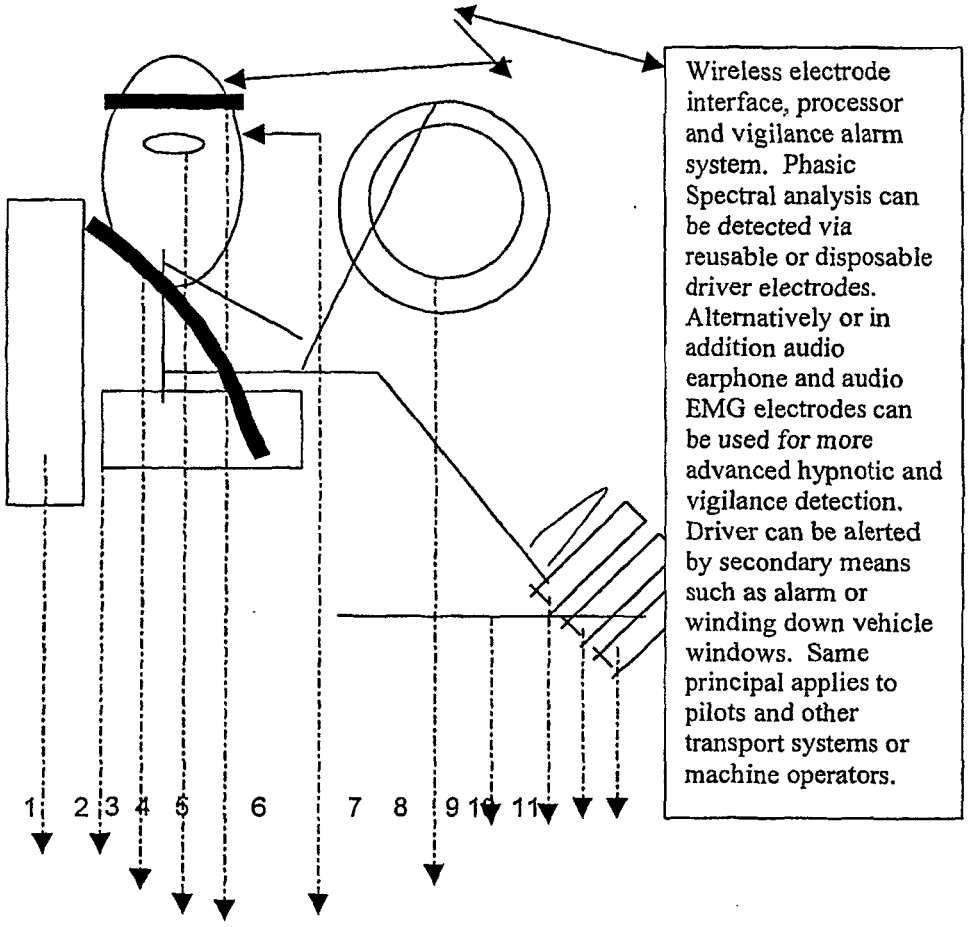

Wireless electrode interface, processor and vigilance alarm system. Phasic Spectral analysis can be detected via reusable or disposable driver electrodes. Alternatively or in addition audio earphone and audio EMG electrodes can be used for more advanced hypnotic and vigilance detection. Driver can be alerted by secondary means such as alarm or winding down vehicle windows. Same principal applies to pilots and other transport systems or machine operators.
1
2
3
4
5
6
7
8
9
10
11

