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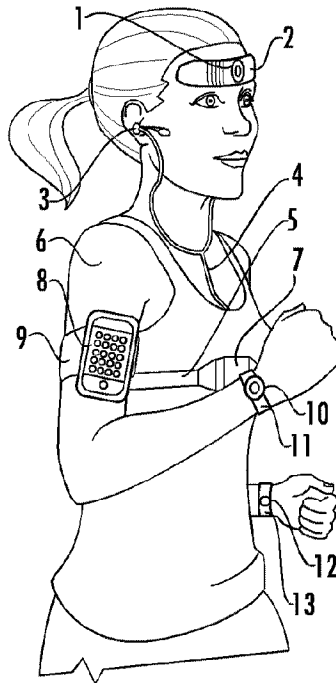
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(54) Titre : SYSTEMES DE SURVEILLANCE POUVANT ETRE MOBILES ET PORTES

(54) Title: MOBILE WEARABLE MONITORING SYSTEMS



(57) Abrégé/Abstract:

This document describes a number of inventions comprising of one or more wearable devices (i.e. attached or applied to limbs, body, head or other body extremities but also applicable to implanted or physiologically attachable systems). These systems have a means of enabling diagnostic or prognostic monitoring applicable to monitoring relevant parameters and corresponding analysis determination and characterisation applicable to the onset or detection of events or health conditions of interest. One application relates to sleep monitoring and associate EEG sensors.

ABSTRACT

This document describes a number of inventions comprising of one or more wearable devices (i.e. attached or applied to limbs, body, head or other body extremities but also applicable to implanted or physiologically attachable systems). These systems have a means of enabling diagnostic or prognostic monitoring applicable to monitoring relevant parameters and corresponding analysis determination and characterisation applicable to the onset or detection of events or health conditions of interest. One application relates to sleep monitoring and associate EEG sensors.

DEMANDE OU BREVET VOLUMINEUX

LA PRÉSENTE PARTIE DE CETTE DEMANDE OU CE BREVET COMPREND PLUS D'UN TOME.

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MOBILE WEARABLE MONITORING SYSTEMS

FIELD OF THE INVENTION

The application relates to methods and devices for subject (consumer/patient) data-acquisition, monitoring and analysis.

BACKGROUND

There are known medicine techniques for evaluating and recording the electrical activity produced by skeletal muscles, such as electroencephalogram (EEG) and electromyography (EMG). The EEG or EMG signals can be analyzed to detect medical abnormalities, activation level, or recruitment order, or to analyze the biomechanics of human or animal movement. There are also techniques such as polysomnography (PSG) used in the study of sleep and as a diagnostic tool in sleep medicine. The PSG monitors many body functions, including brain activity, eye movements, muscle activity or skeletal muscle activation, and heart rhythm during sleep.

More studies and developments on methods and devices for monitoring or analysing activities of a subject or a patient are still needed for maintaining or improving their health conditions.

SUMMARY

The application presents a number of method and device inventions incorporating or enabling communication interface (including one or more wearable devices, or connectivity options (such as WWW, IP, LAN, WAN, supplementary/companion monitoring/sensing or computing systems, SAAS including Cloud-computing services or NAS, peer to peer connections etc.) with the means of sensing, monitoring, tracking, storing and/or analysing any of or any combination of a subject's physiological parameters, pathological conditions, psychological states, wake, sleep, activity, fitness, health, other sentient states, associated transitions, and/or neurological parameters including option of automatic determination of the prediction, onset or incidence of health conditions/disorders or events of interest by way of incorporating characterisation and

determination of processing capabilities or combinations (i.e. multivariate analysis) or clusters or ensembles applicable to any of or any combination of the following;

- a) A patient-wearable sleep, fitness, health, sentient state monitoring device;
- b) An forehead applied sensor system incorporating a wrist-forehead interchangeable or exchangeable active electronic module with option of display capabilities (any of sleep measure and/or or health tracking measure);
- c) The capability of continuously transmitted sleep parameter information enabling reconstitution of the analysis of contiguous 20 or 30 seconds data epochs in order to enable online sleep staging based on these continuous epoch periods. The monitored sleep parameter data can be transferred to a secondary wearable device for sleep status display purposes such as a smart watch device interconnected mobile, clock or other device etc. The monitored sleep parameter data can also be simultaneously transferred to additional communication networks, systems or other interconnectivity options (such as WWW, IP, LAN, WAN, supplementary/companion monitoring/sensing or computing systems, SAAS including Cloud-computing services or NAS, peer to peer connections etc.) in order to enable personalised or remote tracking, reporting or surveillance or an individual sleep and associated outcomes.
- d) Automatic data exchange is possible between a first applied forehead monitoring system and a second information indicator (computer based wrist watch system, mobile device, clock, bangle with indicator, whereby user/patient can track sleep progress during any stage of sleep and also as a means of tracking sleep deprivation or sleep quality (based on prior sleep or wake measures and/or circadian cycle offsets factors).
- e) The monitored and exchanged parameters can include sleep, health and fitness measures and indicator display capabilities, comprising one or more light-detection and applied forehead electrophysiological sleep-parameter(s) (EEG, EOG and EMG) monitoring capability, along with measures or associated indices including (but not limited to) sleep efficiency (SE), wake after sleep onset (WASO);

- f) The sensing, monitoring and analysis of any of or any combination of wake and sleep events, measures, states or health and environmental conditions of interest,
- g) One electronic part of a wearable monitoring system (i.e. in case of an interchangeable module for day activity and night sleep monitoring, for example) or a plurality of electronic parts of wearable monitoring systems (i.e. in case of separate modules such as a wrist device containing a separate module, or a microprocessor based wrist watch incorporating the day-time activity and other health tracking and/or monitoring functions, etc.) containing the for an interchangeable module for day activity and night sleep monitoring, for example) can be deployed in order to provide both day activity and health monitoring and tracking, as well as night homeostatic sleep monitoring capabilities. as part of an overall wake/sleep health monitoring and tracking system;
- h) The said “electronic part of a wearable monitoring system” can comprise an electronic module containing any of or any combination of functions for physiological monitoring, analysis of monitored physiological parameters, storage of monitored physiological parameters, means of information flow interconnectivity, health measures or health status indications, including sleep/wake information and/or activity information (i.e. movement, motion, steps, activity etc.) and/or other health information,
- i) Said “electronic module” incorporating means (i.e. any of or any combination of magnetic, mechanical, and/or interlocking) of being interchanged between a plurality of wearable health or environmental monitoring devices;
- j) Said electronic module can be attached or applied to a subject's forehead via a compatible forehead applied sensor device.
- k) Additionally in order to enable the same electronic module device also be used for daytime or wake activity (i.e. user can transfer more expensive electronic module to wrist band holder device this enabling sleep/wake or day/night 24 hours 7 days a week monitoring from a single electronic module with different wearable devices such as forehead system for sleep and wrist band for daytime fitness or health tracking.

- l) The electronic module can also incorporate display or indicator capabilities so that the module provides users indication of measures or related indices of sleep/wake as well as daytime fitness or general health tracking capabilities.
- m) The electronic module indicator can be monochrome or graphic displays or alpha numeric type. Alternatively the display can be simple bar-graph or other graphic or numeric indicator types presenting a range of measures of daytime fitness or general health tracking capabilities, including the analysis measures further detailed elsewhere, throughout this document.
- n) In one example embodiment of indicator of the electronic module can incorporate real sleep parameters by way of the forehead applied monitoring of sleep parameters (including any of or any combination of one or more of or combined channels of any of or any combination of EEG, EMG and/or EOG signals) whereby sleep quality or sleep parameters (including those of homeostatic sleep and/or circadian clock factors) as well as fitness or other general health or daytime parameters can be displayed in a single wearable indicator system for 24 hour, 7 day sleep/wake health tracking capabilities.)
- o) The said electronic module can also be attached (i.e. interlocked, magnetically coupled, clipped, press-stud attached, or otherwise mechanically engaged or clipped into etc.) into or as part of a plurality of wearable devices (including but not limited to) compatible wrist band device. Additionally, wireless or other connectivity capabilities can manually or automatically transfer the electronic module sleep monitoring parameters from the forehead monitoring module to the smartwatch system. The forehead monitoring module can be a "forehead applied sensor". The "forehead applied sensor" can monitor at least one forehead sleep-parameter signal including any of or any combination of EEG, EOG and EMG;
- p) The deployment of a subject applied forehead-sensor capable of monitoring principle sleep-parameters (EEG, EOG, EMG) combined with interconnectivity with a secondary wearable communication/indicator device enables a range of sleep and wake events or disorders to be tracked and managed, including the option of corresponding countermeasures by way of therapeutic device or other forms of intervention;

- q) The deployment of compatible and interconnected companion patient worn devices (i.e. subject worn or related; placement of sound monitoring or environmental monitoring devices further enables monitoring and automatic tracking of wake or sleep and associated breathing disorders. Information between a group of compatible (i.e. wireless communication and information) devices such as **eLifeWATCH**; **eLifeWRIST**; **eLifeCHEST**; **eLifeEXG**; and **eLifeNEURO** which can automatically and dynamically interchange data between one or more of the said devices, enabling determination and associated indication of any combination of measures or associated indices. Said “measures or associated indices” can include any of or any combination of this for fitness, health and/or sleep-parameters (personalised sleep quality, efficiency/SE, wake after sleep onset/WASO, deep-sleep body recovery period, REM sleep brain restoration period, sleep-in-progress tracking, sleep-quality progress, sleep-journal, comparative population or personalised sleep function, sleep-debt, sleep-disturbance, respiratory-disturbance, sleep-disturbance causation along with corresponding sleep improvement hints or recommendations, sleep-architecture, sleep structure, sleep fragmentation etc.).
- r) The deployment of a data communication system comprising of an internet or other wireless or interconnectivity means of interfacing signals or derived measures from the wearable electronic devices with medical therapeutic or diagnostic Internet Of Medical Devices (IOMD) whereby the wearable devices can form a biofeedback (closed loop or other control incorporating measures as part of decision making processes responsible for controlling therapy administration). Said therapy control can include sleep therapeutic devices such oral mouth adjustment systems, patient positioning devices or trainers, PAP, NIPPV and other devices. Said therapy control can include relaxation or meditation visual outputs or controls (i.e. massage chair control) or music or room lighting or video or 3D projections etc.). Said therapy control can include magnetic or electrical stimulation devices.

DESCRIPTION OF THE DRAWINGS

Figures 1A-1D show examples of wearable monitoring device called Somfit according to aspects of the invention;

Figures 2 and 3 are other examples of the Somfit;

Figures 4A and 4B are perspective views of a forehead Somfit;

Figures 5 shows a patient wearing modules of a forehead sensor, elifeWATCH, elifeWRIST and elifeCHEST;

Figures 6A-6C show examples of interface of eHealthWATCH;

Figure 7A and 7B show example configurations of elifeWATCH;

Figure 8 show steps to a healthy sleep and life;

Figure 9 shows an example of elifeWATCH with Doppler detection sensor;

Figures 10A and 10B show examples of elifeWATCH with gesture or button display and menu toggle selection;

Figures 11A and 11b show examples of elifeWATCH setup and signal validation application screens;

Figure 12 is a gesture control interface of elifeWATCH;

Figure 13 is an example of elifeWATCH with smartphone, sensors interfaces and wireless information access system;

Figure 14 is a wireless earphone device according to an aspect of the invention;

Figures 15 to 18 show an example of elifeCHEST;

Figure 19 shows cloud-computing services or other network application services integrated with the wearable monitoring devices of the inventions;

Figures 20-21C show examples of wearable monitoring device integrated with multiple sensors;

Figure 22 shows an oximeter probe;

Figure 23 shows an wireless, battery powered bipolar elifeEXG system;

Figure 24 shows a bipolar electrophysiological electrode band;

Figure 25 is a forehead wearable device;

Figure 26 is a wristband called SleepFit;

Figure 27 shows embodiment examples of present invention based on top level diagrammatic overview;

Figure 28 shows patient wearable device and companion management system (HMS) platform overview flow diagram;

Figure 29 is a diagram of external noise sensing and cancellation system;

Figure 30 is a multipoint time-synchronisation monitoring (MTM) system overview diagram;

Figures 31A and 31B show a chestband with multiple embedded sensors;

Figure 32 shows a combined armband with option of a phone;

Figure 33 shows an armband combined with embedded metabolism monitoring for calorie-burn tracking;

Figure 34 is a Doppler-watch, ankle, wrist or arm monitoring system;

Figure 35 is an ultrasonic Doppler-watch patient-worn sensor;

Figures 36 and 37 show a Doppler-watch wore by a subject;

Figure 38 presents a subject's wrist with annotated radial artery and ulnar artery applicable to measurement location of the present invention;

Figure 39 shows an vehicle mounted with the device of the invention;

Figures 40A and 41 show eye recognition and facial characteristics as a means of tracking changes;

Figure 42 shows road or driving environment associated with the tracking changes;

Figure 43 shows driver/subject wearable glasses incorporating any combination of binocular and/or video imaging device;

Figures 44A-44C show diagrams of data and management process of the device of the invention;

Figure 45 is a diagram of process for automatic diagnostic and prognostic monitoring and analysis;

Figures 46-54 show various examples of configurations of forehead band monitor system;

Figure 55A-55F show an example of multiple channel high-density monitoring and analysis;

Figure 56 show an example of brain signal response of monitoring;

Figure 57-59B are diagrams of signal analysis process; and

Figure 60A-102E show multiples examples of the present invention with automatic monitoring and/or analysis capability.

DETAILED DESCRIPTION OF EMBODIMENTS

The application presents a number of method and device inventions incorporating or enabling communication interface (including one or more wearable devices, or connectivity options (such as WWW, IP, LAN, WAN, supplementary/companion monitoring/sensing or computing systems, SAAS including Cloud-computing services or NAS, peer to peer connections etc.) with the means of sensing, monitoring, tracking, storing and/or analysing any of or any combination of a subject's physiological parameters, pathological conditions, psychological states, wake, sleep, activity, fitness, health, other sentient states, associated transitions, and/or neurological parameters including option of automatic determination of the prediction, onset or incidence of health conditions/disorders or events of interest by way of incorporating characterisation and determination of processing capabilities or combinations (i.e. multivariate analysis) or clusters or ensembles applicable to any of or any combination of the following;

- a) **A patient-wearable sleep, fitness, health, sentient state monitoring device (Somfit);**
- b) An forehead applied sensor system incorporating a wrist-forehead interchangeable or exchangeable active electronic module (Figure 1 RHS, [1], [7]) with option of display capabilities (any of sleep measure and/or or health tracking measure) (Somfit);
- c) The capability of **continuously transmitted sleep parameter information enabling reconstitution of the analysis of contiguous 20 or 30 seconds data epochs** in order to enable online sleep staging based on these continuous epoch periods. The monitored sleep parameter data (Figure 1 LHS, [1]) can be transferred to a secondary wearable device for sleep status display purposes such as a smart watch device (Figure 1 RHS UPPER, [5]), interconnected mobile, clock or other device etc. The monitored sleep parameter data (Figure 1 LHS, [1]) can also be simultaneously transferred to additional communication networks, systems or other interconnectivity options (such as WWW, IP, LAN, WAN, supplementary/companion monitoring/sensing or computing systems, SAAS including Cloud-computing services or NAS, peer to peer connections etc.) in order to enable personalised or remote tracking, reporting or surveillance or an individual sleep and associated outcomes.
- d) **Automatic data exchange is possible between a first applied forehead monitoring system and a second information indicator** (computer based wrist watch system, mobile device, clock, bangle with indicator such as Figure 1 LHS [8] or [10] or Figure 1 RHS [5]), whereby user/patient can track sleep progress during any stage of sleep and also as a means of **tracking sleep deprivation or sleep quality** (based on prior sleep or wake measures and/or circadian cycle offsets factors).
- e) The monitored and exchanged parameters can include **sleep, health and fitness measures** and indicator display capabilities, comprising one or more light-detection and applied forehead electrophysiological sleep-parameter(s) (EEG, EOG and EMG) monitoring capability, along with measures or associated indices including (but not limited to) sleep efficiency (SE), wake after sleep onset (WASO);
- f) The **sensing, monitoring and analysis** of any of or any combination of wake and sleep events, measures, states or health and environmental conditions of interest,
- g) **One electronic part of a wearable monitoring system** (i.e. in case of an interchangeable module for day activity and night sleep monitoring, for example) **or a plurality of electronic parts of wearable monitoring systems** (i.e. in case of separate modules such as a wrist device containing a separate module, or a microprocessor based wrist watch incorporating the day-time activity and other health tracking and/or monitoring functions, etc.) containing the for an interchangeable module for day activity

and night sleep monitoring, for example) can be deployed in order to provide both day activity and health monitoring and tracking, as well as night homeostatic sleep monitoring capabilities, as part of an overall wake/sleep health monitoring and tracking system;

- h) The said "**electronic part of a wearable monitoring system**" (Figure 1 LHS UPPER, [1] and [10]) or Figure 1 LHS LOWER, [2] or Figure 1 RHS UPPER, [1] and [7]) can comprise of an electronic module containing any of or any combination of functions for physiological monitoring, **analysis** of monitored physiological parameters, **storage** of monitored physiological parameters, means of **information flow interconnectivity**, **health measures or health status indications**, including **sleep/wake information** and/or **activity information** (i.e. movement, motion, steps, activity etc.) and/or other health information,
 - i) Said "electronic module" (**Somfit**) incorporating means (i.e. any of or any combination of magnetic, mechanical, and/or interlocking) of being **interchanged between a plurality of wearable** health or environmental monitoring devices;
 - j) Said **Somfit** electronic module (Figure 1 LHS UPPER [1]) or Figure 1 LHS LOWER [1]) can be **attached or applied to a subject's forehead** via a compatible forehead applied sensor device (i.e. Figure 1 LHS UPPER [2] or Figure 1 LHS LOWER [2]).
 - k) Additionally in order to enable the same **Somfit** electronic module device also be used for daytime or wake activity (i.e. user can transfer more expensive electronic module to wrist band holder device this enabling sleep/wake or day/night 24 hours 7 days a week monitoring from a **single Somfit module** with different wearable devices such as forehead system for sleep and wrist band for daytime fitness or health tracking.
 - l) The **Somfit** electronic module can also incorporate display or indicator capabilities so that the module provides users indication of measures or related indices of sleep/wake as well as daytime fitness or general health tracking capabilities.
 - m) The **Somfit** electronic module indicator can be monochrome or graphic displays or alpha numeric type. Alternatively the display can be simple bar-graph or other graphic or numeric indicator types presenting a range of measures of daytime fitness or general health tracking capabilities, including the analysis measures further detailed elsewhere, throughout this document.
 - n) In one example embodiment of indicator the **Somfit module** can incorporate real sleep parameters by way of the forehead applied monitoring of sleep parameters (including any of or any combination of one or more of or combined channels of any of or any combination of EEG, EMG and/or EOG signals) (i.e. Figure 2 [3] and [2] whereby sleep quality or sleep parameters (including those of homeostatic sleep and/or circadian clock factors) as well as fitness or other general health or daytime parameters can be displayed in a single wearable indicator system for 24 hour, 7 day sleep/wake health tracking capabilities.)
 - o) The said **Somfit** electronic module (i.e. Figure 1 RHS UPPER [1]) can also be attached (i.e. interlocked, magnetically coupled, clipped, press-stud attached, or otherwise mechanically engaged or clipped into etc.) into or as part of a plurality of wearable devices (including but not limited to) compatible wrist band device (i.e. Figure 1 RHS UPPER [8] wrist-band). Additionally, wireless or other connectivity capabilities can manually or automatically transfer the **Somfit module** sleep monitoring parameters from the forehead **Somfit monitoring module** (i.e. Figure 1 RHS UPPER [1]) to the smartwatch system (i.e. Figure 1 RHS UPPER [5]).
 - p) A "Forehead applied sensor" incorporating **at least one bipolar electrophysiological forehead electrophysiological signal** (Figure 4; [8], [9], [10], [11], [12]);
 - q) A "Forehead applied sensor" comprising of a **reusable sensor**;
 - r) A "Forehead applied sensor" comprising of a **disposable sensor**;
 - s) A "Forehead applied sensor" comprising of a sensor with or without a partial or total circumference headband (Figure 4; [13]);
 - t) A "Forehead applied sensor" which can comprise on one **side of a sensor with self-adhesive surface and embedded self-gelled electrophysiological electrodes**, whereby these said "electrode" can be exposed with the **removal of backing paper**;
 - u) A "Forehead applied sensor" which can comprise on **non-electrode side** of said "forehead applied sensor" a **means of interfacing** (i.e. self-adhesive, press-stud,

magnetic, mechanical interlocking or other means) to said “**electronic module**” or a device containing or holding said “**electronic module**” (**Figure 4; [7]**);

- v) A “Forehead applied sensor” The said “Forehead applied sensor” can monitor at least one forehead sleep-parameter signal including any of or any combination of **EEG, EOG and EMG**;
- w) The deployment of a subject **applied forehead-sensor capable of monitoring principle sleep-parameters (EEG, EOG, EMG)** combined with interconnectivity with a secondary wearable communication/indicator device enables a range of sleep and wake events or disorders to be tracked and managed, including the option of corresponding countermeasures by way of therapeutic device or other forms of intervention;
- x) The **deployment of compatible and interconnected companion patient worn devices** (i.e. subject worn or related; placement of sound monitoring or environmental monitoring devices further enables monitoring and automatic **tracking of wake or sleep and associated breathing disorders**. Information between a group of compatible (i.e. wireless communication and information) devices (i.e. as covered elsewhere in this document;; eLifeWATCH (**Figure 5, [5]**), eLifeWRIST (**Figure 5, [8]**); eLifeCHEST (**Figure 5, [4]**); eLifeEXG (**Figure 23**), eLifeNEURO (**Figure 4, [2]**) which can automatically and dynamically interchange data between one of more of the said devices, enabling determination and associated indication of any combination of measures or associated indices;
- y) Where said “**measures or associated indices**” can include any of or any combination of this for fitness, health and/or sleep-parameters (**personalised sleep quality, efficiency/SE, wake after sleep onset/WASO**, deep-sleep body recovery period, REM sleep brain restoration period, sleep-in-progress tracking, sleep-quality progress, sleep-journal, comparative population or personalised sleep function, sleep-debt, sleep-disturbance, respiratory-disturbance, sleep-disturbance causation along with corresponding sleep improvement hints or recommendations, sleep-architecture, sleep structure, sleep fragmentation etc.).
- z) The deployment of a **somnilink** system comprising of an internet or other wireless or interconnectivity means of interfacing signals or derived measures from the **Somfit** system with medical therapeutic or diagnostic Internet Of Medical Devices (IOMD) whereby the **Somfit** can form a biofeedback (closed loop or other control incorporating **Somfit** measures as part of decision making processes responsible for controlling therapy administration). Where said therapy control can include sleep therapeutic devices such oral mouth adjustment systems, patient positioning devices or trainers, PAP, NIPPV and other devices. Where said therapy control can include relaxation or meditation vidual outputs or controls (i.e. massage chair control) or music or room lighting or video or 3D projections etc.). Where said therapy control can include magnetic or electrical stimulation devices.
- aa) The **Somnisync** system incorporates a means of enabling “**dynamic data-exchange of sleep parameters**” or other health or fitness parameters between two or more wearable devices or associated mobile wireless communication devices or computer systems.
- bb) Whereby said “**dynamic data-exchange**” can enable personalised management of wrist-bangle or other wearable device sleep and/or fitness and/or other health conditions or status;
- cc) This **dynamic data-exchange** can be via wireless interconnection between **two or more wearable devices** enabling a means for sleep monitored parameter data and/or associated sleep measures to be automatically displayed on a wearable display device, such as mobile phone (**Figure 1, LHS, [8]**), smart watch (**Figure 1, RHS, [5]**), wrist bangle (**Figure 1 RHS, [8]**) or other wearable system;
- dd) This **dynamic data-exchange** can be via wireless interconnection between **two or more wearable devices** enabling a means for sleep monitored parameter data and/or associated sleep measures to be automatically displayed on a wearable display device, such as mobile phone (**Figure 1, LHS, [8]**), smart watch (**Figure 1, RHS, [5]**), wrist bangle (**Figure 1, RHS, [8]**) or other wearable system;

- ee) An electronic monitoring transfer electronic module from (with applied forehead EEG, EOG, EMG monitoring part), for example, to remove forehead applied sensor and device and transfer electronic module to a wearable wrist device wrist augment conventional daytime wrist pedometer or motion-based fitness devices with sleep measures.
- 5 ff) The **Somnilink forehead applied, wrist device** (i.e. watch or bangle) or **other wearable or attachable devices** can incorporate a means of detecting room or environmental light conditions (i.e. such **means include light dependent resistor** or other photo-sensors essential for internationally accepted standard sleep indices such as sleep efficiency or sleep after wake onset). The output information of the light sensors
- 10 can be linked to online and automatic measures applicable to sleep measures such as sleep efficiency, sleep after wake onset, sleep time, REM sleep (during sleep time), deep-sleep (during sleep-time), NON-REM sleep etc. These said light detections sensor derived measures can be displayed as part of another wearable device to provide a subject instantaneous measures or indicators of sleep function and performance. These
- 15 sleep measures can be displayed in conjunction with other fitness (such as accelerometer and/or motion sensor and/or pedometer sensor measures) in order to provide a sleep and fitness tracking capability applicable to the said subject via a wearable information indicator device (such as watch or bangle) or other subject wearable or attachable device.
- 20 gg) A system automatically computing a subjects **intra-sleep and inter sleep progress and associated outcomes** and related information (disorders, measures, indices, quality or severity of sleep and associated disorders or concerns). The present invention enables distillation of information using an information **triage means** (i.e. **triage means** can include an information dissemination process, whereby such a process is in accordance
- 25 to a predefined (i.e. but not limited to empirical prior data studies, normative or disease/disorder state populations data or studies) or dynamically (i.e. but not limited to determination and/or adaptation and/or adjustment based on preceding monitored or sensed information) computed user access **authority** and **rights** covering **role, qualifications, security** and **privacy** aspects as well as appropriate **user interface and information access or information content complexity levels**. Said "information content" can include sleep architecture, including REM sleep and deep-sleep amount, disruptions or arousals.
- 30 hh) The present invention can **automatically compute and advise a subject when they should be having or need additional sleep, the quality of sleep, the improvement recommendations** based on ongoing tracking and computation of a subject's ongoing sleep tracking outcomes, as well as these said outcomes comparable to a subject's normal sleep requirements or normative population database comparatives. The present invention incorporates a means of referencing said data bases.
- 35 ii) The present invention can enable a questionnaire or **sleep survey such as a validated sleep-scale or validated drowsiness scale to be deployed in conjunction with self-assessment** in order to establish a set of criteria corresponding to a subject's normal, levels or indices (i.e. REM sleep, sleep time, deep-sleep, arousal index, AH respiratory index, RERA index, overall sleep quality, and/or sleep deprived status, enabling a subject or subject's health carer **enhanced information access for improved sleep management**. A further **means of comparing such information** with current inter-sleep and intra-sleep progress reports or related trends in order to establish recommendations based on these outcomes and recommendations of hints for subject or associated health carer (means of **means of comparing such information** can include reference to a subject's personal model of sleep as established with said personal survey assessments and ongoing calibration of related "criteria" as well as comparison to patient
- 40 normative data bases.
- 45 jj) The present invention enables **sleep-stage-linked synchronisation of a clock or alarm system** or other clock or alarm system to choose the more optimal alarm time for awakening based on user's need to awaken versus sleep cycles of minimal adverse
- 50 impact during awakening (i.e. avoid awakening during deep-sleep when longer sleep recovery may be evident, if prediction or eventuation of REM sleep stages are close-by
- 55

that can enable less disruptive awakening without compromising overall sleep or awakening time requirement).

kk) The present invention provides a **minimal configuration comprising** of a single headband sensor (**Somfit**) capable of monitoring brain signals capable continuous monitoring of **sleep parameters (EEG, EOG, EMG)** and automatic online processing to enable the determination of sleep stages (i.e. REM, non-REM stage 1, non-REM stage 2, non-REM stage 3 and stage 1).

ll) The present invention further provides the options of **monitoring room light detection (i.e. LDR)** and/or **breathing sounds (i.e. snoring)** monitoring and/or sleep hypopnoea monitoring via a range of other optional sensors (including any of or any combination of RIP, PVDF, piezo-electric sensor or other thoracic and/or abdomen belt; nasal cannula sensor; airflow sensor)

mm) The present invention further provides the option to have the single sensor strip incorporating an embedded **reflective oximeter sensor (LED with LDR)**, whereby the oximeter sensor can be attached or embedded in the forehead sensor providing plethysmography and oximetry with associated outputs (including any of or any combination of PTT, pulse-wave oscillatory amplitude autonomic markers of obstructive apnoea, pulse wave amplitude, pulse arterial tone). Whereby other sensors can include a "drop-down" (i.e. connects to **Somfit**) airflow sensor (i.e. PVDF, thermo-coupler, thermistor, nasal cannula etc.), whereby said sensor(s) can enable monitoring of sleep disordered breathing including apnoea, hypopnoea, mixed apnoea/hypopnoea.

eLifeWATCH overview

A wearable wrist-based monitoring device incorporating a gyro-meter or positional tracking system capable of inputting to automatic incorporating means of computing gait, walking characteristics (including Parkinson's onset) including automatic analysis of long-term trending of automatic gait analysis capable of detecting fluidity of walking and manoeuvring, along with predictive assessment of associated outcomes (i.e. hint to see GP or specialist based on detected trends that may have further implications) of individual's walking (gait) such as inability to naturally swing arms with walking stride, short or shuffling steps and difficulties (i.e. change of motion of limbs and stride associated with manoeuvring corners). Any combination of measures such as GPS, gyro-meter, motion, location data can be analysed as a marker of predefined events or health condition onset, or incidence (Figure 1 RHS, [5]).