FIG 42

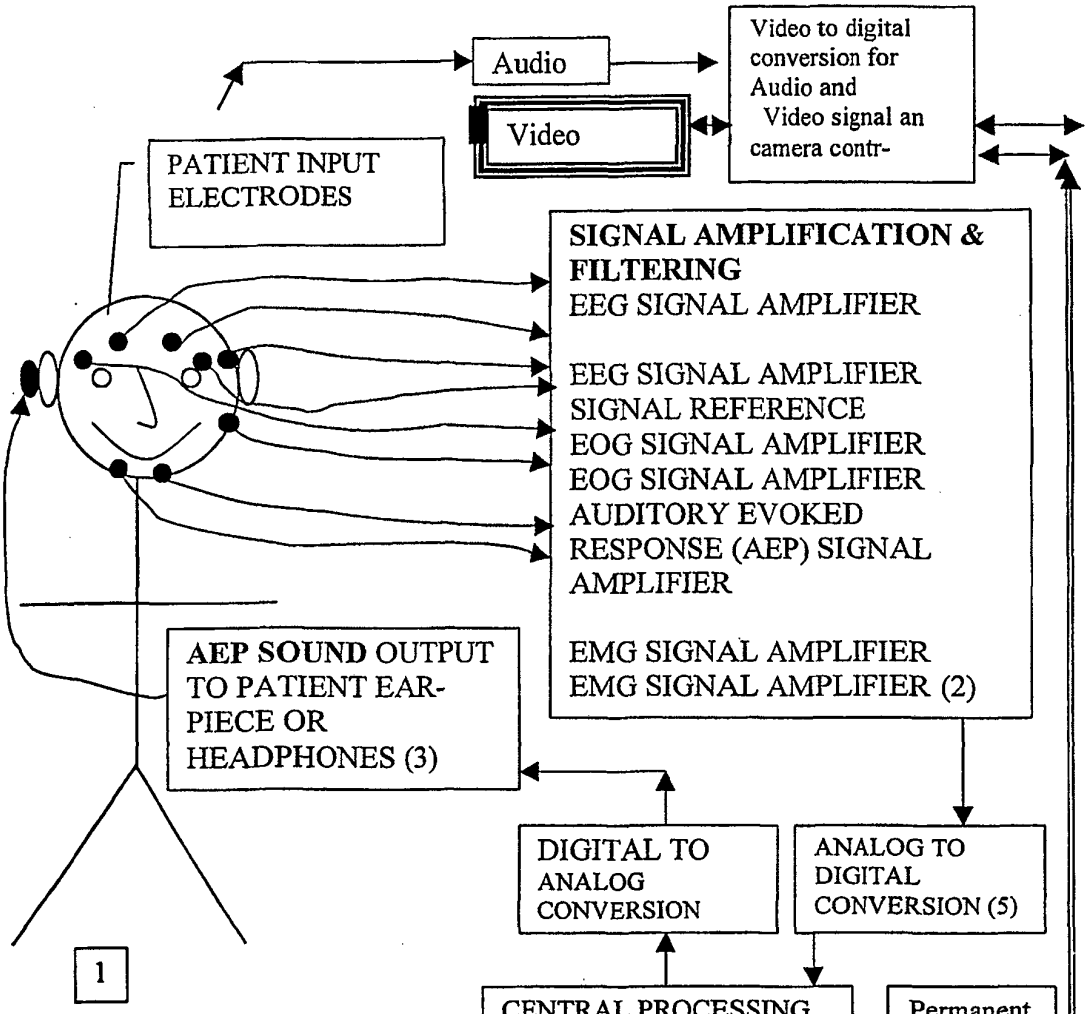

Audio
Video
Video to digital conversion for Audio and Video signal an camera contr-
PATIENT INPUT ELECTRODES
SIGNAL AMPLIFICATION & FILTERING
EEG SIGNAL AMPLIFIER
EEG SIGNAL AMPLIFIER
SIGNAL REFERENCE
EOG SIGNAL AMPLIFIER
EOG SIGNAL AMPLIFIER
AUDITORY EVOKED RESPONSE (AEP) SIGNAL AMPLIFIER
EMG SIGNAL AMPLIFIER
EMG SIGNAL AMPLIFIER (2)
AEP SOUND OUTPUT TO PATIENT EAR-PIECE OR HEADPHONES (3)
DIGITAL TO ANALOG CONVERSION
ANALOG TO DIGITAL CONVERSION (5)
1
CENTRAL PROCESSING UNIT
- CONTEXT AND VIGILANCE ALGORITHM
- (6)
Permanent and/or removable storage device.
Video and Audio processing algorithm provides a means to store video and audio of subject undergoing depth of anaesthesia monitoring in conjunction with time-synchronised reference. Furthermore the HCM System has the video processing capability to zoom into the patient's head and in particular automatically detect, record and alert for eye movement. This function provides a means of validating patient's anaesthesia depth during an operation using audio and visual means, particularly where anaesthesia recall can be claimed by patient's and require verification.

FIG 43

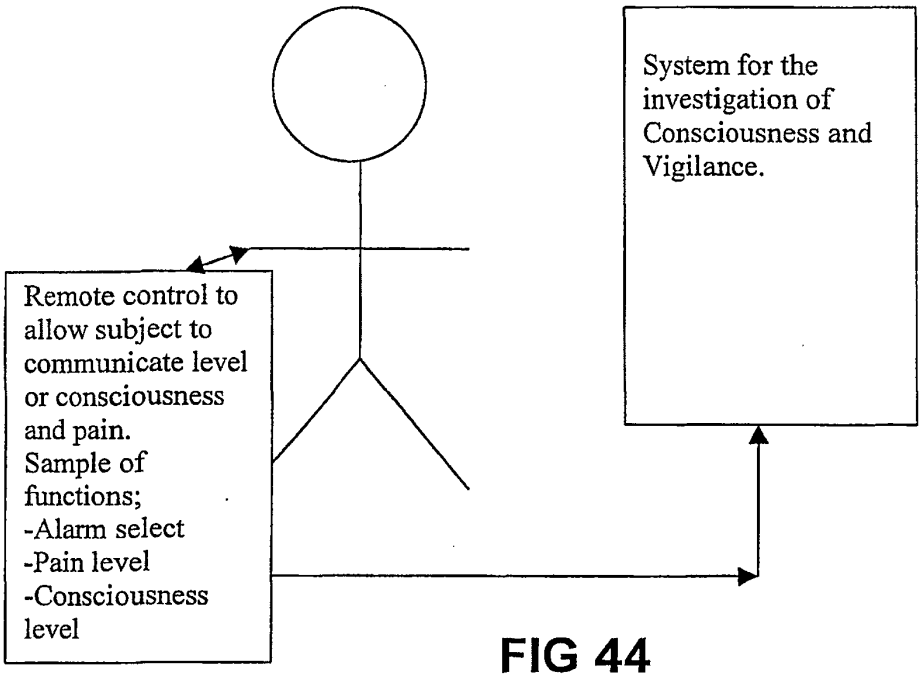

System for the investigation of Consciousness and Vigilance.
Remote control to allow subject to communicate level or consciousness and pain.
Sample of functions;
-Alarm select
-Pain level
-Consciousness level