An example embodiment of watch-body modular sensor platform system incorporating any of or any combination of photo-plethysmography, oximetry plethysmography, temperature, spring-pressure-loaded or fixed sensor electrophysiological monitoring (i.e. conductive rubber), means of galvanic skin resistance (GSR) monitoring, Doppler ultrasound monitoring, light detection monitoring, microphone monitoring (**Figure 7**), a smart-phone system [1] with SAAS including Cloud-computing services interface and other connectivity options (i.e. including simultaneously interconnecting with additional communication networks, systems or other interconnectivity options including WWW, IP, LAN, WAN, supplementary/companion monitoring/sensing or computing systems, SAAS including Cloud-computing services or NAS, peer to peer connections etc.) and range of embedded sensors, applanation tonometry monitoring, Doppler blood-flow [3], PPG, temperature, GSR, pedometer/accelerometer, position, metabolism/calorie-burn tracking (**Figure 7, Figure 9, Figure 13**).

- Whereby said means of GSR can include incorporation of a plurality of non-polarising electrodes applied to skin surface with a small constant current (i.e. 3 to 5uV), whereby electrical resistance of palmar skin is proportional to the voltage potential developed between said electrodes.
- The resistance is mainly due to the semi-permeable nature of the sweat glands and associated epidermis electrical properties.
- Sleep and wakefulness periods generate different electrical properties which can be tracked as a surrogate or contributory measure for sleep and wake state determination.

- An option of the present invention's GSR approach includes switching or alternating the direction of the small constant current between the electrodes in order to minimise electrode polarisation effects.

5 Example embodiment of watch-body modular sensor platform system incorporating DOPPLER ULTRASOUND MONITORING and/or TONONOMETER MONITORING detection system. Interchangeable back section (screws, pressure fits or rotational screw rear-cover fit; rubber seals can ensure water-proofing or water-resistance capability) (**Figure 9**).

10 eLifeBUDS overview

Ear-bud (earphones) worn monitoring device with combined sleep, health and fitness incorporating a range of physiological parameter monitoring sensors including GSR, temperature, pulse, motions and/or energy/heat profile **characterisation for enhanced calorie burn** determination (**Figure 1 LHS, [3]**).

eLifeKIT overview

- eLifeKIT provides a range of wearable or applied monitoring systems capable of working individually or as part of a cluster of interconnected systems across a common framework and health management system platform, enabling personalised health management system framework, based on a compatible health tracking and management technology;

MULTIPOINT TIME-SYNCH MONITORING (MTM) SYSTEM overview

25 **Incorporating a multipoint time-synchronisation monitoring (MTM) system** capable of automatic online characterization (clock drift, offset, stability) of clock properties (i.e. drift, offset, stability) along with the calibration of the said timing characteristics by way of continuous tracking and compensation where required of all associated clock-synchronisation systems, using any combination or phase locked or open-loop control approaches. MTM incorporates **calibration**
30 **modes and corresponding compensation** modes to **minimise online or data reconstruction**
time-alignment errors across disparate transmission medium or multiple, simultaneous
monitoring devices or systems, of a subject at any time or under varying monitoring/
communication conditions. MTM can be deployed across a disparate group of monitoring systems and communication networks with the adoption of **free-running, master-slave or multi-**
35 **modality timing reference approaches**, in order to achieve minimal data acquisition misalignment with precision of time-clock synchronisation of more interrelated monitoring systems ranging from **atomic-clock accuracy** or as required in accordance to accuracy ranging from and reduction of associated phase or data alignment errors applicable to special-purpose or **specific applications**
or requirements.

40 eLifeSLEEP overview

-the present eLifeSLEEP invention enables true sleep monitoring and tracking with the incorporation of a head applied (i.e. Somfit) system capable of monitoring principal sleep parameters for the investigation of sleep and sleep related disorders with a single small electronic device easily applied (i.e. magnetically) and disposable self-adhesive (avoids cross infection or need for pressure
45 application to an individual's head or forehead).

eLifeCHEST/eLifeSCOPE overview (chestband) (**Figure 5[3];[4]; Figure 32; Figure 33**)

50 **Chest-worn monitoring device** with stethoscope sleep and wake breathing sound, central versus obstructive apnoea/hypopnoea and other automatic sleep disorder tracking capabilities (**Figure 1 LHS UPPER [7]**). **Chest-worn monitoring device with combined sleep, health and fitness**

incorporating a range of physiological parameter monitoring sensors including stethoscope sound monitoring with online automatic breathing disorder determination and tracking, reflective plethysmography oximeter and related outputs, photo-pulse, energy/heat profile characterisation for enhanced calorie burn determination (with option of monitoring spatiotemporal dynamics of body-heat emissions using time-gated NFIR analysis) for enhanced calorie burn determination.

The present invention further comprises of obstructive versus central apnoea discrimination by way of correlating respiratory movements with respiratory effort, whereby respiratory effort can be determined by EMG and/or pulse transient oscillatory amplitude measures and/or using thoracic and/or abdominal respiration circumference movement) (Figure 1 LHS UPPER [7]).

Adaptive Physiological-Body Network (APM) overview

The incorporation of an adaptive physiological-body monitoring (APM) system, enabling a group of mobile companion (i.e. interconnection compatibility) monitoring systems to be automatically reconfigured in terms of data-acquisition, physiological parameter data-acquisition-linked system or network properties or intercommunication properties, resources and/or parameters, information, communication and associated data-prioritisation, and other available processing system or communication system resource(s) allocation, usage and/or shared resources across devices, methods, systems and networks or interconnectivity arrangements (i.e. memory storage, buffering, etc.) in accordance to available resources or monitoring and/or communication conditions and/or available communication mediums, networks or other interconnectivity options (including simultaneously interconnecting with additional communication networks, systems or other interconnectivity options such as WWW, IP, LAN, WAN, supplementary/companion monitoring/sensing or computing systems, SAAS including Cloud-computing services or NAS, peer to peer connections etc.) and the and/or communication pathways (i.e. wireless connectivity) at any point in time, in order to accommodate minimal monitoring study type requirements (i.e. professional medical level or consumer level study type, format and criteria) in order to minimise risk of data loss (such as during wireless connectivity degradation or disruption).

The APM system adopts a substantially enhanced degree of data-acquisition/monitoring/sensing system resource and communications "elasticity" for improved system reliability and data dependability by enabling adaptation of automatic compensation of changing or unpredictable monitoring conditions such as subject's body shrouding of wireless communication pathways, associated with wearable-monitoring devices.

eLifeBAND (MOBILE DEVICE & INTEGRATED SENSOR ARMBAND) overview

An armband-worn metabolism-monitoring device such as a mobile phone-case with combined health and fitness monitoring capabilities, incorporating a range of sensors particularly useful for determination of an individual's energy exertion associated with estimating or predicting an individual's metabolic rate (calorie burn) related to exercise effort, incorporating measures based on characterisation of the spatiotemporal dynamics of body-heat emissions (i.e. time-gated NFIR analysis) for enhanced calorie burn determination, whereby such means can include any number and combination of temperature sensor physiological sensing or 3-dimensional infrared heat-mapping imaging capabilities. Heat dissipation can be measured using more sophisticated means such as infrared sensor enabling body-heat dispersion and emission characterisation enabling physiological temperature as well as temporal special dynamic heat imaging for more comprehensive and precise modelling of metabolism and associated calorie burn rates (Figure 1 LHS UPPER [9]).

A phone-case incorporating metabolism-monitoring capability comprising range of sensors and associated multivariate analysis to automatically compute and indicate online (i.e. via mobile App or wearable device indicator with wireless, dynamic-data exchange or exchangeable

electronic module compatibility or interface capabilities.) metabolism or calorie burn measures (Figure 1 LHS UPPER [9]) including spatiotemporal dynamics of body-heat/energy emissions (i.e. time-gated NFIR analysis);

eLifeDOPPLER overview

5

The present invention provides the deployment of Doppler-watch tracking (DWT) system comprising of monitoring any of or any combination of a subject's wrist, ankle, arm, and/or other subject limb or body extremity for any of or any combination of the following Doppler and/or ultrasonic vascular or cardiac characteristics, based on periodic or continuous monitoring of any of or any combination of:

- 10 -Dual channel - radial artery and ulnar artery;
 -Single channel - radial artery and ulnar artery;
 -Single channel - ulnar artery;
 -Single channel - radial artery;

15 eLifePULSE (applanation tonometry) overview

The present invention comprises of the deployment of an **attachable/wearable/applanation tonometry (AAT)** which can comprise of a watch, bangle or other device incorporating a means of periodic or continuous applanation tonometry (Figure 37) whereby said means applies a
 20 **pressure sensor capable of measuring and/or characterisation of radial and/or ulnar artery** (Figure 38) or other body artery pulsation characteristics (pulse wave-shape). Moreover the present invention can further computes the pulse wave analysis (PWA) comprising recording a period (10 seconds for example) of arterial pressure in order to derive the associated ascending
 25 **aortic pressure wave, from which a number cardiovascular measurements such as central aortic systolic pressure, aortic augmentation index, and the central pulse pressure can be derived, and/or other cardiac functional measures.**

Title: Somfit/Somfit

Patent Background: Circadian Rhythm Background

- 30 The human circadian rhythm is an endogenous (*self-sustained* or "*in-built*") biological process with an entrainable physiological oscillation (rhythm) of approximately 24 hours.

A typical circadian clock could be represented by the following 24-hour cyclic sequence:

- 35 00:00 Midnight - start of sleep period
02:00 - deepest sleep period
04:30 - minimal body temperature
06:45 - blood pressure undergoes most rapid pressure increase
07:30 - cessation of melatonin secretion
08:30 - likely bowel movement
 40 08:30 - testosterone secretion at maximum
09:00 - likely bowel movement
10:00 - alertness peak
12:00 noon
14:30 - coordination at premium
 45 15:30 - reaction time most responsive
17:00 - cardiovascular efficiency and must strength at maximum
18:30 - blood pressure peak
19:00 - body temperature peak
21:00 - commencement of melatonin secretion
 50 22:30 - suppressed bowel movements
00:00 Midnight - start of sleep period

02:00 – repeat of typical circadian cycle per above

The circadian clock cycle comprises of the following 3 aspects:

1. A free-running period (referred to as tau or the Greek letter "τ") with an approximate period of 24 hours;
2. An entrainment characteristic which can be reset or adapted (entrainment) by way of exposure to external stimuli such as light or temperature changes. Examples of a person's entrainment or adjustment of their circadian clock are when a person suffers unexpected or unanticipated sleep urges resulting from jet-lag or other disruptions of conventional sleep routines. For example in cases where a person's biological clock (circadian clock or rhythm) body has not yet adjusted or synchronised with the local time or current routine sleep/wake cycle this can occur following international travel, across different time zones, or examples such as adjusting during or following to shiftwork, or as a result of late nights during demanding study period or other events;
3. A "temperature compensation" characteristic, where the body maintains a certain cyclic nature over a range of physiologic temperatures, regardless of changing kinetic (temperatures and different thermal energy of molecular processes in cells).¹

The circadian clock has a profound impact upon metabolism, general well-being and sleep/wake regulation

- An association has been demonstrated between shift work and metabolic disease ²;
- Studies have associated sleep time and circadian disruption with a wide range of disorders such as type 2 diabetes, cancer and gastrointestinal disorder ²;
- "Social Jet Lag" (i.e. the habit of altering sleeping times on weekends has been associated with increased body weight) ²;
- The circadian clock regulates energy homeostasis, and its disruption, similar to social jetlag, can contribute to weight-related pathologies ²;
- circadian factor plays an important role in sleep quantity; i.e. length is not dependent of on the homeostatic sleep factor, but dependent on whether you sleep in accordance to your own circadian sleep cycle (i.e. the circadian sleep cycle factor is more predominant than sleep homeostasis (sleep-urge) ²;
- therefore from a practical or productivity perspective, an understanding and guidance in terms of the interaction and relationship between an individual's homeostatic and circadian processes can be an important aspect as it is important to remain awake for a significant amount of time in order to achieve high quality sleep, and also to have regular bed and rise times to achieve stable sleep duration (i.e. more time in bed to sleep or more sleep is not necessarily better quality sleep but working with versus against your circadian clock can result in the most efficient and effective use of sleep time) ²;
- the homeostatic sleep factors accumulate according to prior wakefulness, i.e. the homeostatic factor (sleep urge) increases the longer you are awake. Consequently this factor is believed to be of major importance for sleep quality. For example, the longer you remain awake the deeper the following sleep episode will be, as marked by an increase in slow wave EEG activity ²;
- In contrast the circadian rhythm fulfills an important role in terms of sleep quantity. For example, the duration of sleep is mainly determined by when you go to bed.

INVENTION DESCRIPTION

Method or device whereby a subject can control a system's indications or associated display information (i.e. **tap or gesture or touch** via capacitive surface detection or touch via resistive surface detection etc.) *to toggle or switch between display modes reflective of brain-based sleep parameter markers or associated indices representative of a subject's monitored sleep status and measures reflective of other fitness and health monitored measures or environmental sensing.*

The present invention provides a method or device whereby a subject can control a system indications or associated display information to toggle of switch between display modes reflective of monitored sleep measures or indices (i.e. brain-signal linked or EEG-signal based on any of or any combination of EEG, EOG and/or EMG signal-based sleep parameter measures, as well as health and fitness measures (such as accelerometer or motion-based measures and/or as also further detailed elsewhere in this document including “physiological or psychological monitoring including” and/or “Environmental sensing” as detailed elsewhere in this document and below;

-Where in one embodiment of the present invention the subject with a wearable device (such as but not limited to headband (Figure 25 [7]); universal –bipolar sensor (Figure 23); oximeter (Figure 22); legband (Figure 24); wristband (Figure 2), ankle-band (Figure 2), armband (Figure 2), earphone(s) (Figure 14), chest-band (Figure 5[3];[4]; Figure 31), other attachable device or watch) can be used to measure and enable rhythm, synchrony, fluidity, motion, degree of various motions, and also interrelationship with other limbs such as wrist or arm motion characteristics;

-Where in one embodiment of the present invention the subject with a wearable device (such as but not limited to wristband, ankle-band, armband, earphone(s), chest-band, other attachable device or watch) can automatically or manually exchange data with a data-interface compatible device (i.e. but not limited to wireless subject-applied head EEG, EOG and/or EMG signal-based sleep parameter monitoring system) in a way that enables a subject to automatically track sleep measures, indices and overall sleep quality (i.e. including measures such as wake after sleep onset, sleep efficiency, REM sleep amount, deep-sleep amount, sleep architecture fragmentation or normality, along with other optionally and user or health-carer programmable accessible prognostic, diagnostic and subject personal-care management measures enabling sleep-debt, sleep architecture, sleep requirements to be easily accessible and trackable based on each user's degree of required simplicity, complexity and sophistication;

-Where in one embodiment of the present invention the subject with a wearable device (such as but not limited to headband (Figure 25; Figure 3; Figure 4), wristband (Figure 2), ankle-band (Figure 2), armband (Figure 2; Figure 32; Figure 33), earphone(s)/earbuds (Figure 14), chest-band (Figure 31), other attachable device or watch (Figure 6; Figure 7; Figure 9; Figure 13) can automatically or manually exchange data with a data-interface compatible device including an alarm clock or mobile phone or other communication-compatible device. For example, information that can be exchanged includes information relating to user/patient coaching (recommendations or guide for improved health or current health status), including indicators capable of recommending sleep requirements based on any combination of daily health, fitness/activity and sleep-monitored parameters (including but not limited to EEG, EOG and/or EMG signal-based sleep parameter measures), and/or environmental monitoring inputs (i.e. temperature, humidity, air pollutants, air-borne pollen or other air contaminants etc.).

Somfit minimum configuration

-the present invention provides monitoring capabilities capable of any of or any combination of physiological channels including, but not limited to, EEG/P1, EEG/P2, EEG/Pz, EOG/L/P7, EOG/R/P8, patient posture or if possible multi-axis combined patient position and patient motion, infra-red breathing detection, microphone sound breathing monitoring, light detection (i.e. light detection resistor), optional reflective oximeter, optional wireless interconnectivity with any of or any combination of sensors required for any of categorisation formats applicable to type 1 to 4 study types or levels as further detailed herein.

The present invention comprises of physiological or environmental monitoring including any of or any combination of:

-Sound monitoring; Stethoscope auscultation sensor, monitoring and automatic analysis, classification, tracking and detection capabilities; Acoustic noise cancellation system; Motion detection; REM sleep behaviour disorder (RBD); Pulse sensor integrated watch of other wrist worn device (band or bangle); Pulse wave analysis (PWA) and pulse wave velocity (PWV) monitoring and

analysis capability; PWA and PWV sensors; Pulse wave analysis (PWA) sensor measures; Ballistocardiograph; Position, locational and movement sensing and monitoring; Gait or movement tracking and characterisation of events of interest; Movement and locational information; ECG sensor(s) and monitoring; Light sensor(s) and monitoring; Breathing band sensors and monitoring; EMG sensors and monitoring; GSR; Cardiac function; Heart rate; Sleep training system; Plethysmography Oximetry; Pulse transient oscillation amplitude measures; Temperature; Energy-exertion/metabolism-monitoring (EM) as a surrogate calorie-burn measure; Sleep Parameters; Physiological and/or Sleep and/or Wake Markers; Sleep Parameters; Sleep Architecture Measures; Environmental sensing; "dynamically-linked capabilities"; Psychological states;

Whereby the present invention comprises sensing, monitoring, data-acquisition, signal processing, analysis, storage, and information access including the online automatic characterisation of a subject/individual's physiological, neurological, nervous system, movement system, muscular system, psychological, pathological, states, events of interest and/or health conditions including any of or any combination of the following:

Rapid Eye Movement (REM) Sleep Characteristics ; Sleep Disorder Classifications; Select Sleep disorders; Dreaming States; HALLUCINATION STATES; Dissociated States; Hypnosis States ; and as further outlined below and elsewhere in this patent application document.

The present invention provides *environmental monitoring or sensing comprising any of or any combination of:*

-Environmental sensing (with alarm or alert or indicator or interface to mobile device associated or messaging, email, phone automated voice message and other information or communication systems), weather elements, wind, humidity, temperature, ionisation monitoring, ionisation smoke alarm, methane monitoring, toxic gas monitoring, toxic chemical monitoring, CO2 gas monitoring, methane gas monitoring, other toxic gases, other toxic chemicals and/or thermometer, and/or "physiological or psychological monitoring including" and/or "Environmental sensing", as further detailed below and elsewhere in this document;

-Where in one embodiment of the present invention the subject with a wearable device (such as but not limited to headband (**Figure 25; Figure 4**), wristband (**Figure 2**), ankle-band (**Figure 2**), armband (**Figure 2; Figure 32; Figure 33**), earphone(s) (**Figure 14**), chest-band (**Figure 31**), , other attachable device or watch) can automatically or manually exchange data with a data-interface compatible device including a subject's room thermostat (or other communication-compatible device) capable of optimising sleep environmental conditions in accordance to a subject's preferences and/or also automatically based on environmentally monitored and/or subject-specific or biological-synchronisation characterisation (i.e. delineation of snoring partner where sound is not biologically synchronised to partner, and where option exists for automatic sleep-training feedback or notification (i.e. recommendations, hints, prognostic or diagnostic supporting data access for health-carers and the like) to offending snorer (for example only) of sleep disruption incidence(s))

-Where in one embodiment of the present invention the subject with a wearable device (such as but not limited to wristband, ankle-band, armband, earphone(s), chest-band, other attachable device or watch) can automatically or manually exchange data with a data-interface compatible device based on subject-specific or biological-synchronisation characterisation and determination, such as the delineation of snoring partner where sound is *not biologically synchronised to partner*, and where option exists for automatic sleep-training feedback or notification or adaptation, or adjustment is possible as it relates to causation of sleep disruption;

-Where in one embodiment example of the present invention the subject with a wearable device (such as but not limited to wristband, ankle-band, armband, earphone(s), chest-band, other attachable device or watch) can automatically or manually exchange data with a data-interface compatible device based on subject-specific or biological-synchronisation characterisation and determination as it relates to another person snoring (for example only) and causing sleep disruption to the user or wearer of the present invention, whereby notification includes automatic alarms (i.e. mobile phone messages, alarms, calendar entries, events and/or sleep-trainer system

and the like) or other sleep disruption deterrents applicable to recommendations, hints, prognostic or diagnostic supporting data access for health-carers or therapeutic adjustment (i.e. any of or any combination of automatic; biofeedback or manual adaptation, adjustment or reconfiguration) of user or subject wearing invention or other nearby person(s);

-Where in one embodiment of the present invention the subject with a wearable device (such as but not limited to wristband, ankle-band, armband, earphone(s), chest-band, other attachable device or watch) can automatically or manually exchange data with a data-interface can include any network connection and/or available communication mediums, networks or other interconnectivity options (including simultaneously interconnecting with additional communication networks, systems or other interconnectivity options such as WWW, IP, LAN, WAN, supplementary/companion monitoring/sensing or computing systems, SAAS including Cloud-computing services or NAS, peer to peer connections etc.).

Full-disclosure online physiological parameters

The present invention comprises of a **portable device** (i.e. mobile wireless system, wrist band, smart watch, phone, PDA, headband, head-worn apparatus, attachable or pocket device etc.) incorporating means of indicating and/or tracking any of or any combination of a *subject's sleep performance/function, sleep parameters, fitness or motion parameters, fitness or motion performance/function, health parameters and/or health performance/function*, the present invention further comprising any of or any combination of:

-*gesture activated* (i.e. tap motion, switch, finger slide, wrist shake etc.) as a means of toggling between any said parameters or performance/function measures or indices;

-wireless monitoring capability **enabling online monitoring of sleep parameters** (i.e. EEG, EMG, EOG etc.);

-full disclosure capacity of online monitoring of sleep parameters (i.e. EEG, EMG, EOG etc.); >whereby full disclosure includes means of displaying any of or any combination of **primary monitored raw data** (i.e. physiological waveform data), **secondary monitored data** (i.e. summaries of compressed data) and/or **tertiary data** (i.e. analysis transformation(s) of primary or secondary data such as, but not limited to, indices or spectral analysis, signal dynamics analysis (i.e. non-linear dynamic analysis), correlation analysis, coherence analysis, multivariate analysis, FFT and associated outputs, etc.);

-incorporation of MTM capability;

-incorporation of APM capability;

-incorporation of HDCM capability;

-synch somniscync (covered elsewhere in this patent application document);

-a wearable headband device incorporating **means of enabling full-disclosure (i.e. raw data such as any of EEG, EMG, and or EOG electrophysiological signal fluctuations**, including capability to enable bandwidth of all sleep and other neurological events including HFOs, spikes, spindles, vertex sharp waves, or other events or health conditions covered elsewhere in this document.

- incorporating means "spectral compensation" and "other compensation" in such a manner whereby EEG signals undergo analysis transformation applicable to a standardised (i.e. AASM or K&K - expand recommendations or standards) or any specific or conventional EEG electrode locations;

-*"spectral compensation" and "other compensation"* can comprise of a spectral transfer characteristics, phase transfer characteristics, signal amplitude, signal distortion, multiple signal superposition, capable of compensating for neural source locations otherwise attenuated by non-obtrusive monitoring constraints (i.e. forehead positions below hair- line such as Fp1, Fp2, F7, F8 and/or Fz) versus standardised positions such as (but not limited to) EEG locations traditionally utilised for EEG sleep monitoring parameters (i.e. including F4 - M1; C4 - M1; O2 - M2; with backup monitoring electrodes including F3 - M2; C3 - M2; o1 - M2 sleep monitoring electrode locations).

- whereby said EEG **signal compensation transfer characteristics** incorporate a means of emulating the EEG signal characteristics similar to another "designated alternative location" or "traditional location",

-whereby said determination of a "**designated alternative location**" can comprise of forward or inverse source localisation computations;

-whereby said determination of a "**designated alternative location**" can comprise of transfer characteristics based on empirical data studies investigating the comparative EEG signal

characteristics of different EEG locations during sleep states in order to enable the relationship and associated transfer function required to convert;

-whereby the EEG signal of a **first monitored location** can be processed by a transfer function capable of generating (modelling) a data set applicable to the approximate data set values of a second monitored EEG location;

-whereby said transfer function is modelled in order to **most precisely simulate** data of the second location applicable to difference sleep stages (i.e. **AASM or R&K sleep scoring recommendations**);

- The present invention enables a means of **full disclosure online signal monitoring**, sleep stage analysis, ongoing (whereby means includes the capability to access real-time sample by sample or regularly *sampld real-time monitored information in order to compute measures indicative of continuous, uninterrupted, raw-data*, versus only summaries or compressed versions of data, in order to enable diagnostic quality and industry standard (i.e. AASM and/or R&K scoring recommendations of human sleep, respiration and other related aspects) and along with the capability to generate accurate measures of monitored sleep variables, derive measure of sleep progress, performance, and status (i.e. and other sleep measure, but not limited to, as further outlined in section "Physiological and/or Sleep and/or Wake Markers;" and other sections detailed elsewhere in this document) and also enable capability for online remote or local online analysis.

-whereby said analysis and monitoring capabilities can be updated online or in virtual real-time **so that an individual can read a display indicator** (including wireless linked to sleep parameter (i.e. EEG, EMG and/ or EOG) monitoring system) at any time during the subject's sleep or associated wake states using a patient worn or mobile or remote computer device or information access system;

The present invention enables a wearable mobile monitoring system comprising of a means of *wake and/or sleep health monitoring* and management, the said means comprising any of or any combination of (but not limited to) descriptions presented elsewhere in this patent application document including a) Forehead applied physiological monitoring sensors, b) Re-usable or disposable sensors, c) Reusable or disposable sensors automatic reload dispenser device, d) Continuous online sleep parameter (EEG, EOG, EMG) monitoring and sleep analysis, e) Wearable monitoring, f) Exchangeable/interchangeable part with dynamic data exchange, g) Infrared respirometry or body heat flux monitoring, h) Body position and/or position and/or movement, i) Movement and/or motion, j) Oximeter, k) PPG, as further outlined here:

a) Forehead applied physiological monitoring sensors

- the present invention enables the monitoring of 1 or more forehead applied physiological monitoring sensors with option of deriving a plurality of sleep parameters from any one or more said sensor(s);

- option whereby said "sleep parameters" monitoring includes any of or any combination of EEG, EOG, EMG, and/or ECG;

- option whereby said "sleep parameters" includes any of or any combination of those further detailed under sub-headings section headed "

Title: eLifeKIT:" and "Title: eLifeCHEST/eLifeSCOPE (chestband) (Figure 5[3];[4]; Figure 16: Figure 31)," described elsewhere in this patent application document;

-option of forehead applied electrodes which can comprise of partial or total head, forehead and or face coverage;

- option of self-adhesive forehead applied strip, whereby pressure interface in order to attain a quality electrode connection for monitoring of sleep parameters from patient/subject's forehead is not required;

-option of disposable self-adhesive forehead applied strip;

b) Re-usable or disposable sensors

-the present invention provides the option of disposable self-adhesive forehead applied strip with electrode dispenser device capable of automatically discarding old sensor and replacing with new sensor;

c) Reusable or disposable sensors automatic reload dispenser device

- the present invention provides the option of disposable self-adhesive forehead applied strip with electrode dispenser device capable of automatically discarding old sensor and replacing with new sensor, whereby said sensor dispensing device is part of packaging system of a pack of new self-adhesive sensors;

- the present invention provides the option of disposable self-adhesive forehead applied strip with electrode dispenser device capable of automatically discarding old sensor and replacing with new sensor, whereby said sensor dispensing device is part of packaging system of a pack of new self-adhesive sensors, and whereby said dispensing device comprises any of or any combination of (but is not limited to) a) enabling replacement of monitoring sensor from forehead monitoring strip, b)

- sensor injector and eject process that removes and safely stores or contains used sensor while or subsequently applying new sensor, with option of single action push, discard old sensor and reload new sensor;

- where, for example forehead sensor strip can be push loaded unto and then retracted from the said sensor dispenser device as a means (i.e. a spring tensioned dispenser mechanism can push new replacement sensor onto forehead sensor holder device, while used sensor at the same time is peeled off and discarded. The reloaded sensor and forehead sensor can then be ejected with single depression of ejection button /lever in order to access reloaded sensor system.

> In this way a package of disposable electrodes can be loaded into a sensor reloading device which in a single push action enables a used sensor to be peeled away from Somfit device and discarded, while new sensor's backing paper can be peeled away ready for adhesion to Somfit device, followed by a further spring-loading mechanism being activated at the downward extremity during insertion of the Somfit insertion into sensor dispenser device, in order for the new sensor (backing paper now peeled back) to now be pressure applied via a sensor spring-loaded mechanism, and finally ejection of the Somfit from the sensor dispenser device can result in a loaded sensor with the option of a quality control code transfer from the dispenser device verifying operation and transmitting a warranty violation and risk code where counterfeit sensors are being used;

>The present invention provides continuous, uninterrupted sleep parameter monitoring including (but not limited to) any of or any combination of EEG, EMG, EOG monitoring for online accurate, continuous, uninterrupted sleep/wake hypnogram and associated sleep quality determination and coaching, and/or intelligent clock interface (i.e. wrist watch or alarm clock settings);

d) Continuous online sleep parameter (EEG, EOG, EMG) monitoring and sleep analysis

> the present invention provides continuous EEG monitoring with associated analysis capable of the determination of epoching (time period segmentation) and epoch-based sleep stages (i.e. such as but not limited to wake, N1, N2, N3, REM) and/or sleep events (i.e. such as but not limited to spindles, k-complexes, vertex-waves, alpha-bursts, body movements, arousals etc.), and/or sleep measures (i.e. not limited to measures covered elsewhere in section including but not limited to) or indices (i.e. but not limited to sleep efficiency/SE, wake after sleep onset (WASO), respiratory event related arousals/RERA, therapeutic event related arousals/TERA, apnoea/hypopnoea index/AHI, sleep disturbance index/SDI, respiratory disturbance index/RDI, sleep fragmentation, percentage and amount of each sleep stage, total sleep time/TST, sleep hypopnoea, sleep delay syndrome delay factors, residual daytime sleepiness/RDS, arousal index/AI, degree and other sleep measures such as but not limited to sleep disorders or other events of interest (i.e. including but not limited to events of interest "**DENIFITION**", as described elsewhere in this document);

-whereby said determination of epoching comprises of segmenting data in blocks of time such as 30 seconds;

-whereby said epoch-based sleep stages determination can comprise of local (micro-processing device or DSP system forming part of monitoring sensor or device) and/or available communication mediums, networks or other interconnectivity options (including simultaneously interconnecting with additional or supplementary communication networks, systems or other interconnectivity options

such as WWW, IP, LAN, WAN, supplementary/companion monitoring/sensing or computing systems, SAAS including Cloud-computing services or NAS, peer to peer connections etc.).

e) Wearable monitoring

- > the present invention wearable monitoring (including option of mobile wireless interconnected) devices or associated system van comprise of any of or any combination of example monitoring embodiments per Figure 1 to Figure 94:

f) Exchangeable/interchangeable part with dynamic data exchange

The present invention incorporates a means of connectivity and/or exchangeable parts between two or more wearable devices/systems as a means on enabling information access applicable to sleep health as well as general health, the invention further comprising any or any combination of:

-the said "means of connectivity" can include any of or any combinations of connectivity with available communication mediums, networks or other interconnectivity options (including simultaneously interconnecting with additional or supplementary communication networks, systems or other interconnectivity options such as WWW, IP, LAN, WAN, supplementary/companion monitoring/sensing or computing systems, SAAS including Cloud services or NAS, peer to peer connections etc.), various data-communication channels and/or different mediums, cellular network, optical communications network, Wi-Fi, blue-tooth, satellite, SMS, copper communications network, Wi-Fi, pager alerts, automatic phone alerts, calendar updates, social or business information interfaces, etc.

-the said "exchangeable/interchangeable part" can comprise of an electronic element or component of a first wearable device which has means of attachment (i.e. but not limited to magnetic interlocking, mechanical interlocking, adhesive interlocking, material or matter interlocking etc.) or interconnectivity with a second wearable device and/or other nearby device,

-the said "means on enabling information access applicable to sleep health as well as general health" can include combining, sharing, exchanging indications, displays, data storage, data processing, deriving indices, based on sleep monitored parameters or associated measurement derivations (i.e. such as EEG, EOG, EMG, breathing sound, room or environmental sound, room light conditions, airflow, reflective plethysmography oximetry and associated outputs (pulse wave amplitude/PWA, pulse arterial tone/PAT, Pulse arterial tone/PTT, pulse-wave oscillatory amplitude autonomic markers of obstructive apnoea to enable central versus obstructive discrimination (i.e. the increased activation of breathing muscles evoke additional blood-flow, which in turn appear as discernible oscillatory or amplitude fluctuations which can be detected using signal morphological, spectral and other events extraction techniques), along with other monitored sleep parameters or associated measures outlined elsewhere in this document) and other health monitored parameters or associated measurements;

-whereby the present invention can enable "separate or combined sleep and/or other health and/or fitness measures and/or information" to be indicated or displayed as part of any wearable devices (i.e. wrist device, watch, clock etc.);

-whereby said "means on enabling information access applicable to sleep health as well as general health" can include dynamically exchanging (i.e. **dynamic data exchange/DDE**) data comprising of any said "separate or combined sleep and/or other health and/or fitness measures and/or information", or other health status or progress;

g) Infrared respirology/thermal airflow or body heat flux monitoring

The present invention can incorporate one or more "attached infrared" breathing monitoring sensor(s) and/or skin heat flux monitoring centre(s) (body energy dissipation via skin surface, enabling measure of energy or calories burning/metabolic-activity of subject);

h) IR sensor/lens

In one embodiment the present invention can comprise of one or more infrared sensors with option of associated lens in a manner whereby the sensor is incorporated as part of a forehead sensor that can be located and the sensor directed to detect a subject's breathing and associated breathing disorders;

IR lens

The said "infrared sensors" can be combined with one or more lens systems capable of focussing respiration heat change associated with subject's oral and/or nasal breathing inspiration and expiration towards direction of infrared sensor;

IR thermal

The said "infrared sensor" can comprise of thermal sensors including any of or any combination of (but not limited to) photo diode, photo conductive, photovoltaic, pyro-electric types;

Photonic

The said "infrared sensor" can comprise of photonic (photo-detectors) including any of or any combination of (but not limited to) charge coupled device or active pixel sensors (CMOS);

h) Body position and/or position and/or movement

The present invention can incorporate one or more subject/patient body/position sensors;

i) Movement and/or motion

The present invention can incorporate one or more movement and/or motion sensors (i.e. but not limited to one or more axis accelerometers) as detailed elsewhere in sections titled "Position, locational and movement sensing and monitoring";

j) Oximeter and/or PPG

-The present invention can incorporate one or more attached photo-plethysmography (PPG) sensor(s), and/or reflective oximeter(s) with the option of plethysmography function, as detailed elsewhere in sections titled "Plethysmography Oximetry and/or photo-plethysmography (PPG)";

k) Forehead or, head or body attached thermal airflow monitoring

-wearable sound monitoring (i.e. but not limited to **forehead or, head or body attached microphone**) incorporating combination of breathing sound (i.e. but not limited to microphone) and other physiological signal (i.e. **thermal airflow monitoring** including, but not limited to infrared sensor capable of tracking airflow temperature changes related to breathing subject/patient) as a means of discriminating between subject/patient/user of interest versus other person (i.e. but not limited to sleeping partner snoring);

-the present invention combines one or more wearable monitoring systems (i.e. but not limited to head attached or applied device with sound or thermal monitoring sensor(s)) and/or one or more **microphone sensors capable of distinguishing of differentiating two or more sound sources** in order to **detect breathing sounds of one or more subject(s)/patient(s)/individual(s)/user(s)**;

-whereby means of monitoring breathing sounds (i.e. a measure of monitoring any of or any combination of sound, airflow, thermal breathing characteristics related to inspiration and/or expiration and/or aspirating and/or nasal aspirating and/or oral aspirating of a subject/patient/user) can incorporate **tracking breath for variations in magnitude or cessation of breathing** in a manner where hypopnoea (i.e. such as but not limited to reduced breathing for a period) and/or **where apnoea** (cessation of breathing for a period) and or **hypoxia** (i.e. such as but not limited to sustained reduction in breathing), along with other sleep breathing disorders;

-whereby such monitoring can incorporate a means of determining one or more sleep/wake states or stages of said subject/patient/user;

l) Forehead sensor with multifunctional physiological parameters applicable to diagnosis and prognosis of a subject/patient's true homeostatic sleep/wake, circadian clock and associated sleep disorder factors

-the present invention provides a **wearable forehead sensor** (one or more sensors and/or electrophysiological electrodes) strip sleep monitoring system incorporating means of monitoring any of or any combination of sleep parameters (i.e. **EEG, EOG, EMG**), along with any of or any combination of (but not limited to) monitoring, determination and/or tracking of:

- **sleep disordered breathing** monitoring and associated event determination (i.e. microphone and/or thermals respiration determination – i.e. infrared breathing detection), and/or environment light sensing (i.e. light dependent resistor enabling computation of sleep efficiency and other measures),

5 - **body temperature measures** applicable to estimation or determination or contribution to circadian clock cycle computation;

- **one or more “clock” determinations** (including circadian clock (CC) factors (as well as any of or any combination of a subject/individual’s travel, work, social, relation, schedule (i.e. clock, calendar, itinerary, agenda, requirements for any of or any combination of (but not limited to) sleep/wake, 10 work, social activities, leisure, relaxation, sports or exercise activities; whereby “clock” refers to daily or weekly schedules according to an individual’s social schedule (i.e. “social clock) or work schedule (i.e. work clock) or travel agenda/schedule (travel clock) etc.;

- **environmental time determination** (i.e. via information access to inbuilt GSM, GPS or interconnectivity with mobile device, clock, clock settings, clock or time applications etc.);

15 -monitoring, determination and/or tracking of activity or motion detection as a measure of actigraphy and/or patient position;

- **circadian clock cycle or offset and other factors** with relation to environmental clock, time-zone conditions, and/or other applicable subject/user time factors (i.e. via calendar or schedule or itinerary information access to enable determination of social clock, work clock, leisure clock, 20 sleep/wake clock and outcomes **including offset with CC** along lack or synchronisation or implications of **sleep quality risk** (i.e. due to asynchronous relationship with CC), **sleep urge risk** (i.e. result of previous sleep/wake historical information), sleep duration versus sleep quality risk as a result of CC offset factor, etc.);

- **sound envelope analogue signal or digital data processing capabilities** (i.e. ability to track sound envelope where memory storage and processing requirements are otherwise prohibitive in terms of processing higher bandwidth sound waveform signals, for example, (i.e. as a data reduction mechanism for sleep breathing disorder monitoring whereby sound envelope can be extracted before or after data acquisition, signal processing or memory storage;

- **with further option of the incorporation of a forehead oximeter** (including option of 30 **plethysmography reflective** with capability of deriving oximeter outputs including any of or any combination of pulse wave amplitude (PWA), pulse arterial tone (PAT), characterisation of plethysmography amplitude as a means of distinguishing obstructive (i.e. generation of oximeter plethysmography waveform oscillation corresponding to autonomic disruption evident during obstructive sleep apnoea autonomic disturbances),

35 - **Wearable forehead strip sleep monitoring system incorporating an active circuit element** able to be interchanged between wrist mounted monitoring system (i.e. containing motion, position, stride (including interaction with mobile phone motion detection as a measure of stride versus arm motion symmetry and/or synchronicity applicable to movement or neural disorders such as Parkinson gait dysfunction);

40 - **characterisation of subject motion, body movements, body vibrations, by using multi-axis accelerometer** (i.e. whereby any one (i.e. spectral segmentation in accordance to primary energy band of various monitoring goals such as gait/fall/cardioballistogram; stride symmetry or synchronicity between and of subjects extremities or limbs and body) or plurality of single or multi-axis accelerometer sensors can monitor and determine any of or any combination of subject/ patient 45 physiological or movement monitoring including **any of or any combination of capable of:**

1) cardioballistogram such as via sensing of cardiac pulse variations;

2) subject/patient body position/posture;

3) subject gait or stride characteristics including but not limited to stride symmetry or synchronicity between and of subjects extremities or limbs and body applicable to activity or disorder tracking (50 i.e. Parkinson’s movement disorder);

4) determination of subject/patient walking or jogging or running steps;

6) fall/trip/stumble determination;

55 -whereby means of “monitoring and/or characterisation of subject motion, body movements, body vibrations, by using multi-axis accelerometer” can comprise any of any combination of:

>FIRST STEP COMPRISING SUBJECT MONITORING with one or more physiological signal channels, including those sensor monitoring channels for motion detection (i.e. accelerometer with one or more axis.), pressure sensor channels such as measurement of cardioballistogram, pulse or tonometry vascular pressure changes;

5

>SECOND PROCESS STEP (SENSOR SIGNAL PROCESSING) involving the signal processing (i.e. amplification and/or filtering of accelerometer) of one or more signals from a single or multi-axis accelerometer (i.e. 3 or more axis but not limited to);

10

>THIRD PROCESS STEP (ACQUISITION) involving acquisition (i.e. by way of analogue to signal acquisition or acquisition of digital data in accordance to sensor format or requirements);

>FOURTH PROCESS STEP(S) comprises any of or any combination of analyses including (but not limited to) the analysis options present elsewhere in this document including but not limited to provisions further detailed under *Figure 1 to Figure 99, but particularly as it applies to examples of ANALYSIS VARIANTS INCLUDING THOSE APPLICABLE TO GAIT OR MOTION*

ANALYSER INCLUDING PARKINSON ONSET SYMPTOMS AND/OR COMBINED SBD SLEEP BEHAVIOUR DISORDER DETERMINATION (Figure 45 [5]): excessive motion associated with REM without atonia as with during RBD, or associated with restless legs syndrome, or with muscle processing disorders such as fibromyalgia per **Figure 75 [20]:[22]**; also as further detailed under heading "Motion detection and/or actigraphy", "REM sleep behaviour disorder (RBD)", "Pulse sensor integrated watch of other wrist worn device (band or bangle)", "Pulse wave analysis (PWA) and pulse wave velocity (PWV) monitoring and analysis capability", "PWA and PWV sensors", "Pulse wave analysis (PWA) sensor measures", "Ballistocardiograph", "Position, locational and movement sensing and monitoring", "Movement and locational information", "Gait or movement tracking and characterisation of events of interest", covered elsewhere in the "eLifeCHEST/eLifeSCOPE" section of this document.

>ADDITIONAL FOURTH PROCESS STEP (ANALYSIS - SPECTRAL OPTION) incorporating FFT or other monitored spectral, morphological/pattern, signal dynamics (i.e. NLDB), coherence (or other analysis correlation or variance approaches) between two or more sensor outputs, amplitude or power analysis designed to characterise characterisation of subject motion, body movements, body vibrations, in terms of signal sources (i.e. in terms of the segmenting movement signals according to motion characterisation along with associated motion source association, such as stride versus arm motion symmetry and/or synchronicity applicable to movement or neural disorders such as Parkinson gait dysfunction; fall-detection; activity versus idiopathic RBD with associated muscle tonicity changes (i.e. REM sleep without atonia); steps; movement; hyperkinesia (exaggeration of unwanted motion), such as twitching or writhing in Huntington's disease or Tourette's Syndrome; tremor, or other movements; diagnosis and treatment of movement disorders, including Parkinsonian Tremor, Restless Legs Syndrome, Dystonia, Wilson's Disease or Huntington's disease; bradykinesia (i.e. slowness of movement) and dyskinesia (i.e. diminished voluntary movements; involuntary movements), whereby any of or any combination of analysis techniques covered elsewhere in this document including but not limited to Figure 1 to Figure 99, but particularly as it applies to examples of ANALYSIS VARIANTS INCLUDING THOSE APPLICABLE TO GAIT OR MOTION ANALYSER INCLUDING PARKINSON ONSET SYMPTOMS AND/OR COMBINED SBD SLEEP BEHAVIOUR DISORDER DETERMINATION (Figure 45 [5]): excessive motion associated with REM without atonia as with during RBD, or associated with restless legs syndrome, or with muscle processing disorders such as fibromyalgia per **Figure 75 [20]:[22]**; also as further detailed under headings "Motion detection and/or actigraphy", "REM sleep behaviour disorder (RBD)", "Pulse sensor integrated watch of other wrist worn device (band or bangle)", "Pulse wave analysis (PWA) and pulse wave velocity (PWV) monitoring and analysis capability", "PWA and PWV sensors", "Pulse wave analysis (PWA) sensor measures", "Ballistocardiograph", "Position, locational and movement sensing and monitoring", "Movement and locational information", "Gait or movement tracking and characterisation of events of interest", covered elsewhere in the "eLifeCHEST/eLifeSCOPE" section of this document.

>FOURTH PROCESS STEP whereby motion and/or patient position analysis techniques including any of or any combination of analysis techniques covered elsewhere in this document including but not limited to **"Position, locational and movement sensing and monitoring", "Movement and locational information", "Gait or movement tracking and characterisation of events of interest", covered elsewhere in the "eLifeCHEST/eLifeSCOPE" section of this document, and whereby these analyses can be applied to any of or any combination of sensor outputs (i.e. including a plurality of accelerometer axes);**

>FOURTH PROCESS STEP can include gyro sensor positional (based on vertical or horizontal positioning degree) outputs as a measure of a subject/patient's gait and/or smoothness and/or staggered stride or walk, whereby motion and/or patient position analysis techniques including

any of or any combination of analysis techniques covered elsewhere in this document including but not limited to provisions further detailed under heading "Position, locational and movement sensing and monitoring", **covered elsewhere in the "eLifeCHEST/eLifeSCOPE" section of this document;**

5 **>FIFTH PROCESS STEP** whereby analysis outcomes can be deployed as part of prognosis or diagnosis determination for a subject/individual;

10 **>SIXTH PROCESS STEP** whereby said analysis outcomes and/or associated results can be disseminated in terms of messages, events, calendar information or data access, information networks (social, work, professional etc.);

CIRCADIAN TEMPERATURE CYCLE DETERMINATION VERSUS LOCAL ENVIRONMENT AND/OR SLEEP/WAKE/ACTIVITY/WORK

- 15 - A nub of the present invention's personal health management system is to **automatically determine and indicate, coach, alert, message, CC entrainment stimulation applicable to subject/patient/user based on CC input factors, a range of scenarios, covering sleep quality and length relating to the interrelationship or the manner the said subject works with or against their natural CC;**
- 20 - Moreover, the present invention can provide a number of **entrainment scenarios such as the intervention with subject-wearable device or environmental lighting** as a means various degrees of advancing or delaying a subject's phase response curve (i.e. a subjects inbuilt circadian curve phase relationship with external clock factors, including social, time-zone, work, work-shift, study requirements etc.) applicable to **minimising delayed sleep phase disorder (DSPD) or advanced sleep phase disorder (ASPD)** according to a subject's health- care oversight or intervention and/or an individual's personal preferences or requirements and/or occupational hazard and safety considerations;
- 25 - The present invention can automatically or via manual assistance **activate light intensity and type** (i.e. visible blue light with short wavelength, and stronger melatonin suppression affect can be deployed as part of an automatically computed CC entrainment treatment regime, versus longer wavelength light) as well as the timing functions of such light therapy (i.e. light-therapy in the evening can enable CC phase delay, while light therapy in the day can product CC phase advancement);
- 30 - The present invention can **automatically (or with manual intervention option) control entrainment factors** (i.e. lighting timing and/or lux intensity and/or melatonin dosage and administration timing or recommendation), as well as the option of recommending or setting bed-times or alarm clock settings, in accordance to a subject/patient (or healthcare advisor) social, work, travel requirements or environmental factors;
- 35 - The present invention can advise/coach **and/or automatically adjust said CC entrainment** in accordance to subject/patient/user preferences, selections or personalised scenario choices (i.e. more aggressive adjustment over a shorter period of days or more moderate CC adjustment over a longer period of days);
- 40 - The present invention can **automatically access a travel agenda** and based on any of or any combination of these or other CC and sleep homeostatic factors:
 - 45 >sleep duration;
 - >sleep time;
 - >bed-time;
 - >sleep quality;
 - >sleep urge or deprivation;
 - >work-clock, social-clock;
 - >CC phase offset with any other said clock;
 - 50 >alarm clock settings;
 - >map application visual annotation showing various travel agendas and likely CC adjustment consequences such as the east-west travel versus west-east varying travel jet-lag factors;
 - >various travel schedule such as in one embodiment the present invention can automatically access or interface travel information relating to one or more travel itineraries as a means of
 - 55 generating optimal travel itineraries in accordance to CC entrainment options or optimal

subject/patient/user performance outcomes in terms of subject's peak energy CC levels or a subject's optimal sleep bed-times and/or sleep duration times;

>agenda interface to a travel scenarios based on user's preferences in terms of prioritising these said factors, various alarm clock schedule scenarios based on subject/patient/user prioritising these said factors;

>various **map application including annotations or associated information annotation** of CC versus other environmental clock/jet-lag/social/work/sleep deprivation-urge/sleep duration/sleep-quality etc.;

> alarm clock schedule scenarios based on subject/patient/user prioritising these said factors) sleep taking into account known etc., applicable to personalised subject/patient/user preferences for CC versus social-clock, versus work-clock, versus solar clock, versus time-zone clock, versus sleep duration versus sleep quality versus bed times versus sleep times;

the present invention can measure environmental lighting conditions applicable to subject/patient/user (i.e. via wearable device such as watch, mobile device etc.) in order to provide coaching or guidance to treat winter depression or other forms of depression or **delayed sleep phase disorder (DSPD)**, or compensate for offset between CC and environmental (i.e. time zone or solar clock factors or behavioural clock properties (i.e. social clock, work-clock, shift-works, travel/jet-lag clock, clock and associated requirements or planning/scheduling preferences), whereby said coaching can include CC offset therapy (i.e. light therapy, melatonin medication, adaptation of homeostatic sleep factors (i.e. optimal increasing of a subject/patient/user's awake period to enable higher quality sleep and alignment of CC with sleep patterns or vice versa);

the present invention can **automatically incorporate all CC entrainment factors, indication aspects, alarm clock functions, light detection functions, coaching and/or messaging and/or alert functions, into a single application as part of a wearable or mobile device;**

The present invention can determine **circadian clock nadir factors** (i.e. body temperature and/or interval from body temperature nadir to sleep offset) including subject/patient/user's with **delayed sleep phase syndrome (DSPS)** in order to optimise CC entrainment (i.e. light therapy including glasses with blue light projected towards subject/patient/user retina as a stimulus – can be blocked form forward projection based on shaded or blocked upper section of glasses in order to minimise obtrusive or obvious nature of such treatment), whereby light exposure prior to the nadir of the core body temperature rhythm can produce phase delay, whilst light therapy (bright light therapy) administered after nadir can result in advancement of phase;

The present invention can track sleep-wake rhythms and characterise a lack of clearly discernible circadian patterns of sleep-wake time, as a marker or **potential prognosis of irregular sleep-wake rhythm;**

The present invention can in incorporate sleep-wake rhythms and characterise a lack of clearly discernible circadian patterns of sleep-wake time, and/or questionnaire outcomes relating to excessive sleepiness , unrefreshing sleep, and/or insomnia that vary in accordance to work schedule as a marker or **potential prognosis of shift work disorder (SWD) ;**

Circadian algorithm: circadian-automatic regressive analysis modelling with context analysis

Whilst conventional scientific laboratory measures of circadian clock temperature cycles implicate core body measures generally not suited to routine or circadian monitoring (rectal temperature probe monitoring), in contrast a nub of the present invention is to enable the derivation of an individual's (subject/patient/user's) natural inbuilt (endogenous) circadian temperature by way of circadian-automatic regressive analysis modelling with one or more external inputs (CRX).

The said circadian-automatic regressive analysis modelling can incorporate context analysis;

a) Circadian algorithm processing: context analysis

whereby said context analysis (not limited to) in one embodiment example of a model only can include inputs to the said model comprising of an individual's inbuilt circadian rhythm clock information can include any of or any combination of (but not limited to):

- b) Circadian algorithm input: survey(s) or tracking subject/patient information
 - input data via patient or other person based on survey(s) or tracking subject/patient information, such as sleep propensity or sleepiness information such as with Epworth Sleepiness scale or other survey/scales/measures, or routine sleep, wake, work, recreation and/or other active routines, similar data derived from applications such as health apps or calendars, schedulers, health applications, wearable or mobile devices etc.;
- 5 c) Circadian algorithm input: sleep study information
 -data accessed or input automatically, manually or via computer-assistance relating to sleep study information;
- 10 d) Circadian algorithm input: sleep monitoring studies or applications
 -data accessed or input automatically, manually or via computer-assistance relating to sleep monitoring studies or applications associated with the present invention's monitoring, system, applications, or other application capabilities (i.e. such as, but not limited to, those further outlined elsewhere this document);
- 15 e) Circadian algorithm input: information relating to fitness, health monitoring and/or related applications
 -information relating to fitness, health monitoring and/or related applications associated with the present invention's monitoring, system, applications, or other application capabilities (i.e. such as, but not limited to, those further outlined elsewhere this document); data
- 20 accessed, input automatically, manually or via computer-assistance or derived relating to
- f) Circadian algorithm input: information or information derivations based on sleep, fitness or other health applications, devices and/or systems
 -information or derivation from any combination of information such as (but not limited to) a clock or mobile phone or other software applications or systems containing information relating to
- 25 subject/patient's activity, sports, work, sleep, wake, alarm clock, schedules or routines or timing data;
- g) Circadian algorithm input: local or new time zone information
 -local or new time zone information (i.e. but not limited to GSM, GPS, radio clock or other timing source);
- 30 h) Circadian algorithm output: phase shift between inbuilt circadian clock and local environment time-zone
 whereby outputs of said context analysis model (not limited to) in one embodiment example of a model only can include any of or any combination of (but not limited to):
 -phase shift between inbuilt circadian clock rhythms and local environment time-zone
- 35 properties or related subject/patient schedules or required routines and/or time cycles;
- i) Circadian algorithm output: coaching or recommendation of optimal alarm clock or scheduling
 -coaching or recommendation of optimal alarm clock or scheduling or time-management aspects based on any of or any combination of said model inputs;
- 40 j) Circadian algorithm processing: auto-regression estimation of natural or inbuilt estimation of local or new environment circadian clock/rhythm
 -auto-regression estimation of natural or inbuilt subject/patient's circadian clock/rhythm;
- 45 -auto-regression estimation of local or new environment subject/patient's circadian clock/rhythm;

k) Circadian algorithm processing options: auto-regression estimation/determination of subject wearable or attachable temperature sensors/probes whereby a low pass filtering function capable of emphasising low frequency cyclic changes for derivation of natural/inbuilt or new environment circadian clock/rhythm status or requirements

The automatic regressive analysis can be subject wearable or attachable temperature sensors/probes whereby a low pass filtering function capable of emphasising low frequency cyclic changes (i.e. 24 hour circadian core temperature changes versus external environment or shorter term activity or exercise mainly independent of circadian core temperature changes);

l) Circadian algorithm inputs: "external inputs" including derivation of natural circadian clock

The said "external inputs" can include any of or any combination of (but not limited to):
- natural or derivation of natural circadian clock (i.e. via any of or any combination of temperature measures and/or EEG measures);

m) Circadian algorithm processing inputs: new environment or time zone 24 hour cycle
- new environment or time zone 24 hour cycle (i.e. based on GSM, GPS, radio clock, mobile phone or watch determination etc.);

n) Circadian algorithm inputs: actual sleep monitored sleep/wake cycle
- subject/patient actual sleep monitored sleep/wake cycle (including but not limited to sleep parameter based (i.e. any of or any combination of but not limited to EEG, EOG, EMG measures and associated sleep stage or sleep cycle or sleep hypnogram derivations);

o) Circadian algorithm inputs: existent known knowledge based on the association between sleep/wake
-existent known knowledge based on the association between sleep/wake and the natural cyclic circadian clock and/or sleep cycles and/or core body temperature cycles (i.e. low core temperature on REM sleep etc.).
-aggregated knowledge (i.e. per accumulated knowledge and transition of information to knowledge per artificial intelligent or expert system self-learning capability examples in Figure 77 knowledge base, real-world inputs, inference engine and workspace: Figure 78; Figure 79, middle-block; to Figure 80. [12],[13],[14]) based on subject/ patient's association between sleep/wake and the natural cyclic circadian clock and/or sleep cycles and/or core body temperature cycles (i.e. low core temperature on REM sleep etc.).

p) Circadian algorithm inputs: "subject wearable or attachable temperature sensors/probes"
The said "subject wearable or attachable temperature sensors/probes" can include any of or any combination one or more the temperature sensors attached or embedded as part of the earbuds/earplugs with combined audio monitoring function described elsewhere in this patent. Moreover the present invention can further delineate between external temperature with thermistors positioned to detect current environmental temperature (i.e.one or more temperature sensors incorporated as part of any of or any combination of wearable devices/probes (i.e. watch, mobile phone, earbuds, chest-wall monitor, armband monitor, head, body extremity, body-orifice etc. monitoring).

q) Circadian algorithm processing options: delineate between body transient or short term fluctuations

Additionally, in order to further delineate between body transient or short term fluctuations (such as due to physical exercise) and core circadian related temperature the present invention's CRX analysis can compare and contrast heat-flux measures versus external environment versus core body temperature versus skin temperature measures (i.e. temperature probes just above skin surface can reflect heat flux emitted from skin surface, versus deeper earbud measures being more reflective of body temperature, versus external environment temperature sensors not as closely associated with body temperature changes, for example only).