FIG 44

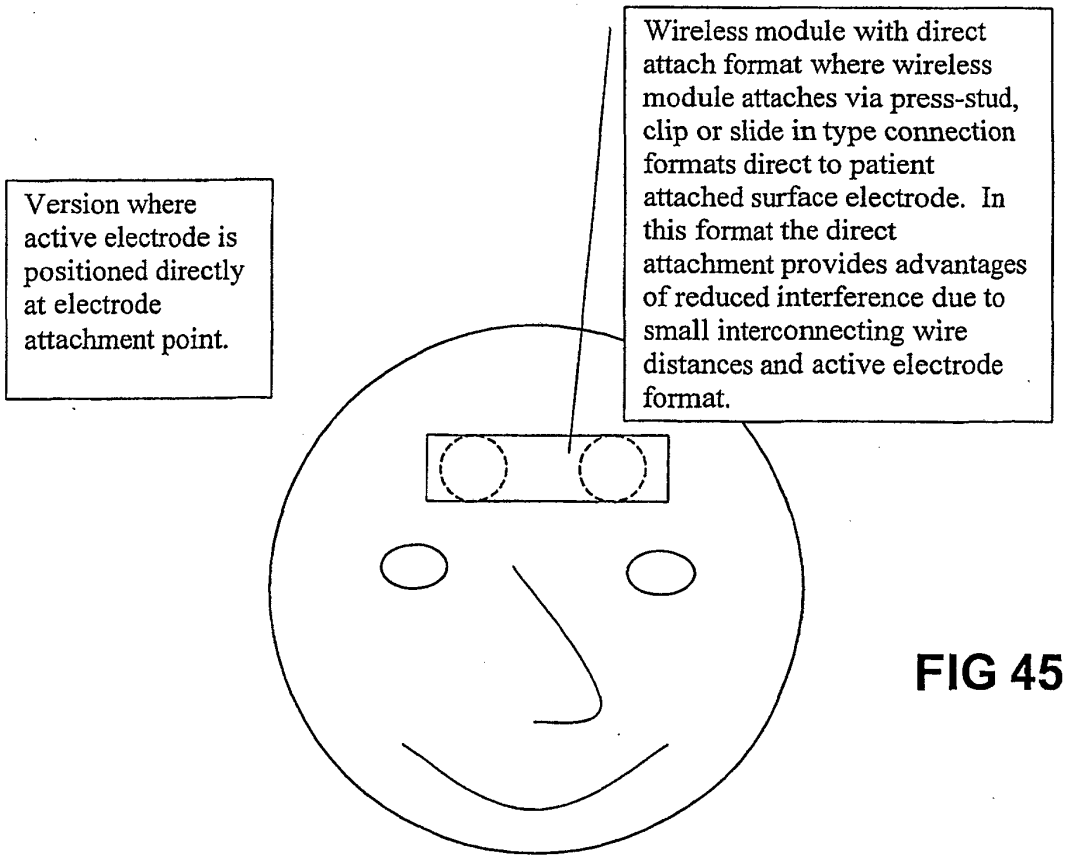
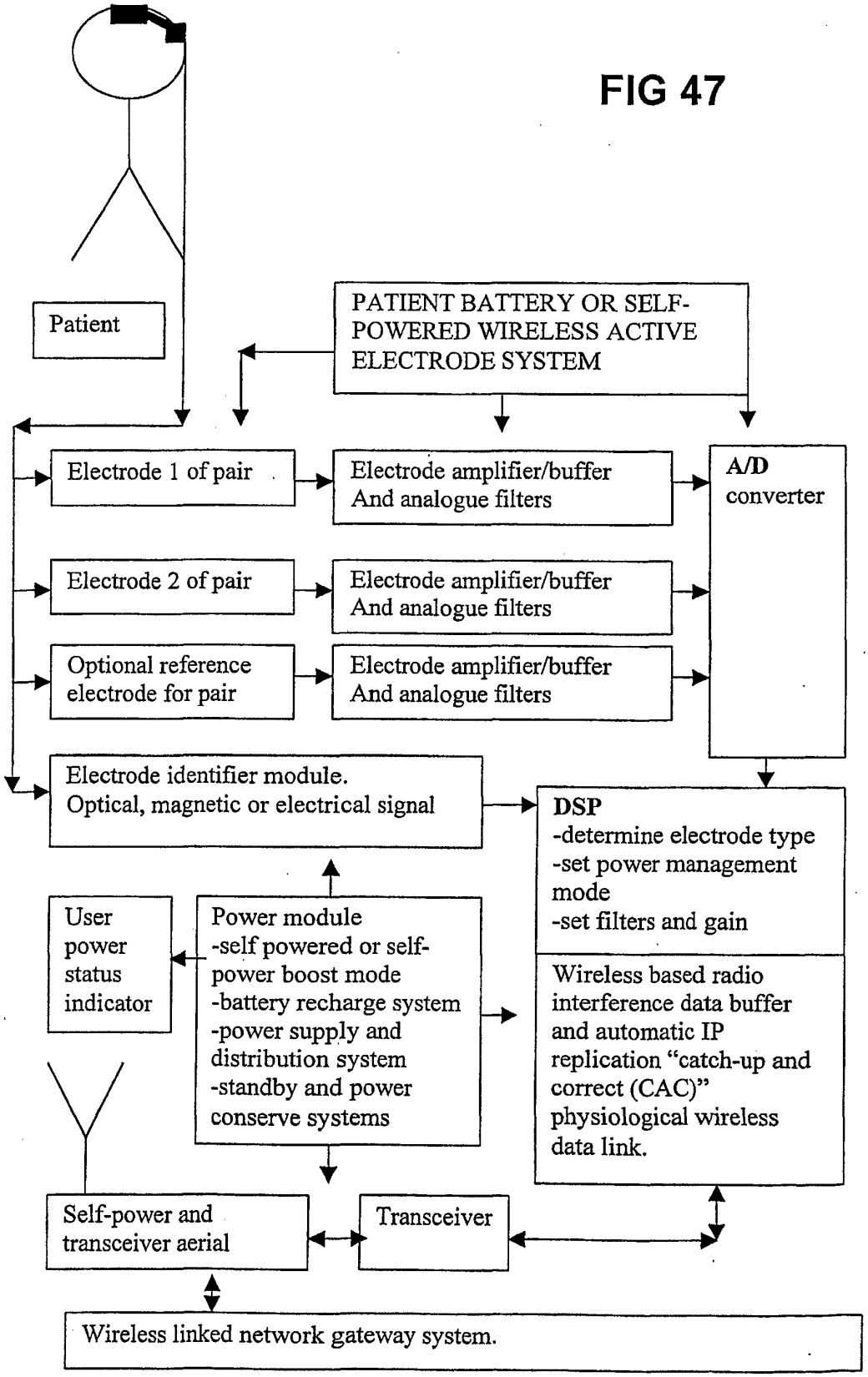