Circadian temperature

Circadian algorithm processing options: wearable health monitoring and/or tracking system/device

-The present invention provides a circadian function within a wearable health monitoring and/or tracking system/device, whereby such function includes any of or any combination of:

a) Circadian algorithm: monitoring physiological variable(s) related to natural (inbuilt) wearable health monitoring, tracking, time-management factors, determination and/or coaching of a subject/patient's local time and/or current or required routine sleep/wake/work/recreation cycle

means of monitoring physiological variable(s) related to natural (inbuilt) or associated factors (i.e. sleep/wake) and/or required time-management factors (external; such as wake, sleep, work, recreation etc. schedules and associated time or performance management demands) influencing said "inbuilt" circadian cycle (i.e. EEG, temperature, sleep/wake staging or associated cycles; noise, activity etc.),

b) Circadian algorithm outputs: "free-running" or "in-built circadian rhythm cycle: means of determination of a subject/patient's "free-running" or "in-built circadian rhythm cycle (i.e. via analysis of monitored circadian rhythm physiological parameters for an underlying cyclic trend nature;

c) Circadian algorithm processing options: determination and/or coaching of a subject/patient's local time and/or current and/or required and/or optimal routine sleep/wake/work/recreation cycle
means of determination and/or coaching of a subject/patient's local time and/or current or required routine sleep/wake/work/recreation cycle (i.e. via clock, watch, subject/patient or other accessible or entered information relating to such factors – i.e. alarm clock, time-zone clocks, GPS or GSM locational information, sleep questionnaires/surveys; etc.) ,

d) Circadian algorithm processing options: comparing and/or contrasting synchronisation of a subject/person's natural "in-built" circadian cycle versus environment time zone factors
means of comparing and/or contrasting synchronisation of a subject/person's natural "in-built" circadian cycle at any time with the said subject/patient's required or current or new environment sleep/wake cycle requirements or expectations at any time,

e) Circadian algorithm processing options: analysing the phase difference associated with the said "in-built" natural versus current or required sleep/wake cycle time
means of analysing the phase difference associated with the said "in-built" natural versus current or required sleep/wake cycle time (i.e. in any of or any combination of tabular or graphic, or user interface, or interactive user interface, vibration or sound or other notification or alert means, via clock or watch-face overlaid or incorporating links or association with circadian "inbuilt" clock and/or any other clock or timing information), with in order to produce a measure of circadian "inbuilt" versus "required" offset time factor,

f) Circadian algorithm output: providing external circadian stimulus
means of providing external stimulus (i.e. temperature change of wearable, environmental, bed or bedding material or bed room etc., or light along with associated power and/or colour and/or frequency of lighting,

g) Circadian algorithm output: "circadian offset time factor"
means of incorporating measure of "circadian offset time factor" as part of the biofeedback or control decision matrix of said external stimulus application of subject/patient, in order to minimise said "circadian offset time factor" ,

h) Circadian algorithm inputs: attached temperature sensors for circadian rhythm determination

-The present invention can incorporate one or more attached temperature sensors for circadian rhythm determination and/or (but not limited to) other physiological measures with option of plethysmography formats as further detailed in eLifeCHEST/eLifeSCOPE chapter under section "Temperature" or eLifeBUDS chapter, and elsewhere in this document describing temperature monitoring and analyses.

Circadian EEG

Forward equation targeted EEG brain region monitoring including circadian clock function

The present invention incorporates forward equation source localisation such as (but not limited to) monitoring and derivation of associated measures relating to the subject/patient's natural circadian rhythm, including (but not limited to monitoring associated brain regions (i.e. suprachiasmatic nucleus (circadian clock) regions) applicable to circadian EEG cycle signals (such as for determination of circadian clock cycle for subject/patient),

Whereby in one embodiment example based on configuration of EEG sensor monitoring system (i.e. but not limited to examples per **Figure 1 to Figure 3, Figure 5, Figure 14, Figure 16, Figure 21, Figure 23, Figure 25, Figure 27, Figure 28, Figure 46 to Figure 55**) coupled with the present inventions monitoring goals and associated wearable monitoring minimisation computation (**Figure 45**), the present invention can compute and determine sensitivity and/or filtering and/or other processing formats (including any of or combinations of NLDBTV, STV, SR, ER, clusters of ERs, clusters of SRs, spectral EOI, interconnectivity of any of same - i.e. coherence and /or Dipole sequences and/or associated clusters, sequences and/or ensembles) and/or neurological amplitude, power, morphological signals or values) in the context of the optimal forward equation coupled with corresponding neurology channel (or body physiological channels where applicable) in order to most effectively "pin-point" or localise the anatomical sources of interest (i.e. circadian clock EEG signals in order to contribute to determination of human phasic sleep-wake clock for example, such as could be used as part of therapeutic medication, light treatment or other sleep coaching or recommendation hints to re-align a subject/patient's circadian clock or sleep-wake phasic cycle)

Circadian source localisation based on pre-diagnostic

The present invention incorporates a means of EEG monitoring and source localisation. The said source localisation comprises of source reconstruction is based on pre-diagnostic subject/patient studies or general population data as a basis of determining signal source or brain sources of interest. In this manner the spectral and sensitivity characteristics of signal processing applicable to a plurality of sensors (including but not limited to **Figure 3; Figure 4; Figure 21; Figure 23; Figure 46; Figure 47; Figure 48; Figure 49; Figure 50; Figure 51; Figure 52; Figure 53; Figure 54; Figure 55; Figure 56**). For example, based on the modelling of the EEG signal attenuation of skin layer, skull and brain matter, combined with the EEG electrode positions and specific distances from the targeted brain regions of monitoring interest, each EEG sensor can be designated a sensitivity (amplification) and spectral (filtering) properties in accordance to EEG forward source reconstructions where the neural origins are known but the head surface electrode signals can be computed (using forward equation modelling). In this way the present invention can provide optimal compensation as it relates to electrode locations designed for subject/patient convenience (i.e. per wearable monitor minimisation formats, (such as in **Figure 45** or sensor configurations such as Somfit forehead sensor per **Figure 16; Figure 28** [4]).

Using this forward equation source reconstruction analysis approach the present invention can determine optimal EEG signal processing applicable to sensor monitoring systems specific electrode location (i.e. per Somfit) in order to emulate standardised AASM sleep monitoring manual recommendations (i.e. F4 - M1; C4 - M1; O2 - M2; with backup monitoring electrodes including F3 - M2; C3 - M2; o1 - M2 versus Somfit Fp1, Fp2, F7, F8 and/or Fz sleep monitoring electrode locations).

Using this forward equation source reconstruction analysis approach the present invention can determine optimal EEG signal processing (i.e. adapting frequency, phase and/or amplitude of sensor signals) applicable to sensor monitoring system's specific electrode location (i.e. per Somfit) in order to emulate location of brain regions (i.e. suprachiasmatic nucleus (circadian clock) regions) applicable to circadian EEG cycle signals (such as for determination of circadian

clock cycle for subject/patient), and/or consciousness switch region (i.e. thalamus), or other brain regions (i.e. but not limited to **Figure 66 source localised regions**).

Circadian clock monitoring and tracking

Circadian-based sleep deprivation determination

- 5 The present invention provides a means of monitoring and indicating as part of a wearable or mobile wireless system one or more measures relating to a subject's circadian rhythm including the incorporation of a subject's brain or temperature measures, the present invention further comprising any of or any combination of (but not limited to):

a) Temperature circadian clock measures

- 10 >>means of monitoring a subject's temperature and by way or analyses (such as regression analyses but not limited to) determine the 24 hour cyclic nature of a subject's body temperature, whereby shorter term temperature time changes such as those applicable to a subject's motion or exercise (such spontaneous or shorter term measures, for example, can otherwise distort slower changing body temperature trends applicable to circadian cycles. Therefore low pass filtering of
15 temperature changes over a 24 hour cycle, coupled with exclusion of temperature measures not fitting within the typical circadian cycle can be compensated for in order to derive a subject's underlying circadian temperature cycle);

b) Brain/EEG circadian clock measures

- 20 >>means of enabling EEG linked circadian clock synchronisation determination, whereby means incorporates determination of phasic or rhythmic pulses of signals from the circadian clock brain region via 1 or more monitored EEG signals, whereby in a first process step the frequency or periodic nature of the circadian brain region (i.e. **suprachiasmatic nucleus (circadian clock) regions**) applicable to **circadian EEG cycle signals** such as for determination of circadian clock cycle for subject/patient, and/or consciousness switch region (i.e. thalamus), or other brain regions
25 (i.e. but not limited to **Figure 66 source localised regions**).

- Whereby the brain region can be monitored, and/or analysed as a means of computing any measure subject's sleep propensity (i.e. sleep deprivation; sleep delay syndrome; sleep recovery recommendations). Whereby, the present invention further enables a means of analysing the periodic nature of EEG signals evolving from the human brain or body circadian clock. so that only
30 small samples versus continuous or uninterrupted circadian clock output signals need to be monitored, in order to accurately compute or estimate the cyclic or phasic position at any time or over any period of the human body or brain circadian clock (body clock).

c) Circadian clock cycle determination and integration with mobile or other map, calendar, messaging, community applications

- 35 The present invention can automatically determine, predict and indicate offsets between an individual's natural circadian cycle, sleep/wake patterns and proposed travel, social, work, recreation. Leisure or other proposed schedule.

- i.e. via calendar application annotations can incorporate an indication of an individual's offset between their natural circadian cycle versus their proposed travel agenda and scheduled
40 activities/events. For example, if the individual has to attend a business meeting at a certain time in the future, following a bout of travel, the present invention can take into account the time-zone changes, the travel schedule (i.e. automatic linking to travel websites or personally managed flight schedules, or travel agent flight data etc.) and then provide a measure of sleep urge based on a range of assumptions or an individual's data entries or selections or default factors. For example, if
45 an 8 hour flight is followed by an important business meeting, and the assumption is that the individual achieves no sleep on the flight prior to the business meeting, then the present invention can estimate the likely sleep urge of the subject in meaningful terms (i.e. based on no or little sleep between departure and scheduled meeting you are likely to have a sleep propensity similar to 3 hours after your normal sleep-time or saying up to 3AM based on your normal sleep/wake cycle.)
50 **(Figure 96 output blocks [4] to [10]).**

Similarly the present invention allows more complex scenarios to be computed and presented (i.e. map settings or annotations, calendar settings or annotations, clock settings, alarms or annotations) in terms of optimal scheduling of an individual's performance or mood factors versus time efficiency factors, based on the determination of any of or any combination of an individual's a) **scheduled or hypothetical schedule (Figure 96 [11]), b) travel itinerary (Figure 96 [11]), c) natural circadian clock cycles (Figure 96 [11]), d) homeostatic sleep/wake monitoring (i.e. including automatic access to the present invention's routine sleep monitoring capabilities and the associated normal homeostatic sleep factors of an individual, and/or actigraphy, and/or environment light conditions, as covered elsewhere in this document) (Figure 96 [11]), e) an individual's preferences in terms of maintaining optimal sleep quality (i.e. taking into consideration previous wake period and the current or prediction such as new environment time-zone adjustment), f) or entrainment factors (Figure 96 [11]) as the background in terms of time-zone shifts and various adjustment periods etc.), g) individual preferences in terms of Jet-lag minimisation versus social clock factors versus work-clock factors, individual circadian clock factors (phase delay, phase advance, delay stability and confidence level in terms of the accuracy of the determination of the individual's previous and up-to-date circadian clock cycle status, along with other factors impacting the determination of current circadian clock status of an individual) (Figure 96 [3]);**

The present invention enables all these functions and capabilities to be incorporated into one or more wearable or mobile devices (i.e. smartwatch, mobile phone, Somfit sleep monitoring headband and/or other covered elsewhere at any section within this patent application document such as (but not limited to) wearable device examples presented in **Figure 1;**

In another embodiment of the present invention an individual (i.e. traveller) incorporation of CC computed parameters as part of automatic **entrainment (i.e. per Figure 96 [11],[7]) programming of CC treatment systems (i.e. such as bright light therapy including glasses or sunglasses (i.e. half-shielded glasses, for example only, tinted in upper section of glass lenses only), whereby said glasses can include reflective oculography (i.e. per Figure 43) capable of both entrainment light-therapy and/or detection of eye-lid movements and/or opening as a marker of drowsiness in order to enable biofeedback entrainment capabilities in order to adjust for CC cycle offset factors and/or sleep propensity and/or sleep urge factors. For example, the present invention can incorporate a series of blue LEDs or other blue lighting arrangement, which can be controlled automatically via wireless interconnect to provide an individual's selected entrainment treatment regime designed to adjust for circadian phase advancement or delay based on the present inventions computation of the individual's current circadian clock versus social, travel, time-zone and or work or recreation schedule/clock requirements (i.e. per Figure 96 [11]);**

Similarly the present invention can automatically link (i.e. wireless or other interconnectivity communication and information access means) to messaging systems (such as mobile phone SMS, emails, calendar, applications and the like) in order to track and/or comment/health-coach and/or enable sleep scheduling as it relates to an individual's current circadian clock versus social, travel, time-zone and or work or recreation schedule/clock requirements, in terms of optimal performance, energy, sleep-urge, occupational-health sleepiness risks, fatigue implications and other factors an individual may be interested in activating (**i.e. per Figure 96 [7]).**

One embodiment of the present invention enables integrated mapping applications (i.e. geographical or road map) or related indications or annotation, to incorporate additional notes or associated information, relating to various travel scenarios indicating or symbolising (i.e. single sine-wave cycle with normal sleep periods marked versus new environment time-clock with respectively positioned such as equivalent start and end times corresponding to new time zone environment) along with indication of CC phase lag or lead factors so that an individual can associate travel plans along with associated travel itinerary with CC and jet-lag factors.

Additionally, CC entrainment suggestions/health-coaching along with projected or estimated sleep propensity factor or sleep quality aspects (i.e. difficulty based on phase relationship of CC's prior wake period and homeostatic sleep patterns. In this way an individual can visually, automatically, instantly and in an integrated or seamless (i.e. mobile personal planning applications including mapping or routing related functions or applications or processes, wearable devices, etc.) associate travel plans with the related health management impact and precautions or

countermeasures to optimise an individual sleep-quality, sleep duration, sleep-timing, daytime energy, sleep-propensity, mood and other elements which clearly can be managed and enhanced in terms of information access, understanding and control via the present invention's circadian health management system **(i.e. per Figure 96 block [3] health management system with associated inputs [1] and [2], adjunct system options [3A], and outputs [4] to [10]; Figure 97, 4-stage entrainment adaptive monitoring system).**

The present invention in one embodiment enables integrated calendar or scheduling/planning application(s) (i.e. geographical or road map) an indications or annotation, with the option of additional notes or associated information, relating to various travel scenarios indicating or symbolising (i.e. single sine-wave cycle with normal sleep periods marked versus new environment time-clock with respectively positioned (i.e. equivalent start and end times corresponding to new time zone environment) along with indication of current individuals CC inbuilt, along with various (i.e. different travel itinerary or different schedules for travel, social events, work events, study, etc.) CC phase-lead, CC phase-lag or adjustment/entrainment (i.e. melatonin dosage and dosage timing and/or bright-light dosage and timing of therapy etc.) strategies to align these conflicting clock cycles (i.e. inbuilt CC versus working against social-clock (i.e. based on natural CC wake/sleep requirements versus conflicting clock time-cycle requirements) versus attempting to synchronous CC phase-lead or phase-lag factors. In this way an individual can visually, automatically, instantly and in an integrated or seamless (i.e. integrated calendar or planning or scheduling related applications or applications or processes, mobile personal planning applications, wearable devices, etc.) associate travel plans with the related health management impact and precautions or countermeasures to optimise an individual sleep-quality, sleep duration, sleep-timing, daytime energy, sleep-propensity, mood and other elements which clearly can be managed and enhanced in terms of information access, understanding and control via the present invention's circadian health management system **(i.e. per Figure 96 block [3] health management system with associated inputs [1] and [2], adjunct system options [3A], and outputs [4] to [10]; Figure 97 4 stage entrainment adaptive monitoring system).**

The present invention in one embodiment enables watch or clock application to be programmed so that information relating to the CC clock cycle and/or individual's required scheduled clock requirements (i.e. travel-clock, time-zone changes, social-clock, work-clock, leisure-clock, special-event clock) along with strategies or scenarios capable of providing trip programs or sequences designed to minimise the disruption of quality sleep or an individual performance in work, sport, play, leisure etc. can be structured and stored in a library or easily recallable such each or clock display face setups, along with various CC embodiments, entrainments, strategies, personalised preferences, planning capabilities and the like, in order to enable user to establish an ideal library of personalise configurations for CC HMS **(i.e. per Figure 96 block [3] health management system with associated inputs [1] and [2], adjunct system options [3A], and outputs [4] to [10]; Figure 97 4 stage entrainment adaptive monitoring system).**

Additionally the present invention CC HMS enables a community or private select grouping function whereby healthcare specialists can coach, guide, assist and intervene in tracking, diagnosing and supporting an individual's occupational safety aspects, sports performance aspects, general health aspects, depression and other psychological disorders greatly impacted by appropriate CC management (i.e. per Figure 96 block [3] health management system with associated inputs [1] and [2], adjunct system options [3A], and outputs [4] to [10]; Figure 97 4 stage entrainment adaptive monitoring system).

Additionally, the present invention can automatically link (i.e. wireless or other interconnectivity communication and information access means) to an individual time reference (i.e. alarm clock, watch, mobile phone clock or other application) in order to automatically set or suggest alarm settings and/or enable sleep scheduling track and/or comment/health-coach as it relates to an individual's current circadian clock versus social, travel, time-zone and or work or recreation schedule/clock requirements, in terms of optimal performance, energy, sleep-urge, occupational-health sleepiness risks, fatigue implications and other factors an individual may be interested in activating.

For example, one said projected or predicted scenario could be based on the assumption that subject/patient continues their sleep patterns or behaviour/quality (i.e. time of sleep, sleep time, sleep fragmentation, sleep architecture, sleep arousals, sleep disturbance, respiratory

disturbance, REM sleep amount and structure, deep sleep amount and structure) unabated, or with various degrees of correction such as mild correction (i.e. gradual increase in sleep quality or decrease in sleep deficit), moderate correction or severe correction (i.e. any of or any combination of medication, light-therapy, sleep hygiene or environmental improvements (i.e. reduce external arousals related to audible noise, temperature, humidity, air pollution or other breathing or asthmas antagonists etc.).

Additionally, the present invention provides a "means of computing circadian cycles" based on projecting or predicting a sleep-circadian-cycle scenario based on assumption that the subject/patient reduces or compromises their sleep for a period (i.e. period of study or to allow for a special event, travel etc.). Said means can also provide a typical measure of sleepiness or propensity based on comparative circumstances (i.e. you will be at extreme risk of falling asleep within 10 seconds (i.e. period of say 1 second to 30 seconds subject to specific scenario) of shutting eyes and you should not drive, undertake decisions of financially material nature, undertake any task where occupational work risks to yourself or others are relevant etc. Additionally, (for example only) the predicted sleep deprivation scenario could be related to other equivalent reaction time or alertness or sleepiness measures such as the predicted equivalent Epworth sleepiness scale outcomes or blood-alcohol readings etc.

-Whereby "means of computing circadian cycles" including for example, but not limited to, examining information of prior monitored circadian physiological variables (i.e. temperature, EEG suprachiasmatic brain region, etc.) and also examining such variables along with other factors influencing the shift of the circadian clock cycle (i.e. sleep parameters and associated sleep measures of subject/patient) in order to determine, based on historical or prior changes versus consequential sleep and circadian clock shift measures. i.e. per algorithm subject/patient-specific learning (ASL) system or wearable-device minimisation (WM) system the subject/patient's prior and/or current and/or predicted (with indicated scenarios) and/or training (i.e. to improve or optimise sleep management based on circumstances and/or scenarios and/or assumptions and or users selection of various desired sleep quality versus work/play schedule preferences – i.e. per **Figure 45 where this example demonstrates** in this context of the present invention, the capability to examine the goals of monitoring (**Figure 45 [1]**) and then in this context advise user of the more complex (**Figure 45 [2]**) monitoring configuration(s) (subject to clinical oversight or requirements or considerations consumer or GP oversight guidance, for example), followed by enabling a monitoring, analysis, determination of outcomes and then statistical assessment of accuracy of outcomes diagnosis or prognosis, in order to determine reconfiguration requirements and related wearable monitoring adaptation for both monitoring sensor configuration(s) or wearable monitoring sensor(s) and related devices (**Figure 45 10, 11, 12 – not in the context of circadian monitoring the same principles apply as neurology minimisation except that the broad range of physiological parameters and related wearable monitoring configurations are taken into account in order to cover relevant monitoring measures including any of (but not limited to) direct or surrogate measures of body temperature monitoring, homeostatic sleep measures, and/or daytime activity measures**) but also the minimal or streamlined/minimalized (**Figure 45 [8], [9], [10]**) sensor and wearable configurations based on achieving relevant and appropriate accuracy of diagnostic and/or prognostic aims and outcomes, applicable to the specific or personalised requirements of user and user's health community (as personalised based on user's privacy, security and preferences or allowance of opt in capabilities and intervention).

d) Inbuilt (natural) circadian clock

-the present invention provides natural circadian clock device means and/or application-linked means and/or application-linked means of characterising, determining, and/or accommodating a subject/patient's natural circadian rhythm;

Whereby said circadian clock characterising can comprise of monitoring slow changing, or typically 24 hour cycles with typical sleep and wake phases of cycle, of a subject/patient's temperature, EEG associated with circadian clock (i.e. associated or directly implicated with suprachiasmatic nucleus (circadian clock) brain regions, per Figure 66), as further detailed elsewhere in this document;

Whereby said natural circadian clock device means or application-linked means includes (but is not limited to) one or more time management systems and/or sleep/wake management systems, along with the interrelationship between such aspects;

Whereby said natural circadian clock device and application-linked time management system means includes (but is not limited to) any of or any combination of:

-alarm clock settings, mobile phone clock settings, map applications, calendar applications, any scheduling applications, any project management applications, any travel planning applications, wrist watch settings, computing devices, online applications, social media applications, social network applications or other systems applicable to an individual's sleep/wake management;

Whereby said natural circadian clock device or application-linked sleep/wake therapy health management system means includes (but is not limited to) any of or any combination of:

-health or personal planning applications, any occupational health management planning applications, any health insurance occupational risk and health applications, 3D or other glasses, lighting systems, curtain control systems, room temperature or environmental control systems, subject glasses with light therapy function (i.e. to enable light therapy for adjustment of sleep delay or sleep quality), sleep/wake coaching, sleep/wake recommendations, sleep/wake alarm clock or subject/patient clock recommendations or hints or other systems applicable to adapting, adjusting therapeutic intervention of an individual's sleep/wake planning or intervention of timing schedules or cycles (including natural circadian clock aspects);

Whereby the present invention can enable an individual to adjust and/or optimise time management systems and/or sleep/wake management systems, along with the interrelationship between such aspects in accordance to optimising an individual health, including (but not limited to) adjustment for sleep delay syndrome, undesirable or unsafe sleep propensity or sleep-urges and/or adjusting and/or accommodating a subject/patient/user's natural circadian clock;

Whereby the present invention can include a computer system programmed with steps comprising of a decision matrix incorporating adjustable properties relating to natural circadian clock device or application-linked means associated with time management systems and/or sleep/wake management systems, along with interrelating factors;

e) Further circadian clock aspects

The present invention further enables

i) natural circadian clock cycle parameters;

ii) users essential awakening time parameters (i.e. work, study, travel commitments etc.);

iii) calendar, travel and other schedule applications with associated commitments or planning details;

iv) travel itinerary long with automatic world time-zone computational implications in terms of association, comparison and contrast with other time-related (i.e. per a) to c) herein;

v) map applications in terms of world travel routes or routing as a mean of planning travel routes to optimise adjustment or readjustment of a subject/patient/user's natural (circadian) time clock in order to adapt back to a timing structure capable of reducing or most appropriately recovering sleep deprivation over a defined (i.e. user preference or essential needs) period of time;

vi) messaging or other mobile phone, watch or other user (or other designated or authorised location or party – i.e. enabling a transportation driver/pilot or shift-worker or shift-worker safety carer to better manage occupational vigilance or safety or risk day-time sleep deprivation/propensity and real-world solutions or coaching assistance, for example);

vii) Clock alert or alarm system – i.e. alarm clock setting, mobile phone clock settings, wrist watch settings, application forming part of existing mobile phone, alarm clocks or other devices settings and functionality;

viii) Personal rhythm or clock health management system – i.e. the ability to enable subject/patient/user to adjust timing indicators and/or alarm clock functions and/or calendar planning coaching or hints and/or messaging system coaching or hints in accordance to optimising schedules or adaptation/adjustment (i.e. recovery from or avoidance of more adverse sleep deprivation, for example) of personal circadian rhythm in accordance to mild, moderate, significant, or severe realignment to optimal sleep wake cycle (i.e. whereby user can configure their optimal

sleep/wake cycle for the immediate sleep/wake periods or any future period, and thereby enabling adjustment from sleep deprivation or unconventional (i.e. departure from standard sleep/wake cycle times due to travel, recreation activities, work demands, exam studies, jet-lag, night-shift etc.);

- ix) health or sleep coaching application capable of advising, adjusting or controlling a range of devices or systems (i.e. internet of things or medical internet of things or other wire, wireless means of interconnecting systems) subject/patient/user different options or programs of clock and timing schedules (i.e. via calendar appointments and alarm clock awakenings, along with option of adjusting room temperature, room lighting or associated lighting adjustments and other sleep/wake environmental influences);

10 f) Forward equation source analysis

>>>> the present invention provides capability of forward equation source analysis based on the know

n typical circadian clock brain anatomical location or other brain functional or structural locations such as the suprachiasmatic region (circadian clock) and/or associated control or interconnectivity regions of the brain (i.e. as well as options for (but not limited to locations outlined in Figure 66, Talairach Atlas; Current atlas tools; Harvard Whole Brain Atlas, MNI Template, The standard template of SPM and International Consortium for Brain Mapping; Atlas of the Developing Human Brain; All Functional including Brodmann areas, Gyri, Sulci etc.

-where the present invention can provide compensation for electrode location based on compensating signals in accordance to the amplification or attenuation, filtering, phase adjustment and any other factors in order to simulate or emulate the conditions applicable to targeting the monitoring of location or other brain functional or structural locations any of or any combination of brain regions or connectivity aspects (i.e. coherence or Dipole measures); For example, in one of the simplest modelling scenarios the present invention can:

- assume in the first step that all EEG electrodes are presented with exactly the same signal,
- in a second step define a location or other brain functional or structural locations of interest:
- in a third step determine the likely attenuation, spectral filtering characteristics, and phase shifts most probable (i.e. based on skin, skull, brain matter attenuation factors applicable between each electrode and the brain region of interest);
- in a fourth step apply the determined attenuation, spectral filtering characteristics, and phase shifts characteristics in term of signal processing for each respective EEG electrode;
- in a fifth step - the determined attenuation, spectral filtering characteristics, and phase shifts characteristics can be further improved by way of contrasting and comparing with actual subject/patient imaging and diagnostic assessment data;

In this way forward equation source modelling enables specifically targeted regions of the brain to be monitored or analysed even with minimised wearable monitoring sensor systems (per example process embodiment in Figure 45 demonstrating example of minimisation of sensors capable of targeting brain regions of interest with minimal possible sensors or electrodes). Moreover, more complex monitoring sensor systems (per example Figure 55) can still be streamlined or minimised (per Figure 46 to Figure 54 providing example (but not limited to) different wearable monitoring formats ranging from the simplest consumer-level monitoring options to more complex clinical diagnostic options) with improved source localisation capabilities using these forward analysis modelling and minimisation processes.

45 g) Intelligent circadian-based, clock, alarm, scheduling, coaching, biofeedback, control system)

> the present invention provides intelligent circadian-based measures with interlinking to clock, alarm, scheduling, coaching, biofeedback, and associate control system whereby intelligent wrist or alarm clock settings can include any of or any combination of (but not limited to):

- a) actual subject/patient's circadian clock-based alarm settings or clock time indicator capabilities;
- b) conventional (i.e. time-zone adjusted) time or alarm indications;
- c) sleep coaching recommendations whereby a subject's sleep/wake behaviour modification recommendations in terms of, for example, adjusting sleep cycle to compensate or minimise time phase shift between a subject/patient's current natural circadian clock cycle and a subject/patient's desired sleep/wake phasic requirements (i.e. adjusting for jet-lag, night-shift, late study or recreational nights and the like);

d) interlinking (wireless communication, for example) with other devices applicable to adjusting or compensating or indicating ((i.e. displaying, comparing or contrasting between circadian phase and cyclic nature versus an individual's required or desired sleep/wake cycle) an individual's sleep cycle and or circadian cycle and such as, but not limited to light therapy (i.e. activation or adjustment of conventional room lighting or special (i.e. any power, brightness, lighting colour, light frequency radiation spectrum etc.) lighting; mobile device or wearable device interface (i.e. smart watch or mobile phone or intelligent alarm clock etc.); room temperature or electric blanket and other environmental controls that can also impact and contribute to adjustment or correction of circadian rhythm;

e) the present invention provides a means of administering, coaching or medication determination, along with online automatic or assisted (including regulatory, security, privacy and personal authorisation and access requirements) medication ordering based on any of or any combination of (but not limited to):

i) schedule of medication,

ii) online access for ordering dosage,

iii) determination of dosage based on any of sleep/wake monitoring outcomes, subject/patient medical information, subject/patient personalised circadian rhythm, subject/patient sleep/wake monitoring outcomes, subject/patient HMS outcomes or related information, subject/patient health survey and other health information records, subject/patient natural circadian versus ongoing sleep/wake schedule requirements, subject/patient circadian monitoring outcomes (i.e. natural circadian rhythm based on EEG circadian clock, temperature and other circadian physiological monitored measures and associated analysis or derived outcomes);

iv) dosage and medication or **medication-dispenser** or medication-coaching (i.e. guidance on pharmaceutical such as recommended dosage and dosage schedule automatically programmed and/or control linked with an automated medication dispenser system (i.e. programmed to best compensate shifts between natural circadian rhythm/clock and new environment (i.e. change in time-zone or day-night activities) or sleep/wake/work requirements);

v) user interface to clock or alarm system (i.e. smart watch, alarm clock or mobile phone application that can enable user to select between optimal circadian rhythm synchronised time indication (i.e. for most natural alarm setting or calendar scheduling etc.) versus actual world time-zone based clock, alarm or scheduling means).

h) Wearable mobile health tracking and indicator means

-the present invention provides a means (i.e. means including integrating into a smart watch device any measures or combination of measures including but not limited to temperature sensing of subject, galvanic skin resistance of subject, photo-plethysmography, ECG, oximetry or plethysmography oximetry measures, all of which have a very slow underlying circadian cycle component which can be derived using any such measures, with further option of incorporating other wearable or mobile wireless monitoring systems local/distributed analyses outlined elsewhere in this document) of monitoring, computing and tracking, indicating a subject's/patient's circadian rhythm.

Such means can also include a means to display any of or any combination of conventional 24 hour time clock and/or date/and or calendar and/or sleep schedule means (i.e. such means can include calendar, messaging, clock display, or other means of indicating any of or any combination of actual subject/patient's actual circadian cycle, one or more predicted or projected circadian cycles, inclusion of the indication of normal variance or the range of sleep deficit and/or surplus that can be accommodated without mild, moderate or severe consequences (moreover this information can be based on comparative population data bases or aggregated subject/patient-specific monitored or other input information (i.e. per artificial intelligence or expert system analysis methods per **Figure 77 [A]** whereby a **Knowledge Base** is accumulated based on the evaluation of inputs from the **Interface to the Real World [8]** and the associated of the rule interpreter which is based on standardised scoring rules applicable to disease, disorders or **health conditions of interest**.

The said "**health conditions of interest**" can include (for example but not limited to) sleep disorders this can refer to the American Academy of Sleep Medicine rules for staging sleep scoring sleep-related respiratory disorders (i.e. per section eLifeCHEST/eLifeSCOPE section titled "Monitoring, Determination and Tracking of Sleep, Wake and other Mental States, Events of Interest or

Health Conditions of Interest”), epilepsy prognosis or diagnosis including detection of events or clusters of events such as HFOs, ripples, spikes, waves, K-complexes or spindles as further details in **Figure 75 [29]** Automatic analysis model Determination.

The said “**health conditions of interest**” can include (for example but not limited to) the diagnosis or prognosis of Parkinson’s, whereby the determination of the said The said “**health conditions of interest**” can include (for example but not limited to) monitoring and analysis identification of biomarkers and related “expert system rules” (i.e. per **Figure 77 [D]**) associated with analysis of events of interest (i.e. symptoms corresponding to diagnosis or prognosis or disorders, health conditions or diseases of interest). These said “**expert system rules**” are described elsewhere, including sleep behaviour disorder combined with movement (i.e. motion or activity characteristics) as further covered under prognostic and/or diagnostic movement disorder marker monitoring and analysis associated with Parkinson’s or other movement, muscle or nervous system disorders markers (i.e. per vibration or uncontrolled, jerky movements, symmetry of movement, flow or movement, synchronisation of movement between two or more body parts or as further details in section eLifeCHEST/eLifeSCOPE section headed “INVENTION DESCRIPTION” including (but not limited to) section titled “Gait or movement tracking and characterisation of events of interest” (with automatic analysis option) combined with (or assessed as independent factors) the monitoring and analysis or per example (but not limited to) **Figure 75 [21], [24]** and associated features enabling the determination of sleep behaviour disorder (with automatic analysis option) as a diagnostic or prognostic marker of Parkinson’s. Similarly, these artificial intelligent or expert system analysis processes can be deployed in order to automatically analyse circadian offset factors (i.e. but not limited to section headed Somfit “INVENTION DESCRIPTION” including (but not limited to) section titled “CIRCADIAN TEMPERATURE CYCLE DETERMINATION VERSUS LOCAL ENVIRONMENT AND/OR SLEEP/WAKE/ACTIVITY/WORK”.

The said “**health conditions of interest**” can include (for example but not limited to) the diagnosis or prognosis of other neural disorders such as ASD as further described in section headed “PATENT TITLE: DEMENTIA /ALZHEIMER’S /ASD /ASP” along with associated “INVENTION DESCRIPTION” section as well as combined measures covered in section headed “eLifeALERT” and associated “INVENTION DESCRIPTION”.

The said “**health conditions of interest**” can include (for example but not limited to) the diagnosis or prognosis of other neural disorders such as ASD as further described in section headed “eLifeALERT” along with associated “INVENTION DESCRIPTION” section.

Additionally, as part of the input factors to the expert system or artificial intelligence process **concordance analysis** (i.e. means of assessing and rating the accuracy of the expert or artificial system analysis accuracy, compared to comparative expert analysis outcomes in order to both quality control and also continually improve the present invention’s prognostic and diagnostic analysis outcomes in terms of validation with professional medical or scientific experts at all times and ultimately provide the highest quality medical and health tracking for subject/user) can be automatically deployed in order to validate and where required continually modify and improve the interpreter rules **Figure 77 [D]** to enhance the accuracy of the Knowledge Base [A] and ultimately the quality of the subject/patient’s diagnosis or prognosis **Figure 78 [2]; [5]**.

The present invention can incorporate **minimisation** rules as part of the system’s artificial intelligence or expert system self-learning capability so that based on the **broad-scoped or narrow-scope monitoring criteria or monitoring goals** the present invention can both continually validate and improve the monitoring algorithms personalised or specific to the subject/patient as well as streamline and **adapt the most appropriate** and minimized wearable monitoring sensors and associated **prognostic and diagnostic analyses**, once again tailored specific to the patient/subject. The said artificial analysis or expert system analysis self-learning capabilities can be part of one or more mobile and/or wearable monitoring system or supplemented by interconnecting software network or associated services or resources (i.e. SAAS including Cloud-computing services , LAN, WAN, peer to peer, WWW, NAS etc.).

Additionally as outlined in **Figure 78** inputs from experts (including diagnostic review or expert oversight observations per **Figure 78** blocks [1]), patient survey or monitoring data [2], can

be examined within prognostic **Figure 78 [2]** or diagnostic **Figure 78 [5]** modules, for example, in the context of artificial intelligence or expert analysis (as outlined in **Figure 77** as described above.

In one embodiment, conventional clock face time keeping can be supplemented with a series of circadian clock overlays indicating subject/patient's actual circadian cycle status and/or one or more projected circadian sleep cycle scenarios and/or interlinking with local smart watch and/or interlinking with a remote (i.e. wireless or mobile wireless linked alarm clock application designed to enable recommended sleep alarm recommendations for minimal to maximal sleep quality and/or minimal to maximal work scheduling and/or any compromise or balanced position. Additionally, one or more subject/ patient's room or house lights and/or wireless linked lights can be controlled in the context of light therapy to help adjust or optimise a subject/patient's circadian cycle.

i) Determination of optimal circadian sleep cycle

The present invention enables current or new environment (i.e. world clock time zone) time, along with current sleep/wake (and option of comparison with work and/or recreation time cycles – i.e. via calendar and/or clock settings of subject/patient/user's mobile device and/or sleep/wake monitoring) as well comparison and contrasting analysis with normal rhythm or typical cycle or phasic nature of subject/patient/user individual during healthy or peak sleep performance or health condition (i.e. via ESS or other sleep propensity or sleep scale performance, sleep/wake studies, sleep study outcomes indicating normal or healthy sleep propensity or daytime performance of an individual);

>>> indicator means such as watch face (i.e. shows clock time of body versus actual clock and/or phase lag or gain and/or recommendation or coaching go catch up with sleep or potential amount to sacrifice sleep without excessive adverse consequences (i.e. modest or minor sleep deprivation/sleep propensity) , mobile, alarm clock - linkage, alarm clock etc.

>>in a manner whereby the periodic nature of the circadian clock of the human body can be determined and the elapsed cycle or time of the human circadian clock can be computed and compared to the typical circadian clock cycle for the particular subject/patient or the typical normalised population example of circadian clock cycle in a health individual.

>> interlinking to lighting/glasses/pharmaceutical timing and dose recommendations or administration in order to correct or realign natural body clock (circadian) versus desired clock and scheduling requirements;

>>The present invention can incorporate into a **triaged health-watch, or scheduling /activity/calendar application** or shared social or business media information to enable on a personal or community/group level explicit health data or coaching and/or associated treatment (i.e. light therapy circadian clock adjustment entrainment linked to internet of things or various lights and other associated controls) in order to assist with the management of crucial sleep stages such as deep-sleep (body recovery) or REM sleep (brain restoration), circadian clock alignment (i.e. **offset and management of healthy realignment between homeostatic sleep/wake stages/stages' local versus travel clocks, work schedules, leisure schedules, relaxation schedules, of a subject and conflicting or other social or business or travel agendas/itineraries**) whereby user/subject can preference or weighted in order to **influence and/or impact and/or modify and/or adapt** upon the on scheduling or alarm clock setting or **calendar functions and availability** can be segmented such as colour coded in accordance to impact various **schedule or commitment will have on homeostatic or circadian sleep alignment, sleep-debt, sleep-urge and other sleep-health factors**) the importance from their private or personalised perspective in terms of sleep propensity or sleep urge risks, sleep debt factors, sleep urge factors, work time priority, work productivity or performance factors, leisure time or leisure enjoyment, sleep time, quality sleep and other sleep, wake, circadian-clock, sleep health and general health associated factors. For example, in one embodiment example of the present invention a mobile wireless personalised mobile device or **wearable devices (i.e. watch, phone, computer etc.)** can incorporate a watch function with ability of user to toggle through related watch-face or scheduling modes applicable to any of or any combination of **homeostatic sleep/wake stages/stages' local versus travel clocks,**

work schedules, leisure schedules, relaxation schedules, of a subject and conflicting or other social or business or travel agendas/itineraries. Moreover, the present invention can coach, guide and recommend calendar entries, activity scheduling, clock alerts or alarms, shift-work schedules or sleep/wake-planning in accordance to the personalised preference of **work-productivity and/or focus/attention** (i.e. work-mode), personalised occupational work hazard and risk factors (i.e. incorporates a means of monitoring, analysing, correlating and alerting of health conditions such as excessive sleep/wake disruptions including crucial aspects of quality sleep such as amount of REM sleep, amount of deep-sleep, and also the circadian-clock offset factors **versus** (for example only) **population normative requirements along with personalised requirements** etc. versus **also the level or risk or responsibility of job –i.e. truck driving with indications of snoring or OSA sleep disruptions could be indicated on a personalised and personal safety management level to allow private information but potentially critical personal health guidance and support** and **cognitive performance** (i.e. mind-mode), leisure time (fun without consideration of sleep deprivation or fun with various degrees of sleep deprivation or sleep-urge consideration or weighting factors in terms of the present inventions associated fitness or training coaching, sleep training or coaching, work schedules or coaching, leisure schedules or coaching and/or relaxation schedules or coaching

j) Sleep survey and artificial intelligence

>> the present invention enables a means of self-assessment of a subject/patient via sleep or other health surveys (i.e. but not limited to **Epworth sleepiness scale**), whereby sleep urge or sleep propensity can be tracked in accordance to sleep patterns of an individual in order to determine (i.e. artificial intelligence or expert system means per examples **Figure 77, Figure 78, Figure 79**, but not limited to) sleep patterns and/or sleep start and end times most conducive to minimising sleep urge day-time sleepiness; the present invention can further associate these measures with monitored sleep measures along with associated sleep scoring (scoring of human sleep via sleep stage analysis) and/or respiratory scoring (i.e. detection of sleep disordered breathing) in order to determine, indicate, therapeutic device control (i.e. biofeedback or configuration or pressure dynamics of pressure ranges or dynamical changes of pressure associated with APAP/CPAP/PAP/NIPPV in order to minimise sleep disruptions or sleep fragmentation, maximise sleep architecture quality and/or minimise sleep disordered breathing while taking into account improved sleep propensity or daytime sleepiness (or residual daytime sleepiness). This can involve **minimising or eliminating therapeutic event related arousals and/or respiratory event related arousals (TERA and RERA) events.**

>>computation of an individual's circadian clock cycle can be based on any of or any combination of:

-temperature of the subject/patient and/or cycle EEG signals indicative of the brains circadian clock and/or activity or motion of subject/patient and/or homeostatic sleep monitored characteristics and/or sleep/wake or other health survey information;

-the present invention enables wearable **mobile wireless monitoring of information and derivation of a subject/patient's natural circadian rhythm**, whereby such measures can be based on measurement sensors attached or forming part of smart watch, wristband, forehead sensor, armband or other wearable monitoring sensor system incorporating measures that can be analysed in a manner where slow (typically 24 hour slow changing cyclic measures can be derived based on monitoring temperature and/or galvanic skin resistance, and/or heat-flux, and photo-plethysmographic (PPG) measures such as pulse rate, and/or heart rate variability etc., which are physiologically aligned with the natural 24 hour circadian clock function.

-The present invention can monitor and compute a measure of residual excessive sleepiness (RES) in addition to computation of, comparing, and contrasting measure(s) of any of or any combination of the following as a means of determining association or causation of RES (i.e. TERA versus other factors as a mechanism to optimise automatic positive airway pressure titration in order to maximise obliteration of sleep disordered breathing, optimise cardiac function and optimise sleep

quality) with CC or homeostatic factors (i.e. sleep propensity versus circadian clock (CC) asynchronous factors – i.e. delay or advanced CC phase): 1) a subject/patient's sleep parameters (i.e. any of or any combination of but not limited to EEG, EMG, EOG), 2) sleep breathing disorders, 3) therapeutic event related arousals (TERA)^{3,5}, 4) respiratory event related arousals (RERA) arousals, 5) circadian clock factors, 6) previous sleep duration(s), 7) previous wake period, 8) previous waking periods, 9) previous sleep periods in terms of sleep architecture, 10) previous sleep periods in terms of deep sleep (i.e. N3) and/or REM sleep, 11) previous sleep period versus CC, 12) current sleep duration(s), 13) current wake period, 14) current waking periods, 15) current sleep periods in terms of sleep architecture, 16) current sleep periods in terms of deep sleep (i.e. N3) and/or REM sleep, 17) current sleep in terms of sleep architecture;⁶

>>>Somfit or other forehead monitoring device with sleep posture training function

with inbuilt (self-contained) training system capable of detecting snoring (i.e. via inbuilt breathing sound or snoring monitoring function (i.e. accelerometer vibration or microphone sensor) in a manner whereby subject/patient can be alerted or awoken (including headband attached vibration or sound alarm device) based on determination of any of or any combination of:

- 1) sleep alarm setting (i.e. watch, mobile phone, alarm clock etc.),
- 2) sleep stage determination including wake, N1, N2, N3, REM, Non-REM, arousal, spindle, k-complex, alpha bursts, EMG bursts, EMG atonia status etc.,
- 3) subject/patient posture,
- 4) subject/patient posture preference where snoring is least evident (i.e. side versus back position etc.),

5) subject/patient biological synchronisation with breathing cycle (such as derived from any of monitoring sensors including infrared heat flux or subject/patient breathing signals, in order to mitigate against risk of detection of sleep partner breathing measures (or snoring) versus actual subject/patient snoring measures;

6) in one example embodiment the present invention can (for example only):

-in a first process step determine from the users selection of alarm request the amount of time before the alarm activates;

-in a second process step track sleep stages (i.e. wake, N1, N2, N3, REM), and sleep events (i.e. spindles, arousals, k-complexes), while continually assessing the time before the alarm is activated;

-in a third process step and in circumstance when a subject/patient is entering a sleep state which is prone to or has been defined as being prone to cause "grogginess" or "weariness" when interrupted or awakened from, the present invention can activate alarm in a more favourable sleep state that is less prone to cause such "weariness upon awakening. For example, if a subject/patient sets alarm for a daytime 1 hour power nap to try and overcome jet-lag or other forms of sleep-urge or sleep propensity, and the present invention determines or tracks (via online sleep analysis capability) that the user/subject is in REM sleep (less adverse recovery impact than N3 deep-sleep state, for example) then the alarm will sound at the selected alarm setting.

-in a fourth process step and if (for example), the present invention determines or tracks (via online sleep analysis capability) that the user/subject appears to be transitioning from REM to N1/deep-sleep stage (prone to result in high adverse recovery impact than REM stage, for example) and also there is only say 10 minutes time before the alarm set time is activated, along with the condition that the maximum pre-wake alarm time is set (or defaulted) to greater than 10 minutes, then the present invention will sound the alarm and allow subject/patient to be awakened in the preferred REM state versus the potential N3 deep-sleep state.

The maximum pre-wake alarm time is the setting related to the maximum time allowed before awakening that the present invention can use its processing capabilities to optimise awakening event based on subject/patient sleep stage.

Maximum pre-wake alarm time can be set in accordance to sleep time (i.e. hours and minutes) or selected in terms of sleep time (i.e. percentage of total sleep time, where typical start and end sleep times or typical total sleep time periods are entered or set as default by system) or time prior to alarm 10% of total sleep period, for example.

Circadian drug delivery clock patent

The present invention includes (in one example embodiment) the capability for a smart watch with attachable or integrated (embedded or on-board as part of smart watch and/or wireless interconnected processing system(s)) a biofeedback feedback drug delivery (BFDD) system and or "associated therapy" system, whereby said biofeedback drug system can comprise of any of or any combination of: a) a drug delivery dispenser system, b) an automatic analysis system and/or c) a drug delivery control system;

The said "drug delivery dispenser system" can comprise of any attachable drug delivery system including a manually or automatically controlled drug dispenser capable of "optimal medication dispensation" including any of or any combination of:

- A) dispensing medication at an optimal time, and/or rate,
- B) and/or compound (i.e. Drug type or drug compound mixture including but not limited to melatonin) and/or
- C) concentration and/or delivery concentration and/or
- D) delivery rate,

- whereby said in order to minimise the effects of sleep delay syndrome (i.e. Offset between a subject's sleep/wake cycle and/or work cycle/schedule/clock/calendar (i.e. shift work) and/or social cycle/schedule/clock/calendar and/or travel cycle/schedule/clock/calendar (i.e. itinerary), whereby said "optimal medication dispensation" can be applicable to any physiological and/or neurological and/or sleep disorder and/or other adverse health condition;

-whereby said "biofeedback" system and/or "associated therapy" system can include any of or any combination of:

- i) circadian rhythm entrainment system;
- ii) circadian rhythm entrainment system including light radiation control or light radiation;
- iii) Internet or other interconnected circadian rhythm entrainment system including light radiation control or light radiation;

-whereby the said "automatic analysis system" can comprise of determination of a subjects sleep/ake patterns and/or homeostatic sleep characterisation and/or determination of an individual's circadian clock cycle of an individual as outlined elsewhere in this document;

-whereby the said "drug delivery control system" can comprise of a drug dispensing mechanism (including, but not limited to, a cartridge loaded drug dispenser which can dispense medication/drugs in order to minimise sleep delay or sleep offset syndrome in a manner which can be configured to be moderate, severe, or other graduated entrainment (i.e. Compensating for an individual's sleep delay or circadian clock offset factor);

-whereby the said "biofeedback feedback drug delivery system" can be a part of any of or any combination of: a) any wireless mobile system; b) any wearable monitoring system; c) any telemedicine system;

AUTOMATIC SLEEP/WAKE /CIRCADIAN MEDICATION AND/OR THERAPY SYSTEM

The present invention provides a mobile wireless phone or wearable device or separate mobile device **PLUS** option for automatic or manual medication dispenser system (i.e. sleep suppression or antagonist medications such as melatonin etc.) **PLUS** option for sleep/wake cycle analysis system (automatic or manual via local or on-broad processing and/or interconnected processing such as network or cloud-computing or other wireless interconnectivity format) **PLUS** option for circadian rhythm analysis system (automatic or manual) **PLUS** option for light therapy entrainment (i.e. internet of things including light and/or alarm or music and/or audio controls designed to adjust an individual's circadian rhythm cycle) **PLUS** option for meditation and/or relation music and/or audio **PLUS** option for linkage of said one or more therapy types to be linked to biofeedback including processed brain signals (i.e. EEG) and/or other physiological signals (i.e. temperature, oxygen saturation, heart-rate, perspiration or galvanic skin resistance, ECG, EMG, EOG, room light status, subject motion, subject location, subject position, and/or subject activity;

(automatic monitoring and model configuration capability; Figure 83)

-The present invention provides a means of determining, selecting, configuring, whereby said means includes the capability of any of or any combination of (but not limited to): automatic means) of sleep monitoring study type and/or sleep study configuration and/or indication of required sleep monitoring kit (including option of single select options of sleep study device(s) monitoring kit and/or consumable sensor kits), adjustment of computer and other related local or remote device and computer resources applicable to selected or required study format (can also include consideration of "high dependence connectivity monitoring (HDCM)" or "adaptive physiological-Body Network (APN/APM)", automatic sensor connectivity requirements and connection or quality status, automatic pre-acquisition signal processing (i.e. filtering, sensitivity etc.) configurations, automatic data-acquisition configurations (i.e. analogue to digital sampling rates, sample resolution/steps for each respective monitored, analysed, transmitted, stored and/or displayed channel), automatic sensor or electrode location information registered for each monitored channel, automatic post-acquisition signal processing (i.e. filtering, sensitivity etc.), automatic interconnectivity and/or intercommunication relating to data characteristics (i.e. but not limited to sampling rates, sample resolution/steps for each respective monitored, analysed, transmitted, stored, locally displayed, remote displayed, reports, alerts, alarms and/or other communication access or transmission),

-the present invention provides a means of determining configuring or enabling configuration (with automatic configuration option) of any of or any combination of (but not limited to): automatic wireless of or wire interface interconnectivity means whereby the present invention can automatically detect subject/patient/user study type, including a predefined series or monitoring protocols which can be classified in accordance to both physiological monitoring parameters and quality or specific properties associated with each said physiological channel and specific signal characteristics monitored (including any of, but not limited to automatic pre-acquisition signal processing (i.e. filtering, sensitivity etc.) configurations, automatic data-acquisition configurations (i.e. analogue to digital sampling rates, sample resolution/steps for each respective monitored, analysed, transmitted, stored and/or displayed channel), automatic sensor or electrode location information registered for each monitored channel, automatic post-acquisition signal processing (i.e. filtering, sensitivity etc.), automatic interconnectivity and/or intercommunication relating to data characteristics), consideration of "high dependence connectivity monitoring (HDCM)" or "adaptive physiological-Body Network (APN/APM)", and/or automatic sensor connectivity requirements and connection or quality status;

-Whereby said predefined series or monitoring protocols which can be classified include automatically adjusted or upgraded monitoring types and/or levels and/or categorisation and/or scope (or "SCOPE" per in clinic and out of clinic study approaches and/or recommendations and/or health insurance requirements or guidelines and/or government health rebates etc.) along with associated sleep monitoring study scope including type and categorisation of sleep, cardiovascular, oximetry, position, effort, and/or respiratory monitoring requirements);

-the present invention provides automatic determination and corresponding configuration of the sleep monitoring system configuration;

>Whereby said determination can comprise of detecting consumer/non-regulatory versus professional/regulated (i.e. China-FDA, USA-FDA etc.);

>whereby said determination can comprise of detecting actual study criteria or local regulatory (i.e. health insurance reimbursement or government reimbursement or market clearance body (i.e. USA, China FDA etc.) in contrast or comparison to actual sleep study configuration details;

>whereby indications, hints, automatic prompting, are provided in terms of any of or any combination of:

-compliance of professional/regulated (i.e. China-FDA, USA-FDA etc.) requirements;