Wireless module with direct attach format where wireless module attaches via press-stud, clip or slide in type connection formats direct to patient attached surface electrode. In this format the direct attachment provides advantages of reduced interference due to small interconnecting wire distances and active electrode format.
Version where active electrode is positioned directly at electrode attachment point.

FIG 45

FIG 47


Patient
PATIENT BATTERY OR SELF-POWERED WIRELESS ACTIVE ELECTRODE SYSTEM
Electrode 1 of pair
Electrode amplifier/buffer And analogue filters
A/D converter
Electrode 2 of pair
Electrode amplifier/buffer And analogue filters
Optional reference electrode for pair
Electrode amplifier/buffer And analogue filters
Electrode identifier module. Optical, magnetic or electrical signal
DSP
-determine electrode type
-set power management mode
-set filters and gain
User power status indicator
Power module
-self powered or self-power boost mode
-battery recharge system
-power supply and distribution system
-standby and power conserve systems
Wireless based radio interference data buffer and automatic IP replication "catch-up and correct (CAC)" physiological wireless data link.
Self-power and transceiver aerial
Transceiver
Wireless linked network gateway system.

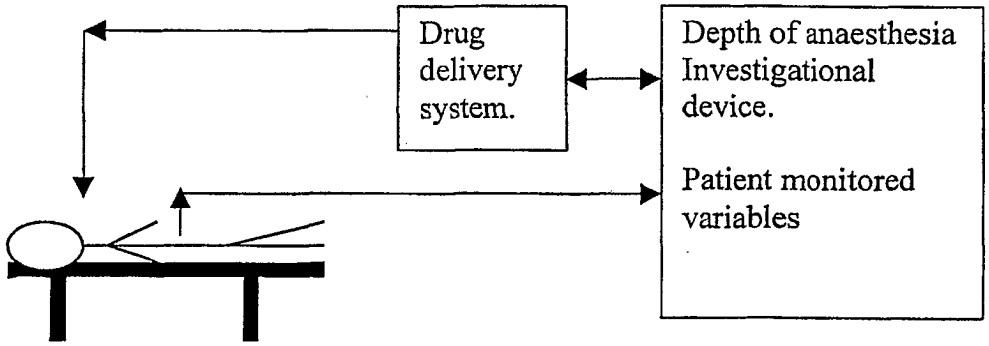

Drug
delivery
system.
Depth of anaesthesia
Investigational
device.
Patient monitored
variables