-actual progress or steps of process in terms of required (outstanding) versus completed progress of study status or study setup/configurations, professional oversight and authorisation versus China-FDA, USA-FDA etc. oversight and authorisation;

-determination of authorised completion by board certified sleep specialist (BCSS) **evaluation of suspected subject/patient obstructive sleep apnoea (OSA)**;

-BCSS determination of whether subject/patient has symptoms or **signs of comorbid medical disorders**;

5 -BCSS determination of whether subject/patient has symptoms or **signs of comorbid sleep disorders**;

-compliance of **professional/regulated** (i.e. China-FDA, USA-FDA etc.) sleep or other subject/patient health questionnaire(s) requirements;

(sleep scope)

10 -whereby said **predefined series or monitoring protocols which can be classified** includes, any of or any combination of (but not limited to) sleep, cardiovascular, oximetry, position, breathing effort and/or respiration measures;

-where said **Sleep categorisation 1** (for example only) can include the monitoring of sleep parameters such as (but not limited to) sleep by using 3 active EEG channels, at least one EOG channel and chin EMG channel;

15 -where said **Sleep categorisation 2** (for example only) can include the monitoring of sleep parameters such as (but not limited to) sleep by using at least 2 active EEG channels (plus separate reference EEG channel), with or without EOG channel or chin EMG channel;

20 -where said **Sleep categorisation 3** (for example only) can include (but not limited to) the monitoring of sleep surrogate channels such as actigraphy;

-where said **Sleep categorisation 4** (for example only) **based on other** sleep measures than those detailed in Sleep categorisation 1, 2 and 3;

Cardiovascular scope

25 -whereby said **Cardiovascular categorisation 1** (for example only) can include the monitoring of cardiovascular parameters such as (but not limited to) more than 1 ECG lead with option of deriving events;

-whereby said **Cardiovascular categorisation 2** (for example only) can include the monitoring of cardiovascular parameters such as (but not limited to) peripheral arterial tonometry (such as described in **Figure 37: Figure 38**);

30 -whereby said **Cardiovascular categorisation 3** (for example only) can include the monitoring of cardiovascular parameters such as (but not limited to) a standard (1 lead) ECG measure ;

35 -whereby said **Cardiovascular categorisation 4** (for example only) can include the monitoring of cardiovascular parameters such as (but not limited to) derived pulse, such as oximetry;

-whereby said **Cardiovascular categorisation 5** (for example only) can include the monitoring of cardiovascular parameters (but not limited to) based on other cardiac measures than those detailed in Sleep categorisation 1, 2, 3 and 4;

Oximetry scope

40 -whereby said **Oximetry categorisation 1** (for example only) can include the monitoring of oximetry (but not limited to) finger or ear sensing with sampling of 3 s averaging and at least a 10 Hz sampling rate but preferably 25 Hz;

45 -whereby said **Oximetry categorisation 1a** (for example only) can include the monitoring of oximetry (but not limited to) finger or ear sensing with sampling properties less than 3 s averaging and 10 Hz sampling rate;

-whereby said **Oximetry categorisation 2** (for example only) can include the monitoring of oximetry (but not limited to) located at an alternative site such as forehead;

-whereby said **Oximetry categorisation 3** (for example only) can include the monitoring of other oximetry formats;

50 Position scope

-whereby said **Position categorisation 1** (for example only) can include the monitoring of video or visual position measurement;

-whereby said Position categorisation 2 (for example only) can include the monitoring of nonvisual position measurement;

Breathing Effort scope

-whereby said Breathing effort categorisation 1 (for example only) can include the monitoring of two respiratory inductive plethysmography measures (abdominal and thoracic measures);

-whereby said Breathing effort categorisation 2 (for example only) can include the monitoring of one respiratory inductive plethysmography measures (either abdominal or thoracic measure);

-whereby said Breathing effort categorisation 3 (for example only) can include the monitoring of one respiratory inductive plethysmography measures a derived breathing effort measure, such as forehead forehead venous pressure (FVP);

-whereby said Breathing effort categorisation 4 (for example only) can include the monitoring of other breathing effort measures, such as piezo respiration belt measures;

Respiratory scope

-whereby said Respiratory Breathing effort categorisation 1 (for example only) can include the monitoring of nasal pressure and thermal sensor device;

-whereby said Respiratory Breathing effort categorisation 2 (for example only) can include the monitoring of nasal pressure sensor device;

-whereby said Respiratory Breathing effort categorisation 3 (for example only) can include the monitoring of thermal sensor;

-whereby said Respiratory Breathing effort categorisation 4 (for example only) can include the monitoring of end-tidal CO₂ (ETCO₂) sensor;

-whereby said Respiratory Breathing effort categorisation 5 (for example only) can include the monitoring of another respiratory measure;

-whereby any said or any combination of sleep categorisation formats (including an of or any categorisation 1-to 5 types or levels) and/or associated monitored signal channels (including any or any combination of sleep, Cardiovascular, Oximetry, Position, Breathing Effort, Respiratory scopes per above) can comprise of automatically meshing one or more distributed wireless interconnected monitoring sensors with time- synchronisation (i.e. as described in but not limited to Title: MULTIPOINT TIME-SYNCH MONITORING (MTM) SYSTEM and associated "INVENTION DESCRIPTION").

-The present invention provides an automatically connected and configured consumer or professional wearable mobile HMS (including device, corresponding online services, sensors, therapeutic intervention and control with option of biofeedback capabilities) activation linked in accordance to any of or any combination of (but not limited to) : a) monitoring study or HMS goal requirements, b) monitoring or HMS "categorisation" format, c) monitoring study or HMS "type or level" requirements, d) sensor-kit, monitoring-kit, e) professional-authorised and secure opt-in healthcarer, f) consumer services provider, g) professional services provider, h) personal-care-management platform, i) application , j) opt-in practitioner (regulatory – i.e. China FDA; USA FDA; CE etc.), k) online-buy-kit (i.e., Amazon, AppleStore, Samsung, Microsoft, Telco, MobileCo, Xiaomi, Baidu, Alibaber, Huawei, etc.), China Mobile, k) HMS eHealth online shop selection, l) HMS eLife online shop selection, k) HMS eHealth App selection or functions, k) HMS eLife App selection or functions, l) HMO, m) health insurance organisation, n) Government health rebait linked-system) AMD, n) AICC, o) SQE, p) SQI&C;

-where said Sleep monitoring study type (level) 1 (most comprehensive level) (for example only) includes the following monitored channels: EEG, EOG, ECG/Heart rate, Chin EMG, Limb EMG, Respiratory effort at thorax and abdomen, air flow via nasal cannula thermistor and/or breathing effort, (respiratory plethysmography), pulse oximetry, additional channels for CPAP/BiPAP levels, pressure, CO₂, pH etc.;

-where said Sleep monitoring study type (level) 2 (for example only) includes the following monitored channels: EEG, EOG, ECG/heart rate, Airflow, Respiratory effort, oxygen saturation;

-where said Sleep monitoring study type (level) 2 AU (for example only) includes the following monitored channels: EEG, ECG, airflow, thoracic-abdominal movement, oxygen saturation, body position, and either EOG or chin EMG;

-where said Sleep monitoring study type (level) 3 (for example only) includes the following monitored channels: 2 respiratory movement/airflow, 1 ECG/heart rate, 1 oxygen saturation;

-where said Sleep monitoring study type (level) 4 (for example only) includes the following monitored channels: minimum of 3 channels including Arterial oxygen saturation, airflow, optionally thoracic-abdominal movement, along with the direct calculation of AHI or RDI measure;

-The present invention further provides a means of Automatic Mode Determination (AMD).

whereby the AMD function works in conjunction with the AICC, SQE and SQI&C functions to enable the system configuration to be set up in accordance with the specific electrode configurations and quality status during the system operation. The AICC, SQE and SQI&C functions are detailed in the patient interface section. Specifically, the SQE system tracks the status of the electrode connections and quality. The corresponding control functions are relayed by the SQI&C function to the AMD system. The A&CD monitoring mode is then adjusted in accordance to the validity and connections status of the sensors and electrodes at any point in time.

As shown in Figure 83 (below) the activation of automatic mode determination (Figure 83 ;[3:Y]) if activated (Figure 83 ;[5]) prompts the A&CD system to configure the monitoring operational mode in accordance to the ISA format and signal quality. However, if the AMD function is not activated (Figure 83 ;[3:N]) the operator interface is configured in accordance to the operator manual mode selection (Figure 83 ;[4]). The integrated attachment sensor (Figure 83 ; [6]) is connected to the patient interface module [7] which detects and determines the ISA format, along with the sensor attachment and quality status (Figure 83 ; [8]). This information is input as part of the decision matrix involved with the automatic identification and channel characterisation (Figure 83 ; [9]; AICC) system. The mode determination (Figure 83 ; 5) then enables the various affiliated systems including the dynamically linked signal conditioning (Figure 83 ; [11]) and the dynamically linked analysis conditioning (Figure 83 ; [12]) system to configure or adapt the A&CD systems corresponding to operational, environment and signal quality conditions. The combination of on-line signal quality tracking and the AMD enables special on-line adaptation such as when the AEP click stimulus is disconnected, whereupon the system can revert from the a hybrid (AEP and EEG-based) to an EEG-based monitoring mode.

-The present invention further provides a means of automated Identification and Channel Characterisation (AICC).

whereby the AICC system is designed to automatically detect the integrated sensor attachment (ISA) system configuration (i.e. Figure 82) and also per (but not limited to Figure 1; Figure 28; Figure 31; Figure 38; Figure 46; Figure 55) other monitoring system examples (i.e. but not limited to) the wearable mobile or other monitoring system monitoring modes (hybrid, EEG based etc.) and format (standard or advanced). Additionally, the specific signal filtering and processing characteristics required for each respective channel can be automatically configured. In this way a single quick snap ISA connection (for example) can automatically prepare the system for monitoring.

-The present invention further provides a means of Signal Quality Estimation (SQE), whereby the said Signal Quality Estimation (SQE) System enables continuous tracking of the input signal's integrity and overall quality. Additionally, such measure can be continually compared to predetermined and acceptable signal ranges, limits, and other important characteristics.

The SQE function works in conjunction with on-line impedance measurement functions (OIM).

-The present invention further provides a means of Sensor/Electrode Quality Indicator and Control (SQI&C).

Whereby the said SQI&C system can be integrated within the patient interface (such as Somfit or other wearable monitoring devices (i.e. but not limited to Figure 1 wearable device

examples) or monitoring head-box (i.e. for clinical or laboratory monitoring) provides a number of key functions including visual user-prompts indicating the connection and sensor quality status at all times.

Low-disturbance Continuous On-line Impedance Measurement (LCOIM) System

The LCOIM system generally refers to the use of active on-line impedance measurements undertaken in such a manner that the measurement periods are flagged and excluded from the downstream analysis results. Furthermore the impedance measurement periods can be minimised by measuring a transient response signal versus conventional steady state waveform measurement methods. The present invention enables a combination of passive signal quality tracking (i.e. examination of monitored signal in terms of typical and expected signal characteristics versus signal characteristics typical of interference and other artefact sources (i.e. main, sweat artefact, electrode popping noise etc.).

The present invention further enables active impedance measures to be interleaved with monitored signals in such a manner that measurement periods (which can cause monitoring signal disturbances) can be limited to "non-critical" or "less-critical" monitoring periods (i.e. not during periods that are critical to the determination of sleep staging epochs (i.e. not during transitional sleep stages and the like). Non-critical periods can also be predefined as periods when vital measures such as spindles or K-complexes marking sleep stage changes are not evident.

Artifact Compensation and Rejection (AC&R) System

The present invention's AC&R system incorporates a series of algorithms capable of eliminating or minimising noise or artifact. Automatic online artifact routines can identify the specific severity level, interval and classification of artifact. Reduction or removal of the effects of unwanted background physiological artifacts including EMG signal intrusion, eye-blinks, EOG intrusion, arousals (various neural and autonomic categories to be included), body movements, movement time, and unwanted PAMR signal intrusion can be automatically and , continuously tracked and implemented online. The present invention enables high tolerance and quality sustained signal monitoring during severe interference from electrical, EMF and other body movement artifact and other signal interference sources. The present invention can incorporate a high impedance environmental noise-sampling input channel configured to operate like an antenna for noise and sample interference in a manner that the signal characteristics or environmental interference can be monitored and/or stored. In this way the environmental noise can be characterised in terms of determining filtering types and characteristics required to minimise or eliminate noise from monitored signals channels. For example, environmental noise-sampling sampled input channel can be used to help cancel out noise in input channel of interest, by way of phase shift, magnitude adjustment and ultimate unwanted cancellation of unwanted environmental noise. i.e. a noise cancellation channel can be created and then phase shifted to be precisely equal but opposite phase (180 degree phase shift) to noise present in other signal channels, in order to null out or cancel out unwanted noise.

The present invention's AC&R incorporation of an open-ended "noise-sampling channel" as a means to cancel out unwanted signals is illustrated in **Figure 29**.

healthpal

The present invention enables a health payment system which "appropriately" (i.e. compliance with relevant privacy, security, government, medical, patient-care, safety aspects, which can be linked in or programmed in as a function for the present invention in accordance to the location or patient specific details and health information) incorporates a means of separating patient or consumer information from health services or products supplier but while still enabling a means of accessing a personalised medical data -base service that enables access to important information such as health insurance compliance or approval data, medical prescription data including verification of therapeutic type and/or adjustments (i.e. PAP, NIPPV devices), in addition to conventional means of enabling online payment transaction; -further aspects of the present invention include the capability to "appropriately" assess contradictions, side-effects, checks against contradictions between patient medical history (i.e. allergies, reaction with certain drugs etc.) and prescribed medications) and alert or notify subject/patient and relevant health-carers as required;

-further aspects of the present invention include the capability to automatically handle Government/insurance reimbursement by way of advice, coaching, simple steps, GP, practitioner, advice/steps, HMOs, etc.

- further aspects of the present invention include the capability utilise two-way separated or buffered data access so that a guaranteed disconnect and both privacy security of information exists between subject/ patient and supplier to conceal private ailments and medical history or privacy in general (i.e. private medications or the like with "healthpal" with health-sensitive and health specialist security).

10 Patent---Elife gait or motor-neuron (including Parkinson's) process or apparatus invention

The present invention provides a means of *characterising an individual's gait or motion characteristics*, including any measure of the *interrelationship of motion between any plurality of body extremities or limbs*, the present invention further including any of or any combination of (but not limited to):

(walking, running, striding motion characteristics)

The present invention provides a means of *analysing the motion characteristics* of a subject/patient by way of analysing (i.e. *spectral analysis such as FFT and segmentation of specified frequency bands applicable to different components of a subject's motion, including analysing the frequency band characteristics associated with arm swings and correlating these arm swings with leg steps in terms of phasic nature and synchronisation between signals*. Said motion characterisation can include resolving motion properties such as any of or any combinations of the *linear length* (i.e. millimetre), *cyclic time* (i.e. seconds), *regularity* (i.e. deterministic or regularity of arm swing or leg stride motion characteristics;

(body extremities motion interrelationship)

Said *synchronisation and phasic interrelationship between arm swing and corresponding leg motion characteristics* will change over time with the progression of movement and neural disorders, and particularly during the navigation by subject of more challenging motor control circumstances associated with corners, changing direction and the like.

(NLDB motion analyses)

Similarly, analyses of motion sensor out puts (i.e. accelerometer) can comprise of the deployment of *non-linear dynamic based (NLDB) analyses transformations* whereby, for example only, the regularity (i.e. deterministic or regularity of arm swing or leg stride motion characteristics can be measured in terms of *non-linear dynamic characteristics* indices such as (but not limited to) complexity or entropy;

(motion pattern or signal morphology analyses)

Similarly, analyses of *motion sensor outputs* (i.e. accelerometer) can comprise of the deployment of pattern recognition analyses transformations whereby the *leg stride and arm swing motions can mapped and recorded with signal characterisation* in order to characterise *gradual changes in pendulum action, fluency, flow of motion, synchronisation* with any other limb or extremity as a measure of subtle or more severe deterioration or improvement applicable to reversal/recovery or degradation of movement, neural or nervous disorders including any of "events of interest/EOI" (per "EOI DEFINITION" detailed" in abbreviation table at rear of this document);

(motion correlation with location/GPS analyses)

The present invention further incorporates means of combining *locational tracking* such as *GPS information* to map out an individual's motion characteristics in a manner whereby progressive deterioration over a period of time and as it relates to *different category of movements* (i.e. *walk, jog, stair climbing, sports or gym exercise systems such as treadmills, running*) can be analysed in context of *navigational or gait difficulty* (i.e. mild, moderate or severe manoeuvring difficulty, straight line pathway, etc.) along with corresponding gait or balance output measures (i.e. such as but not limited to any or any combination of:

>>measures of *interrelationship* (degree of *phasic synchronisation* between any two or more body limbs or extremities or main body motion sensing locations);

>> *cyclic and/or phasic interrelationship* between any two or more signal or data outputs of two or more motion sensing systems (i.e. can be a part of or attached to a wearable device or

5 subject's mobile phone or mobile phone case incorporating sensing device (i.e. single or multiple axis accelerometer measurement sensor),

- whereby motion analysis or characterisation of *any one or limbs or extremities and/or main body section(s)* comprises any of or any combination of (but not limited) to any length of arm swing (linear or arc millimetres) *walking fluency; walking arm movement; swinging arm pattern;*

10 *swinging arm movement* (i.e. via wrist watch or bangle such as (but not limited to) single multi-axis accelerometer; degree of walking leg synchrony with arm synchrony; terms of phasic nature and synchronisation between signals. Said motion characterisation can include resolving motion properties such as any of or any combinations of the linear length (i.e. millimetre), cyclic time (i.e. seconds), regularity (i.e. deterministic or regularity of arm swing or leg stride motion characteristics; and *pendulum motion of each arm swing or step; symmetry factor being correlation between*

15 *arm and leg movements* during walking, the present invention further comprising of analyses of association, comparison or other phase, or cyclic or other means of determining the interrelationship between a plurality of said extremities, limbs or body section motion of a subject/individual;

20 >>>the present invention provides measurement assessment and characterisation of combined *SBD REM atonia* and motion analyses applicable to prognosis or diagnosis of movement or neurological disorders including "health conditions of interest" or "events of interest/EOI" (per "EOI DEFINITION" detailed in abbreviation table at rear of this document);

25 -the present invention incorporates a *means of correlating SBD* (per **Figure 75**) *and/or motion analysis means* such as described elsewhere in this document;

Description of the Figures

30 CIRCADIAN HMS FIGURE DESCRIPTIONS

Figure 96.

The present invention provides a process as part of microprocessor programmed within one or more of any of or any combination of software application(s), mobile device(s), wearable technology, or

35 interconnected communication systems(s) (i.e. SAAS including Cloud-computing services , LAN, WAN, NAS etc.) capable of providing circadian clock health management by way of inputs such as but not limited to any of or any combination of inputs functions, application or systems covered here in Figure 96.

40 **BLOCK 1 AND BLOCK 2** or processing/determination per BLOCK 3 or respective outputs in **BLOCKS 4 to 10, or other inputs, determinations or outputs covered elsewhere in this document.**

[Block 1] CIRCADIAN CLOCK (CC) HEALTH MANAGEMENT SYSTEM (HMS) INPUTS

>>**ENVIRONMENTAL INFORMATION CC ENTRAINMENT** inputs;

45 -**Block 1** incorporates inputs including new and current environments time-zones and/or solar daylight conditions, temperature changes, information on population studies or health information such as typical sleep deprivation or sleep urge/propensity associated with various degrees of circadian clock asynchrony (including incorporation as part of self-learning algorithm processes (i.e.. but not limited to self-learning processes per examples .);

50 >>**INPUTS/ INFORMATION**

- Questionnaire activation with interaction via subject/patient/user and information or related derived information or associated outcomes as they relate to characterisation of an individual's sleep/wake cycle and/or circadian clock cycles; i.e. example (but not limited to) questionnaires include Horne-Ostberg Morning-Eveningness Questionnaire (MEQ); Epworth Sleepiness Scale (ESS); Munich Chronotype Questionnaire (MCTQ) etc. (see also CC HMS processing/determinations);

55

- endogenous circadian cycle;
- subject/patient/user target or desirable circadian cycle entrainment outcome;
- subject/patient/user target (desirable) circadian cycle;
- actual versus target circadian cycle;

5

>>ENVIRONMENTAL MONITORED AND TRACKED CC ENTRAINMENT input;

i.e. but not limited to any of or any combination of:

- Entrainment stimulus or environmental condition changes (i.e. light-therapy controlled inputs; magnetic stimulation controlled targeting and dosage and property adjustment of inputs; temperature controlled inputs etc.;
- Zeitgebers;

10

>>ENVIRONMENTAL MONITORED AND TRACKED CC ENTRAINMENT input;

i.e. but not limited to any of or any combination of:

- >>Entrainment stimulus or environmental condition changes (i.e. light-therapy controlled inputs; magnetic stimulation controlled targeting and dosage and property adjustment of inputs; temperature controlled inputs etc.;

15

>>REGULATION OF SLEEP BY WAY OF CIRCADIAN AND HOMEOSTATIC SLEEP/WAKE FACTORS

i.e. but not limited to any of or any combination of:

- actual sleep-wake cycle (i.e. timing and structure of sleep and waking such as derived from monitored sleep parameters and/or associated measures including (but not limited to **Figure 77;** **Figure 78;** **Figure 79** as covered elsewhere in this document);
- subject/patient/user target (desirable) sleep-wake cycle;
- actual versus target sleep-wake cycle -temperature measures;

20

25

>>PHYSIOLOGICAL AND/OR PSYCHOLOGICAL MONITORED AND TRACKED CC ENTRAINMENT input;

i.e. but not limited to any of or any combination of:

- EEG measures;
- retina light measures;
- GSR measures;
- activity measures;
- position measures;
- pulse measures;
- measures of blood-pressure;
- brain activation measures;
- sleep/wake measures;
- light measures;
- Objective measurement of rest-activity cycle timing can be made with actigraphy;

30

35

40

- Point of care body fluid measures such as melatonin (i.e. the rhythm of the melatonin concentration provides an optimal circadian phase marker for humans) or cortisol (i.e. measures via periodic testing of samples of saliva, blood/plasma or urine or associated blood/plasma, saliva or urine sampling test trips and related point of care testing systems, with option of automatic integration or interface with mobile health monitoring or tracking systems);

45

[Block 2] CIRCADIAN CLOCK (CC) HEALTH MANAGEMENT SYSTEM (HMS) BRAIN SLEEP/WAKE REGULATION INPUTS

- The present invention enables forward and/or reserve equation EEG electrode minimisation/monitoring** (i.e. see also **Figure 45** minimisation process) and/or source localisation applicable to an individual's health management and associated markers of consciousness, sleep/wake homeostatic or circadian rhythm determination/monitoring, brain centres regulating wakefulness and sleep (including neuromodulators and neurotransmitters producing EEG activation, such as histamine, acetylcholine, norepinephrine, hypocretin and glutamate), further including any of or any combination of brain regions (but not limited to):

50

55

- the thalamus or associated areas;
- posterior cingulate or associated areas; medial parietal cortex or associated areas;
- medial basal forebrain or associated areas;
- occipital cerebral cortex regions or associated areas;
- 5 -cingulate gyrus or associated areas;
- prefrontal cortex or associated areas;
- reticular formation or associated areas;
- pons or associated areas;
- visual cortex (visual cortex part of cerebral cortex;
- 10 -located in occipital lobe) or associated areas;
- hypothalamus or associated areas: anterior (ventrolateral preoptic nucleus, responsible for promoting sleep) or associated areas;
- posterior (tuberomammillary nucleus, responsible for generating histamine; medulla oblongata; orexin [A/B], relating to wake-promoting neural activity);
- 15 -midbrain and pons (central point of the generation of coeruleus (norepinephrine; NE), raphe nuclei (serotonin; 5-HT), and
- pedunculopontine) or associated areas;
- olfactory bulb or associated areas;
- cerebellum or associated areas; and/or
- 20 -suprachiasmatic nucleus (circadian clock) regions or associated areas;
- along with related coherence or Dipole modelled connectivity interrelationships (including thalamus-cortical interrelationship);

[Block3] CIRCADIAN CLOCK (CC) HEALTH MANAGEMENT SYSTEM (HMS)

25 PROCESSING/DETERMINATION

>>-CC SYNCHRONISATION WITH ENVIRONMENT CLOCKS OR CYCLES (I.E SOCIAL, TRAVEL, TIME-ZONE, SOLAR, WORK-SHIFT, REQUIRED-SCHEDULE, REQUIRED AGENDA, REQUIRED ININERARY CLOCK ETC.)

- 30 -determination of optimal synchronization with the environment or entrainment, which can be mediated by way of controlling steady state or periodic stimuli (also referred to as zeitgebers) to stimulate or act upon the subject/patient/user's circadian clock (see also CC HMS inputs);
- interactions and interrelationship between the biological clock (or circadian clock (pacemaker) and subject/patient/user sleep homeostatic process (i.e. dependent on prior sleep/wake and associated characteristics)
- 35 -modelling/computation of interactions and interrelationship between the biological clock (or circadian pacemaker) and subject/patient/user sleep homeostatic process as a means of determining a range of sleep disorders or sleep disturbances, such as (but not limited to the interpretation of possible rhythmic circadian clock abnormalities implicated with depression, along with the determination of associated framework and recommendations and/or biofeedback and/or
- 40 control for associated treatment via therapeutic treatment or related circadian rhythm adjustment;
- determination of the time variation between the phase of a subject/patient/user's circadian rhythm such as sleep onset and the phase of a zeitgeber such as the solar clock cycle (i.e. dusk or dawn);
- sleep timing information such as the sleep midpoint (i.e. between sleep onset time and
- 45 wakeup time);
- Objective analysis of rest-activity cycle actigraphy i.e. FFT and frequency analysis of accelerometer outputs followed by segmentation of likely source or causation of activity and then association of said categorisation of movements with sleep, wakes and other activities as a means of deriving final sleep/wake/activity cycle of subject/patient/user;
- 50 - Sleep/behaviour questionnaire activation with interaction via subject/patient/user and information or related derived information or associated outcomes as they relate to characterisation of an individual's sleep/wake cycle and/or circadian clock cycles; i.e. example (but not limited to) questionnaires include Horne-Ostberg Morning-Eveningness Questionnaire (MEQ); Epworth Sleepiness Scale (ESS); Munich Chronotype Questionnaire (MCTQ) etc. (see also CC HMS
- 55 outputs);

-**determination from melatonin samples** of the "Dim light melatonin onset" (DLMO), which is the marker of body clock time which can be measured in saliva or urine or blood/plasma before a person goes to sleep. Moreover, during 24-hour rhythm measurements the points including peak, midline crossing point, offset of secretion, and other points can be determined as a derivations of subject/patient/user circadian clock;

-the present invention can provide a **point of care testing system** which is automatically interfaced to a mobile or wearable device or via interconnectivity to a communication network or system in order to enable saliva, blood/plasma, urine sampling (i.e. melatonin assays including (but not limited to) chemically impregnated test strips designed to react in accordance for the presence or concentration of melatonin and then have option for said test-strips to be automatically scanned and analysed as a means of outcomes to be indicated or communicated);

-the **incorporation of an algorithm** capable of providing a **clinical utility or personalised subject/patient/user health monitoring or tracking capabilities** including the use of (but not limited) the sleep midpoint (by way of sleep/wake monitoring capability, and so long as sleep is not too disturbed, of the present invention's as detailed anywhere in this document) deployed as a surrogate but reasonable measure of approximated circadian phase cycle determination;

-the **incorporation of an algorithm capable of providing the calculation of the time of therapy usage (i.e. bright light therapy)** should be applied in accordance to a subject/patient/user's internal circadian versus external environment clock time conditions. In this manner automatic, patient-wearable technology and/or mobile device integrated systems can contribute to the incorporation of circadian principles in order to enable the determination of important therapeutic treatment (i.e. alignment or adjustment between circadian (internal) and environment (external) clock cycles for optimal health, safety and occupational hazard minimisation. The said therapy can extend to optimising subject/patient/user room, alarm clock settings, or other environment or temperature conditions to personalised versus general conditions;

-**determination of sleep midpoint** on a single or routine basis by way of analysing sleep midpoint computation based on sleep/wake monitoring of the present invention and/or MEQ, MCTQ questionnaires and/or subject/patient/user sleep journals (i.e. start sleep period time, lights off for sleep time, awakening sleep time) in order to determine an approximation of internal circadian cycle clock time;

-**Determination of light therapy phase-advancing treatment** or adjustment/adaptation strategy based in phase relationship and correction requirements in order to shift internal circadian clock to synchronise with external environment (time zone and and/or solar clock factors and/or required sleep/wake cycle), such as advancing time of circadian clock cycle by way of applying light therapy (i.e. activation of bright lights in room) in co-incidence with alarm clock awakening time in an automatic manner (i.e. wireless linked light activation or light controller deployment). Such process can be deployed to counter disorders such as "cabin" or winter "depression" in winter or snow-bound regions or in the incidence of non-seasonal depression etc.;

In this manner the present invention incorporates an **alarm and/or sleep coaching determination capability** and, along with an algorithm designed to assist or guide people with notification of optimal rest periods (i.e. naps or recovery sleeps) the user can set preference (i.e. for a driver or pilot for the purpose of drowsiness occupational-risk aversion or mitigation, for example) in order to enhance vigilance or performance capabilities, whereby the present invention enables subject/user to enter desired sleep period and selection of "best sleep recovery strategy" means (said means can associate any CC determination and/or wake, sleep, REM or arousal state with determination of wake function (i.e. alarm via audio, vibration, including vibration function within monitoring wearable device (i.e. forehead Somfit/forehead- strip etc.);

-**Determination of long-term activity** (i.e. actigraphy), sleep/wake (i.e. monitoring capabilities and/or sleep journal entries) applicable to causation and/or treatment and/or coaching applicable to depression;

-**Determination of unstable rest-activity** cycle as a marker of potential poor circadian entrainment and potential contribution to adverse physiological or psychological health status;

-**Determination of sleep/wake parameters** such as (but not limited to) sleep onset, wake-up time, wake bouts, sleep efficiency, mid-sleep time etc.) based on any of or any combination of sleep/wake monitoring data or associated outcomes, and/or actigraphy (i.e. accelerometer outcomes measures);

- Determination of circadian variables such as circadian relative amplitude versus cycle time** and/or CC maximum amplitude and/or CC minimum amplitude, CC day by day stability (inter-day stability or related fragmentation factor) and/or CC daily stability (intra-day stability or related fragmentation factor);
- 5 -**Determination of circadian variables such as strength of coupling or correlation** between external CC environmental stimulus factors (zeitgebers) versus CC cycle;
- Determination of objective verification and/or characterisation of chronotype** (time subject/patient/user goes to bed and awakes up and/or optimally requires to do same),
- 10 -Determination of objective verification and/or characterisation of **chronotype** (time subject/patient/user goes to bed and awakes up and/or optimally requires/desires to go to bed and awakes) as it relates to **special period such as exams**, celebrations, illness, associated with or following treatment; associated with or following medication; depression etc.;
- Determination of any of or any combinations of CC processing/determination** aspects based on longer term measures or trends (i.e. but not limited to weekly, monthly, yearly summaries or overviews) and/or shorter term measures or trends (such hourly etc.) and/or in correlation with work periods, recreation periods, relation periods etc., along with the option of indications, coaching, entrainment determinations, etc. in order to stabilise CC clock cycle and/or synchronise internal CC cycle with external environmental clock factors (time-zone; solar-clock; zeitgeber factors);
- 15 -**Stability of entrainment (i.e. dim light melatonin onset; DLMO** (marker of body clock time based on measuring saliva prior to subject/patient/user going to sleep) over successive days, week, months etc.) by way of any of or any combination of measures of environmental environmental/room light, solar light, temperature and/or physiological subject/patient/user light, temperature, actigraphy, EEG;
- 20 -**Environmental/room light** and/or solar light log;
- 25 -**Social zeitgebers** by way of Social Metric Rhythm Questionnaire;
- Sleep log via any of or any combination of related Questionnaire and/or sleep/wake monitoring and/or actigraphy;
- determination of CC amplitude** by way of any of or any combination of core body temperature, melatonin sample testing, EEG measures, surrogate or derived or estimated body temperature measures;
- 30 -**determination of light input frequency/colour composition** and/or strength;
- determination of sleep homeostatic characteristics** including the increase or decline short-terms or long-term wise as it **relates to slow wave sleep (i.e. NREM such as 0.75 Hz to 4.5 Hz)**;
- 35 -**determination of sleep homeostatic characteristics** including the increase or decline long-term or short-term-wise **as it relates to REM sleep**;
- determination of sleep homeostatic characteristics** including the increase or decline long-term or short-term-wise **as it relates to wake EEG**;
- determination of sleep homeostatic characteristics** including the increase or decline long-term or short-term-wise as it relates to faster beta waves in active waking and/or **slower alpha waves in quiet waking**;
- 40 -**determination external zeitgebers applicable to sleep and wake structure aspects and/or variations**;
- Determination of zeitgeber strength** based on degree of light subject/patient/user receives. along with associated time of day as it relates to entrainment requirements and/or current entrainment determination;
- 45 -**the present invention can automatically incorporate all CC entrainment factors**, indication aspects, alarm clock functions, light detection functions, coaching and/or messaging and/or alert functions, into a single application as part of a wearable or mobile device;
- The present invention can determine circadian clock nadir factors** (i.e. body temperature and/or interval from body temperature nadir to sleep offset) including subject/patient/user's with delayed sleep phase syndrome (DSPS) in order to optimise CC entrainment (i.e. light therapy including glasses with blue light projected towards subject/patient/user retina as a stimulus – can be blocked from forward projection **based on shaded or blocked section of glasses** in order to minimise obtrusive or obvious nature of such treatment);
- 50 -**The present invention can track sleep-wake rhythms** and characterise a lack of clearly discernible circadian patterns of sleep-wake time, as a marker or potential prognosis of irregular sleep-wake rhythm;
- 55

-**The present invention can in incorporate sleep-wake rhythms** and characterise a lack of clearly discernible circadian patterns of sleep-wake time, and/or questionnaire outcomes **relating to excessive sleepiness**, unrefreshing sleep, and/or insomnia that vary in accordance to work schedule as a marker or potential prognosis of shift work disorder (SWD) ;

[BLOCK 3A] - OPTION AN INTEGRAL OR ADJUST SPECIAL WEARABLE TECHNOLOGY, MOBILE OR OTHER SYSTEM

-MULTIPOINT TIME-SYNCH MONITORING (MTM) SYSTEM : **Figure 30**

-IR reflective oculography and/or video imaging (with IR capability) and/or light therapy integrated and/or mobile CC HMS application interfaced systems ((i.e. glasses): **Figure 43**

-Automatic diagnostic and prognostic EEG-monitoring and analysis system incorporating minimisation process enabling professional and consumer-level monitoring and automatic analysis determination (**MINIMISATION SYSTEM**) per example **Figure 45**;

-HMS WITH AUTOMATIC TRACKING OF EOI per example **Figure 75**;

-HMS sensor or monitor device/system (SOMDI) interface per example **Figure 76**;

-Driver/subject wearable glasses incorporating any of or any combination of binocular or monocular

-Self-learning and Personalised Self-Adaptation System AI; ES per example **Figure 77; Figure 78; Figure 79; and/or**

-Personalised subject/patient- health management system (HMS) [1] incorporating any of or any combination of monitoring goals per example **Figure 80**.

[Block 4] CIRCADIAN CLOCK (CC) HEALTH MANAGEMENT SYSTEM (HMS) OUTPUTS INPUTS

-**Control of environmental and/or other stimulation factors capable of enabling or transition towards optimal synchronization with the environment or entrainment.** This can be mediated by way of controlling steady state or periodic stimuli (also referred to as zeitgebers) to stimulate or act upon the subject/patient/user's circadian clock (see also CC HMS inputs);

-Circadian sleep-wake cycle,

-Neurobehavioral performance,

-mood,

-cortisol,

-melatonin,

-temperature,

-heart rate, etc.

-**A computed circadian clock generating a cycle to match the solar day**

-**A control or measure of control to maintain or correct (i.e. move circadian and sleep wake clock into closer synchronisation) the phase relation between the subject/patient/user circadian clock cycle (i.e. prior sleep/wake cycle) and the current environment clock cycle (i.e. solar clock, time-zone or schedule requirements of subject/patient/individual) and/or target clock (i.e. desired subject/patient/user and/or the subject/patient/user desired or preference clock or schedule (i.e. any of or any combination of considerations including wake cycle, sleep cycle, work cycle, recreation cycle, fitness cycle, relaxation cycle, travel cycle, work-shift cycle, study-cycle, exam-peak-performance-cycle, jet-lag cycle, current time-zone cycle, one or more new time-zone cycles etc.);**

i.e. but not limited to any of or any combination of:

>>Circadian clock entrainment outputs or outcomes. i.e. but not limited to circadian clock interactive (or one way information access) options (CCIO);

-whereby said CCIO include any combination of (but not limited to) - map display or application with map functions or indications or associated annotations or information, with automatic and/or dynamic data exchange or update options;

- clock or watch indications, with automatic and/or dynamic data exchange or update options;

-clock or watch alarm indications or settings, with automatic and/or dynamic data exchange or update options;

-as part of circadian clock entrainment stimulus or environmental adjustment decision matrix or control of environmental or therapy deployment (i.e. any of but not limited to light-therapy, with automatic and/or dynamic data exchange or update options;

-temperature or environmental changes, with automatic and/or dynamic data exchange or update options;

-vibration or other stimulus, magnetic stimulus, steady state or flashing "light stimulus", with automatic and/or dynamic data exchange or update options;

5 -whereby said "light stimulus" can include (but is not limited to room or glasses or other head mounted/applied system including concealed steady state light therapy means using forward light blocking means and/or less obvious subject/patient steady state light and light colour selection or light-colour control properties;

10 >>the present invention includes any combination of or any of motion tracking (such as actigraphy or accelerometer measures), body temperature, GSR measures, pulse measures, light measures as a means of approximating or determining and/or indicating a subject/patient/users circadian clock cycle;

15 **[BLOCK 5]- CIRCADIAN CLOCK (CC) HEALTH MANAGEMENT SYSTEM (HMS) OUTPUT- MAP-LINKED FUNCTIONS**

The capability to automatically access a travel agenda

20 -**integrated mapping application** (i.e. geographical or road map) an indications or annotation, with the option of additional notes or associated information, relating to various travel scenarios indicating or symbolising;

[Block 6] CIRCADIAN CLOCK (CC) HEALTH MANAGEMENT SYSTEM (HMS) OUTPUT- SOCIAL/PROFESSIONAL/COMMUNITY-LINKED APPLICATIONS OR FUNCTIONS

25 The present invention enables a ***range of clock or watch face programmable functions***, including a sequence of watch displays which can be ***toggled through and selected as required***. For example, any combination of solar-cycle, sleep-wake cycle, time-zone, social-clock, and associated phase shift with circadian clock can be programmed by users, presented as default library of displays and/or programmed display formats shared amongst different users.

30 The present invention CC HMS enables a community or private select grouping function whereby healthcare specialists can coach, guide, assist and intervene in tracking, diagnosing and supporting an individual's occupational safety aspects, sports performance aspects, general health aspects, depression and other psychological disorders greatly impacted by appropriate CC management (***Figure 96.; Figure 97***).

35 **[Block 7] - CIRCADIAN CLOCK (CC) HEALTH MANAGEMENT SYSTEM (HMS) THERAPEUTIC/CONTROL/FEEDBACK/BIOFEEDBACK**

40 - **determination of associated framework and recommendations and/or biofeedback** and/or control for associated treatment via therapeutic treatment or related circadian rhythm adjustment including neural magnetic stimulation targeting and dosage determination and/or light therapy stimulation targeting and dosage determination and/or room temperature targeting and dosage determination

45 - **provision for the determination and/or enabling of a number of entrainment scenarios such as the intervention with subject-wearable device or environmental lighting** as a means various degrees of advancing or delaying a subject's phase response curve (i.e. a subject's inbuilt circadian curve phase relationship with external clock factors, including social, time-zone, work, work-shift, study requirements etc.) applicable to minimising delayed sleep phase disorder (DSPD) or advanced sleep phase disorder (ASPD) according to a subject's health- care oversight or intervention and/or an individual's personal preferences or requirements and/or occupational hazard and safety considerations;

50 - **automatically or via manual assistance activate light intensity and type** (i.e. visible blue light with short wavelength, and stronger melatonin suppression affect can be deployed as part of an automatically computed CC entrainment treatment regime, versus longer wavelength light) as well as the timing functions of such light therapy (i.e. light-therapy in the evening can enable CC phase delay, while light therapy in the day can product CC phase advancement);

55 - **automatically (or with manual intervention option) control entrainment factors** (i.e. lighting timing and/or lux intensity and/or melatonin dosage and administration timing or recommendation), as well as the option of recommending or setting bed-times or alarm clock settings, in accordance to a subject/patient (or healthcare advisor) social, work, travel requirements or environmental factors;

- the present invention can **advise/coach and/or automatically adjust said CC entrainment in accordance to subject/patient/user preferences**, selections or personalised scenario choices (i.e. more aggressive adjustment over a shorter period of days or more moderate CC adjustment over a longer period of days);

[Block 8] CIRCADIAN CLOCK (CC) HEALTH MANAGEMENT SYSTEM (HMS) OUTPUT- PERSONALISED HEALTH MANGEMET AND COACHING-LINKED FUNCTIONS

-**capability to measure environmental lighting conditions applicable to subject/patient/user** (i.e. via wearable device such as watch, mobile device etc.) in order to provide coaching or guidance to treat winter depression or other forms of depression or delayed sleep phase disorder (DSPD), or compensate for offset between CC and environmental (i.e. time zone or solar clock factors or behavioural clock properties (i.e. social clock, work-clock, shift-works, travel/jet-lag clock, clock and associated requirements or planning/scheduling preferences), whereby said coaching can include CC offset therapy (i.e. light therapy, melatonin medication, adaptation of homeostatic sleep factors (i.e. optimal increasing of a subject/patient/user's awake period to enable higher quality sleep and alignment of CC with sleep patterns or vice versa);

[Block 9] CIRCADIAN CLOCK (CC) HEALTH MANAGEMENT SYSTEM (HMS) INTEGRATED (INTERCONNECTED) APPLICATIONS AND NOTIFICATIONS

-**determine, predict and indicate (i.e. optional calendar application annotations;**

-**scheduled or hypothetical schedule, travel itinerary, natural circadian clock cycles, homeostatic sleep/wake monitoring;**

-**determination of accuracy or confidence level in terms of the accuracy** of computing individual's previous and up-to-date circadian clock cycle status, along with other factors impacting the **determination of current circadian clock status** of an individual (i.e. based on prior sleep/wake study data quality and availability, along with atigraphy and other availability of circadian clock related measures;

-incorporation of CC computed parameters as part of automatic **entrainment programming of CC treatment systems** (i.e. such as bright light therapy including glasses or sunglasses (i.e. half-shielded glasses, for example only, tinted in upper section of glass lenses only), whereby said **glasses can include reflective oculography capable of both entrainment light-therapy** and/or detection of **eye-lid movements** and/or opening as a **marker of drowsiness** in order to enable biofeedback entrainment capabilities in order to adjust for CC cycle offset factors and/or sleep propensity and/or sleep urge factors;

- **determination of CC confidence level factors (i.e. accuracy – i.e. error factor)** in terms of the accuracy of the determination of the individual's previous and up-to-date circadian clock cycle status, along with other factors impacting the determination of current circadian clock status of an individual); The present invention enables all these functions and capabilities to be incorporated into one or more wearable or mobile devices (i.e. smartwatch, mobile phone, Somfit sleep monitoring headband and/or other covered elsewhere at any section within this patent application document (**Figure 1**);

- **automatically link (i.e. wireless or other interconnectivity communication** and information access means) to messaging systems (such as mobile phone SMS, emails, calendar, applications and the like) in order to track and/or comment/health-coach and/or enable sleep scheduling;

- **integrated calendar or scheduling/planning application(s)** (i.e. geographical or road map) an indications or annotation, with the option of additional notes or associated information, relating to various travel scenarios indicating or symbolising;

[Block 10] CIRCADIAN CLOCK (CC) HEALTH MANAGEMENT SYSTEM (HMS) DISPLAY INDICATIONS

-**A nub of the present invention's personal health management system is to automatically determine and indicate, coach, alert, message, CC entrainment stimulation** applicable to subject/patient/user based on CC input factors, a range of scenarios , covering sleep quality and length relating to the interrelationship or the manner the said subject works with or against their natural CC;

Figure 97

DEMANDE OU BREVET VOLUMINEUX

LA PRÉSENTE PARTIE DE CETTE DEMANDE OU CE BREVET COMPREND PLUS D'UN TOME.

CECI EST LE TOME 1 DE 7
CONTENANT LES PAGES 1 À 58

NOTE : Pour les tomes additionels, veuillez contacter le Bureau canadien des brevets

JUMBO APPLICATIONS/PATENTS

THIS SECTION OF THE APPLICATION/PATENT CONTAINS MORE THAN ONE VOLUME

THIS IS VOLUME 1 OF 7
CONTAINING PAGES 1 TO 58

NOTE: For additional volumes, please contact the Canadian Patent Office

NOM DU FICHIER / FILE NAME :

NOTE POUR LE TOME / VOLUME NOTE:

CLAIMS

1. Apparatus for determining and monitoring brain activity, comprising:
a plurality of sensors for acquiring electrophysiological signals from a brain, each sensor having a designated sensitivity or spectral properties;
means for determining a location of sources of the electrophysiological signals; and
sensors for generating and applying magnetic stimulation to the brain;
wherein the magnetic stimulation is applied according to the determination of the location of the sources of the electrophysiological signals.
2. The apparatus of claim 1 wherein the location of the sources of the electrophysiological signals are biomarkers or events of interest for the magnetic stimulation.
3. The apparatus of claim 1 or claim 2, wherein the apparatus is implantable in a body.
4. The apparatus of any one of claims 1 to 3 wherein a targeting, the location, an energy or an associated beam control of the means for generating stimulus or changing brain state or signals is controlled by a computer program.
5. The apparatus of claim 4 wherein a target for the means for generating magnetic stimulation events is adjustable according to input from a feedback loop, or in accordance to a corresponding brain analysis or brain changes or neurological or physiological events or related activity.
6. The apparatus of claim 5 where the input from the feedback loop includes biomarkers or events of interest that indicate physiological or neurological changes.

7. The apparatus of any one of claims 1 to 6, further comprising means for pharmaceutical administration or formulation or dosage or delivery.
8. The apparatus of claim 7 wherein the pharmaceutical administration or the formulation or the dosage or the delivery is determined according to the signals induced by the magnetic or electrical stimulation.
9. The apparatus of any one of claims 1 to 8 wherein the means for generating magnetic stimulus targeting or beam, energy, level, energy pulsations, or envelope of the energy beam can be adjusted in accordance to resulting brain analysis outcomes or predetermined or required brain changes or associated mental, physiological, cognitive or neurological states or responses or conditions or associated changes.
10. A method for monitoring and stimulating brain function, comprising:
 - a. acquiring multiple electrophysiological signals from predetermined positions on the head;
 - b. defining a location of source of the electrophysiological signals based on predetermined characteristics of an underlying region of a head for each of the electrophysiological signals;
 - c. determining whether the electrophysiological signals are representative of a health condition of interest;
 - d. determining a source of the electrophysiological signals from a current density model or a dipole analysis model;
 - e. applying a magnetic stimulus to a region of the head according to the determined source locations in steps b or d; and
 - f. repeating steps a to e.

11. The method of claim 10, further comprising the step of determining whether changes in the electrophysiological signals are representative of a change in the health condition of interest.
12. The method of claim 10 or claim 11, wherein signals from a suprachiasmatic region of the brain can be acquired.
13. The method of any one of claims 10 to 12, further comprising the step of evoking the electrophysiological signals by applying a stimulus.
14. The method of claim 13, wherein the stimulus is auditory.
15. The method of any one of claims 11 to 14 wherein the health condition of interest is Parkinson's disease, dementia, or a sleep disorder.
16. The method of any one of claims 10 to 15, further comprising the step of administering a pharmaceutical treatment.