FIG 48

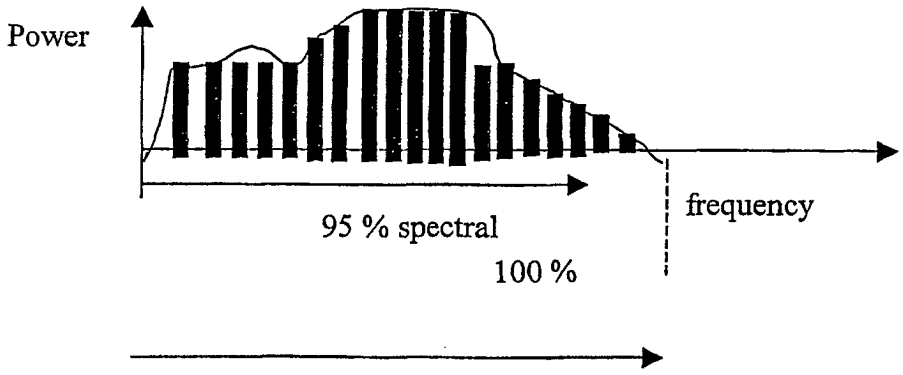

Power
95 % spectral
100 %
frequency

FIG 49

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- AU 9901166 W **[0004]**
- US 6067467 A **[0011]**
- AU 63293245 **[0013]**

Non-patent literature cited in the description

- **ALLAN RECHTSCHAFFEN ; ANTHONY KALES.** A Manual of Standardized Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects. Brain Information Service/Brain Research Institute **[0013]**
- *British Journal of Anaesthesia,* June 2000 **[0049]**
- **GAJRAJ RJ.** Comparison of bi-spectral EEG analysis and auditory evoked potentials for monitoring depth of anaesthesia during propofol anaesthesia. *British Journal of Anaesthesia,* May 1999 **[0050]**
- **GAJRAJ RJ.** Analysis of the EEG bispectrum, auditory evoked potentials and the EEG power spectrum during repeated transitions from consciousness to unconsciousness. *Br J Anaesth,* January 1998 **[0051]**
- **WITTE H.** Analysis of the interrelations between a low-frequency and a high-frequency signal component in human neonatal EEG during quiet sleep. *Neurosci Lett,* November 1997 **[0053]**

专利名称(译)	用于监测意识的方法和装置		
公开(公告)号	EP1989998B1	公开(公告)日	2014-03-12
申请号	EP2008163209	申请日	2002-06-13
申请(专利权)人(译)	COMPUMEDICS有限公司		
当前申请(专利权)人(译)	COMPUMEDICS医药创新PTY LTD.		
[标]发明人	BURTON DAVID ZILBERG EUGENE		
发明人	BURTON, DAVID ZILBERG, EUGENE		
IPC分类号	A61B5/0476 A61B5/048 A61B5/11 A61B5/16 G06F17/00 A61B5/0484 A61B5/00 A61B5/021 A61B5/0402 A61B5/0496 A61B5/1455 A61B5/0205 A61B5/08 A61B5/087 A61B5/145		
CPC分类号	A61B5/021 A61B5/0402 A61B5/0476 A61B5/048 A61B5/0496 A61B5/11 A61B5/14551 A61B5/16 A61B5/411 A61B5/4809 A61B5/4812 A61B5/6821 A61B5/7207 A61B5/7239 A61B5/7257 A61B5/7264 G16H50/20		
优先权	60/298011 2001-06-13 US		
其他公开文献	EP1989998A3 EP1989998A2		
外部链接	Espacenet		

摘要(译)

该申请公开了如下几个发明：（a）监视感知对象的意识并通过获得EEG信号自动检测过渡状态并比较这两个信号以检测过渡并在过渡发生时提供警告信号的方法；（b）用于处理非平稳信号的方法或设备，包括具有增加和减小幅度的片段，其通过执行片段的句法分析来比较感知对象的生理特征，比较片段的高度，宽度和误差参数以识别噪声片段和替换在将信号分类为属于预定义睡眠状态之一之前，具有直线的噪声段；（c）监视被动对象的生理特征的方法，包括用第二备用电极信号代替退化的第一电极信号，并在两个信号都退化时提供警告信号；（d）用于检测眼睑开度的电容或电感元件传感器，包括指示可与眼睑一起移动的部件与参考部件之间的相对位置的信号提供装置。