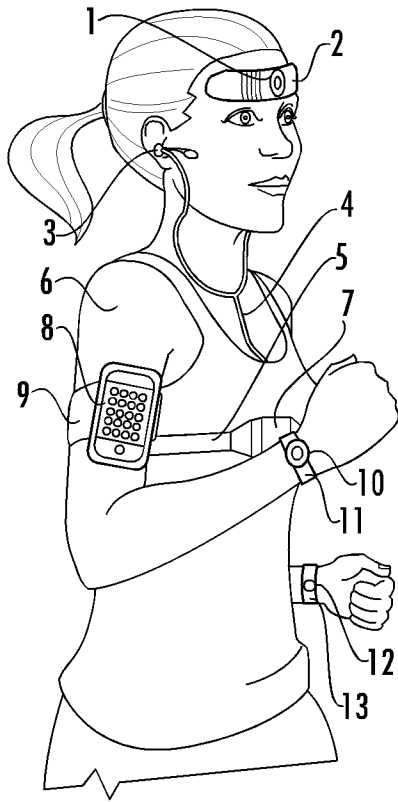


FIG. 1A

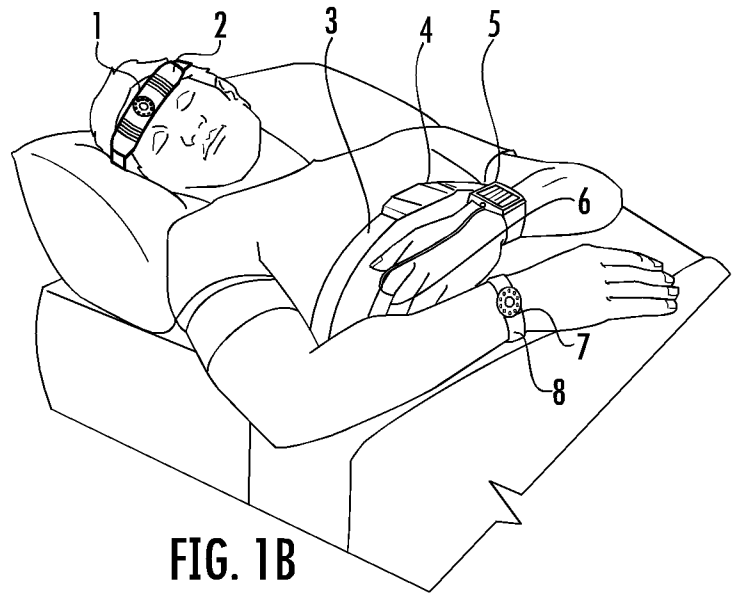


FIG. 1B

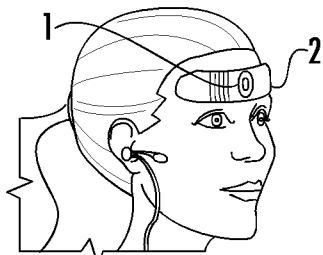


FIG. 1C

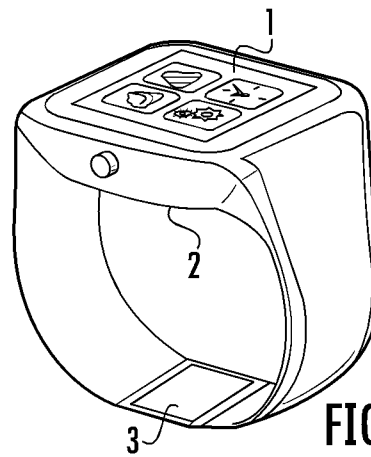


FIG. 1D

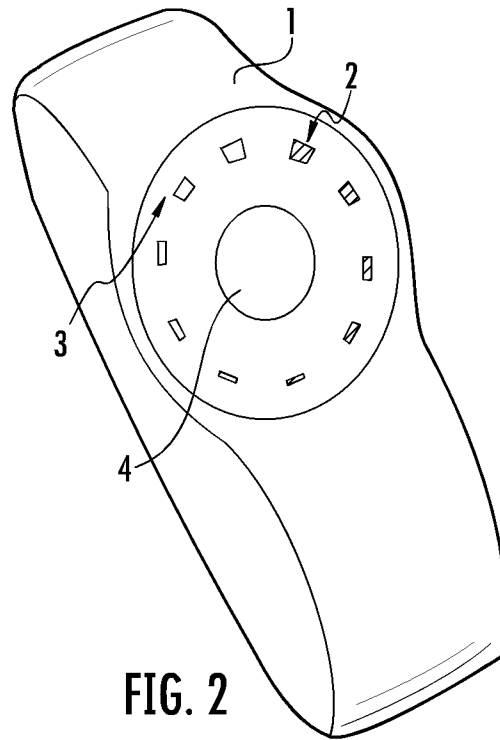


FIG. 2

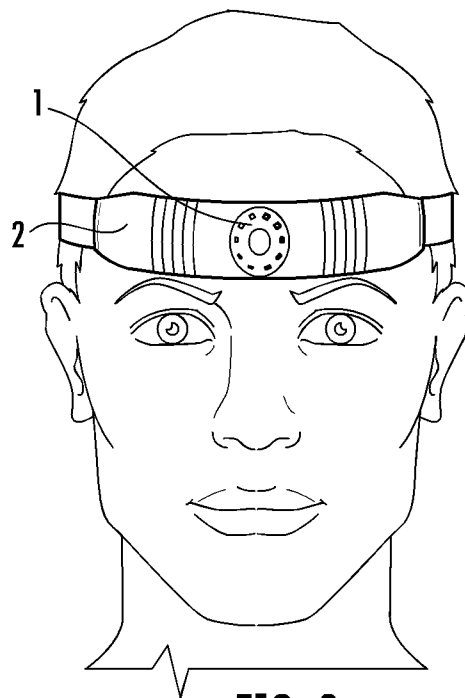
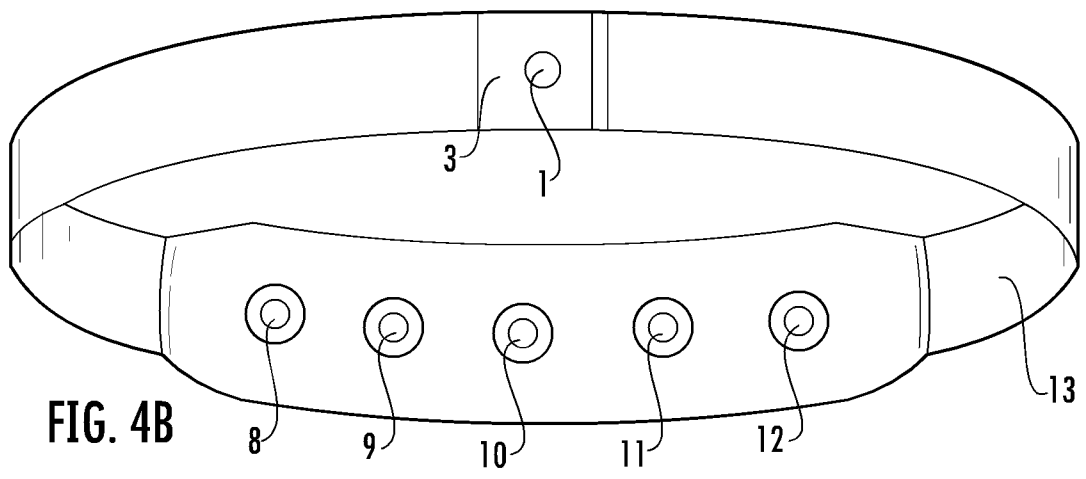
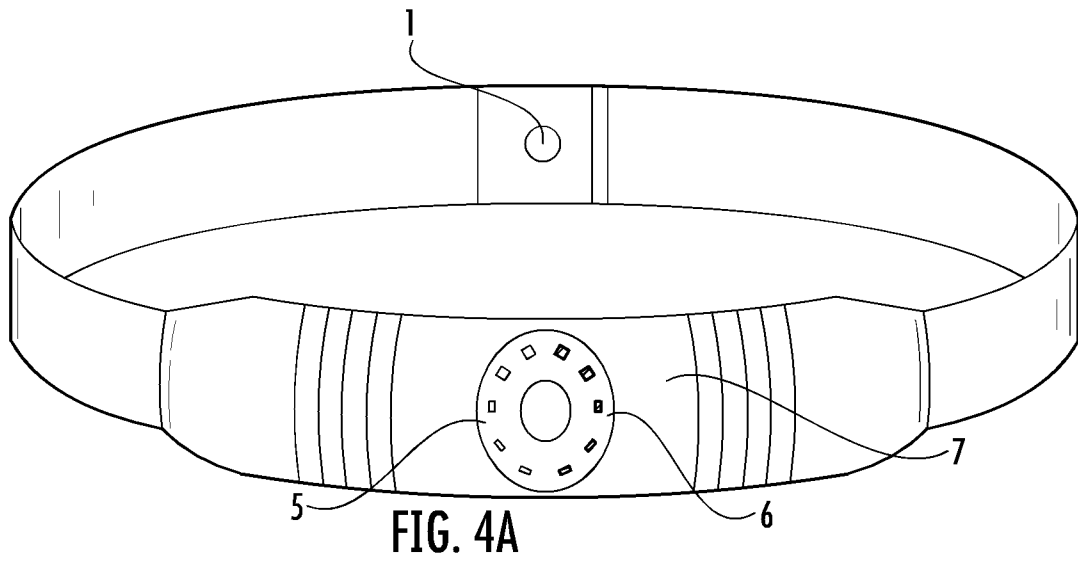
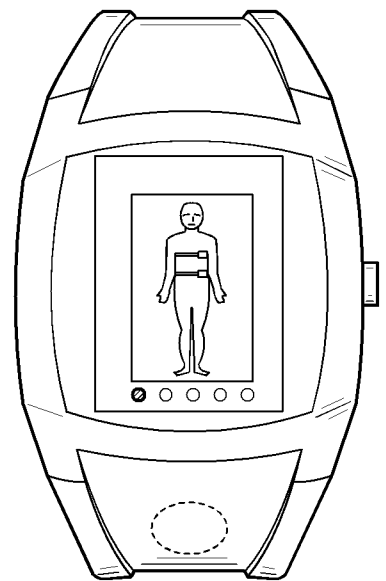
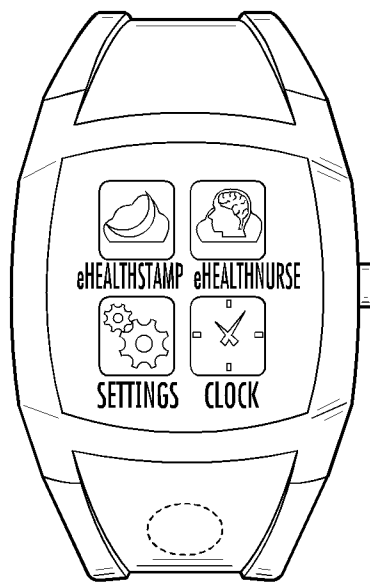
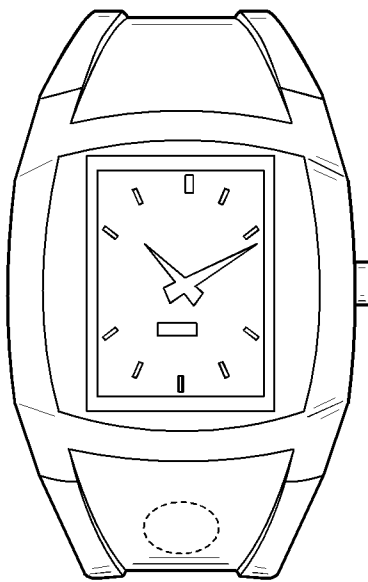
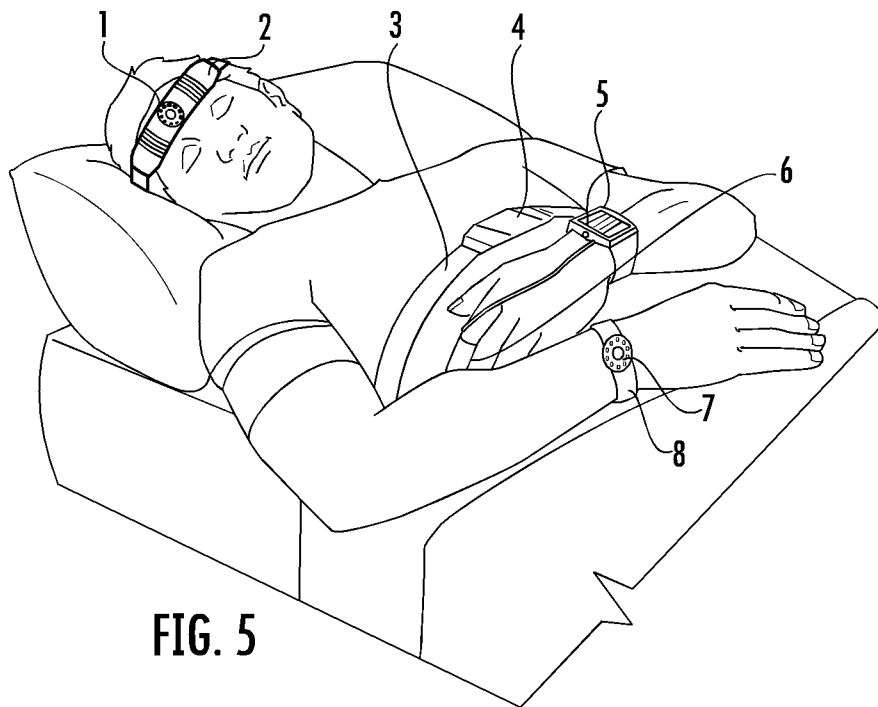
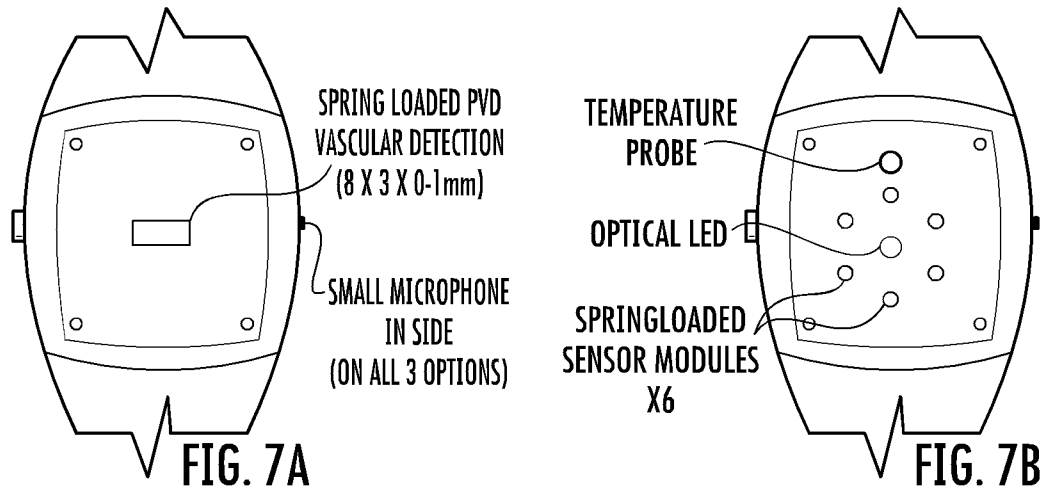


FIG. 3







4 STEPS TO A HEALTHY SLEEP & LIFE

1

GO TO AMAZON OR eLIFECART AND CLICK TO BUY A eLIFE KIT FOR YOUR PERSONALIZED HEALTHCARE EVERYWHERE WITH INBUILT TEMP; PULSE; ACTIVITY POSITION; SKIN/GSR; PLETH-OMETER; SOUND; LIGHT. THE MODULAR REAR COVER PROVIDES SPECIALIZED AND PATENTED ADVANCED eLIFEWATCH OPTIONS INCLUDING PLETHYSMOGRAPHY OXIMETER (PATENT PENDING), VASCULAR PRESSURE PULSE SENSING SYSTEM (PATENT PENDING), INTERSTITIAL GLUCOSE (PATENT PENDING), GSR ENERGY/ METABOLIC EXCURSION, BLOOD-PRESSURE ANALYSER, ETC. CHARGE eLIFEWATCH AND SENSOR KIT (LASTS 1 WEEK WITH NORMAL OR STANDBY USAGE) VIA eLIFEWATCH POD.

2

GO TO AMAZON OR eLIFECART, AND CLICK TO BUY eLIFEWATCH SENSOR KITS OF YOUR CHOICE COVERING CONSUMER SLEEP TO PROFESSIONAL MEDICAL eLIFE SLEEP TESTING (eLIFEHST) CAPABILITIES, IE. US HOME SLEEP TEST TYPE i), ii), iii) AND/OR iv) OR AU LEVEL 2 OPTIONAL: WHILE YOU ARE THERE OR ALTERNATIVELY GO TO eLIFEDATAPLAN

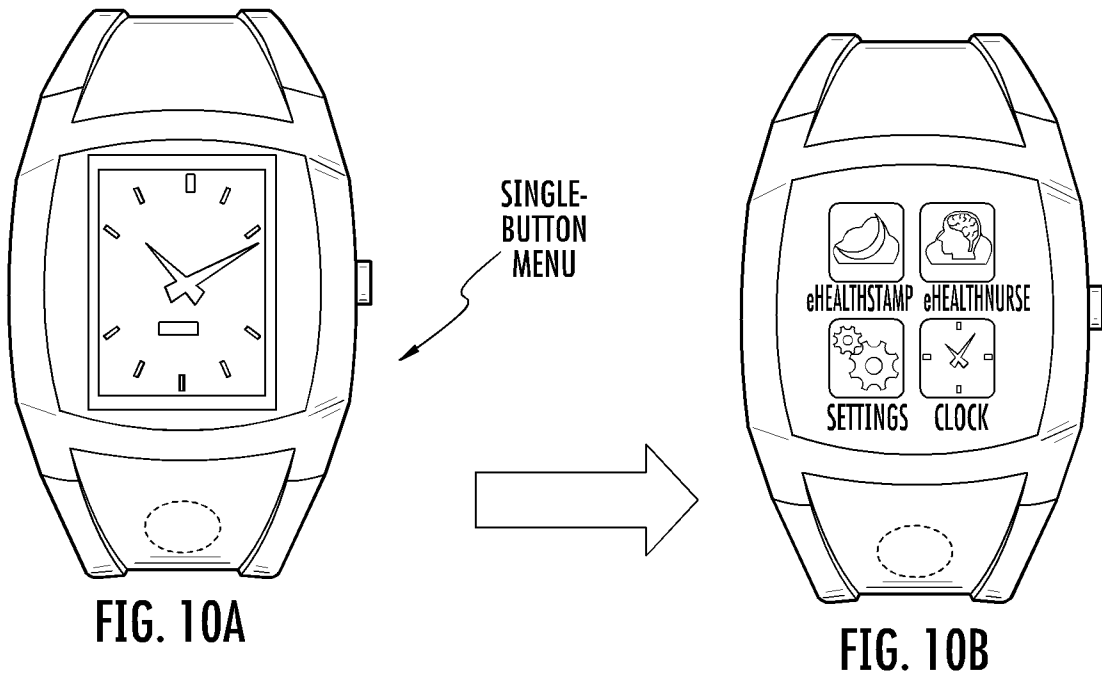
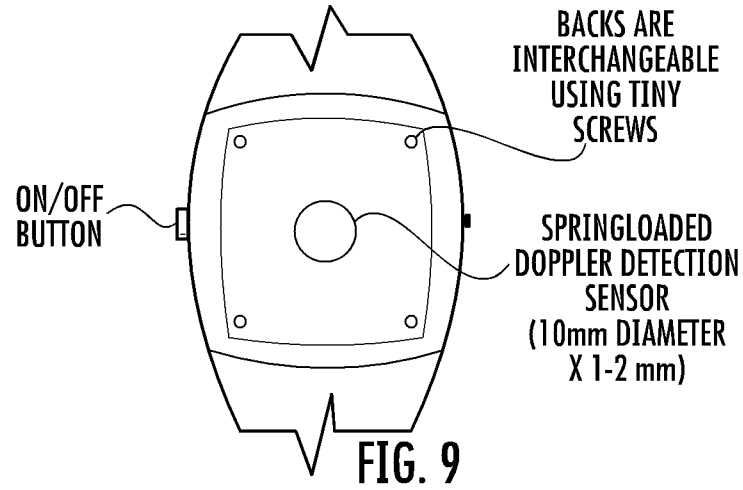
3

GO TO eHEALTHME AND "OPT-IN" OR OPT-OUT" YOUR PERSONALIZED HEALTH COMMUNITY HELP, OVERSIGHT OR INTERVENTION.

4

ENJOY eLIFEMEDICS AND eLIFEWATCH HEALTHCARE EVERY WHERE!

FIG. 8



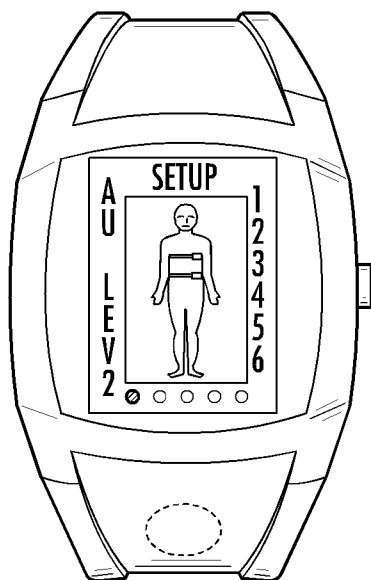


FIG. 11A

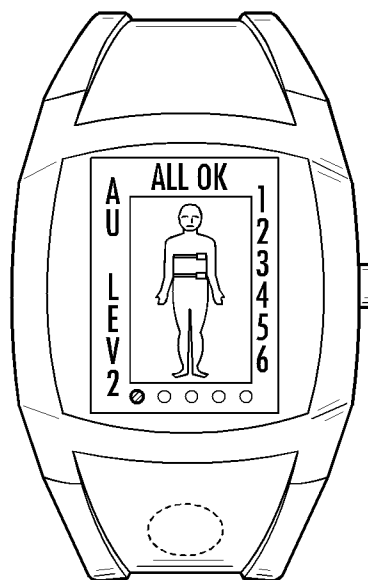


FIG. 11B

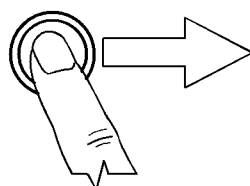


FIG. 12

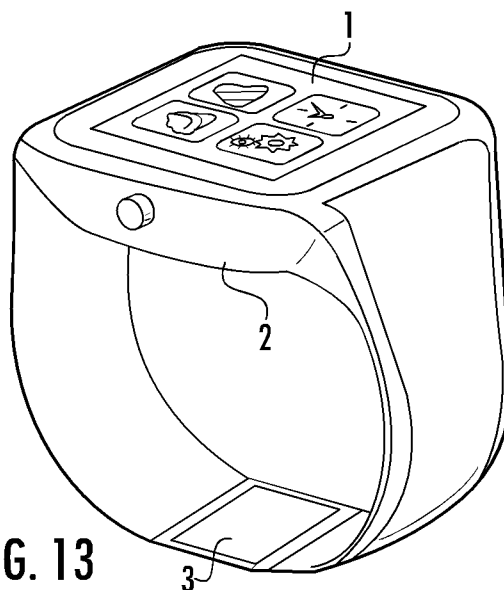


FIG. 13

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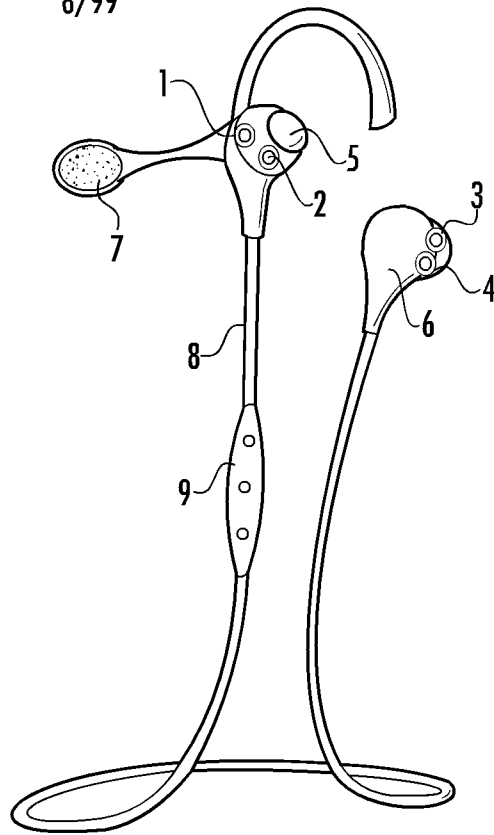


FIG. 14

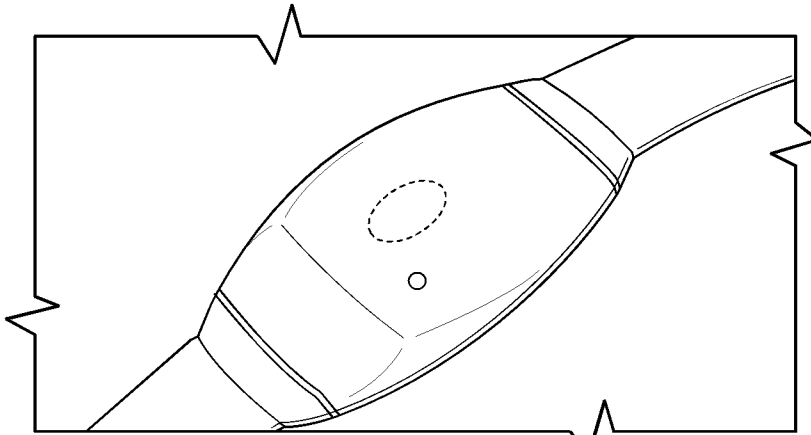


FIG. 15



FIG. 16

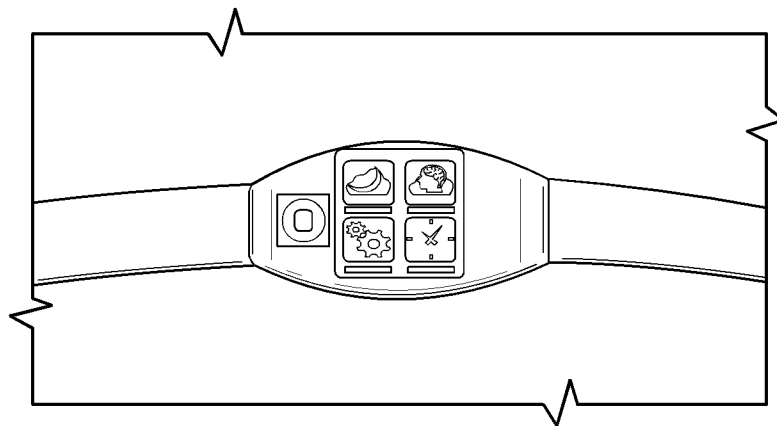


FIG. 17

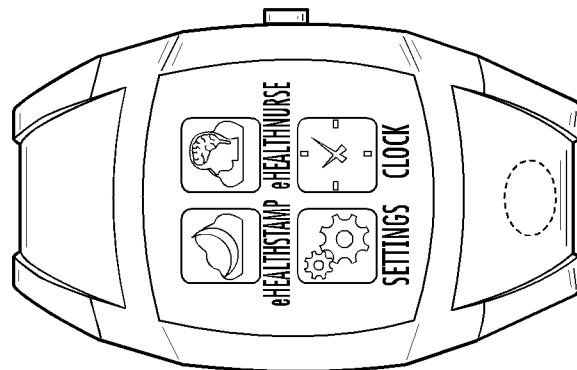


FIG. 18

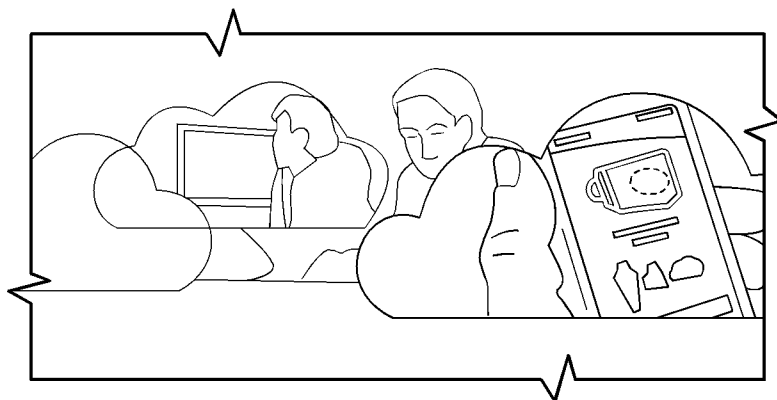


FIG. 19

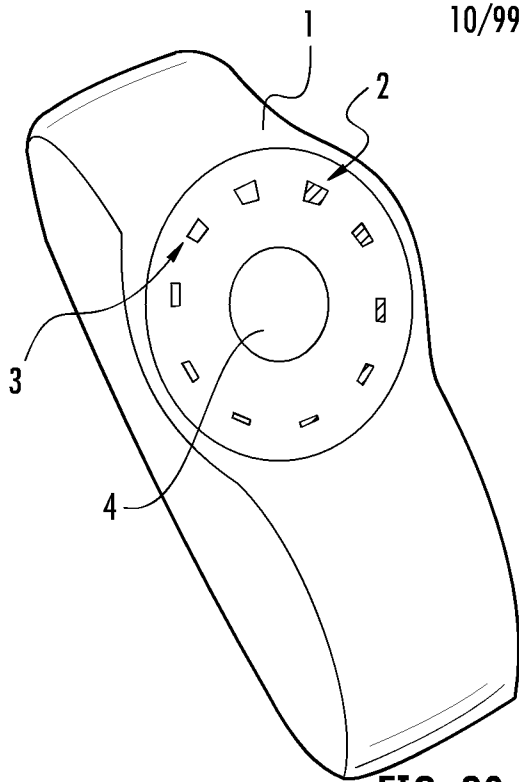


FIG. 20

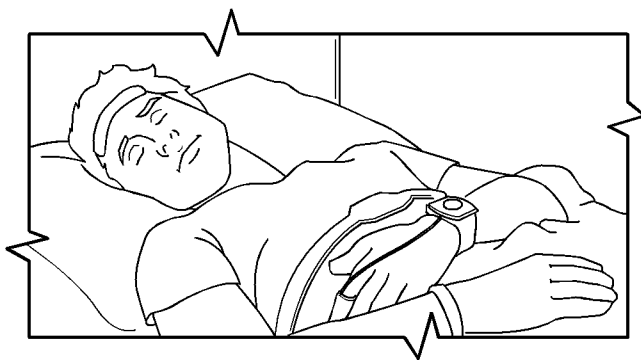


FIG. 21A

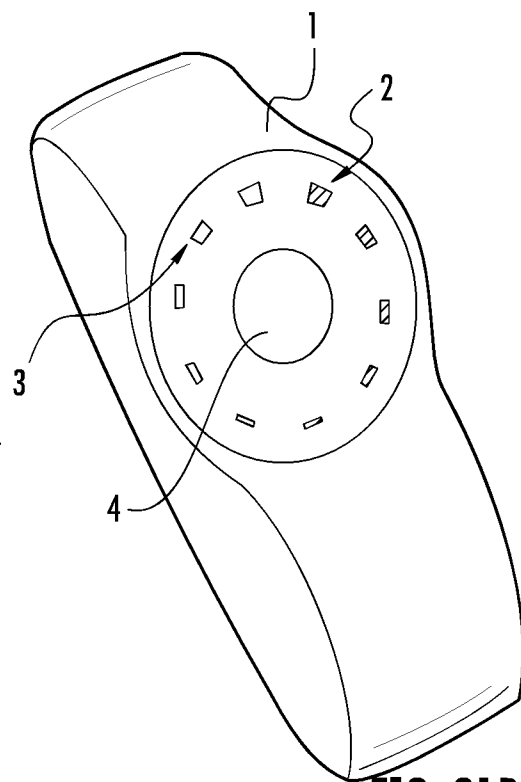


FIG. 21B

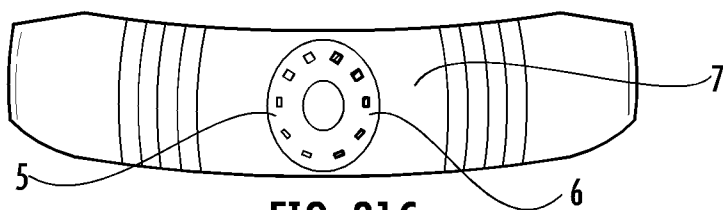


FIG. 21C

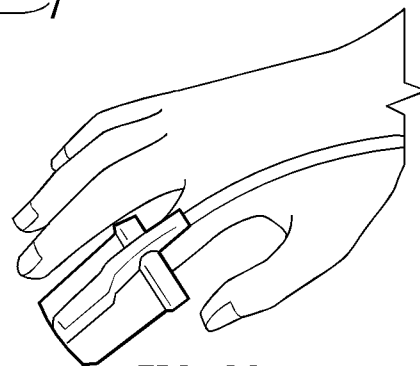


FIG. 22

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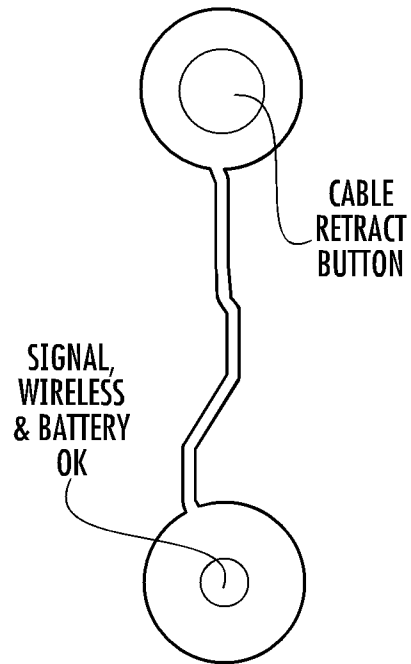


FIG. 23



FIG. 24

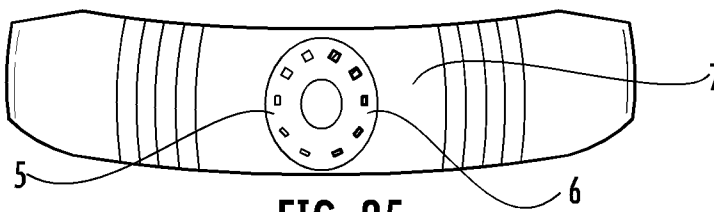
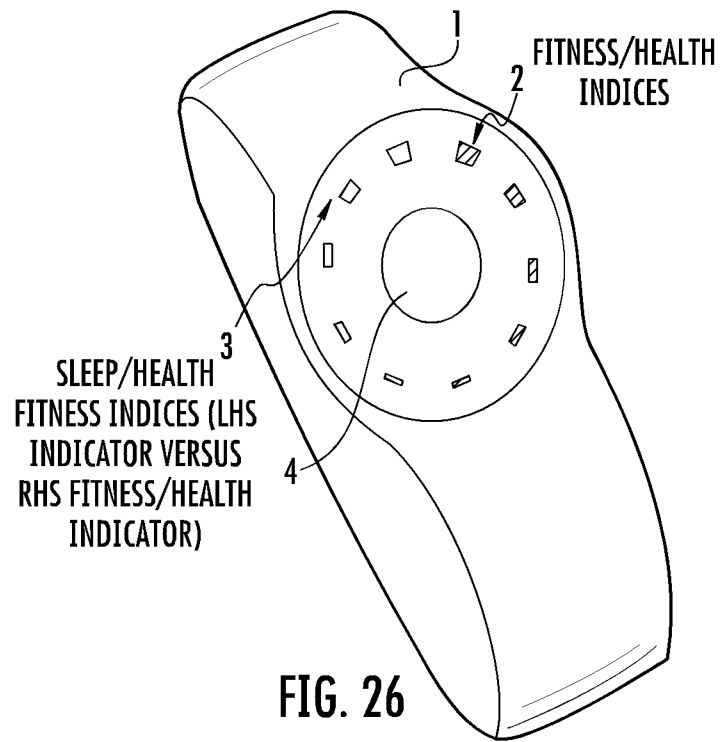


FIG. 25



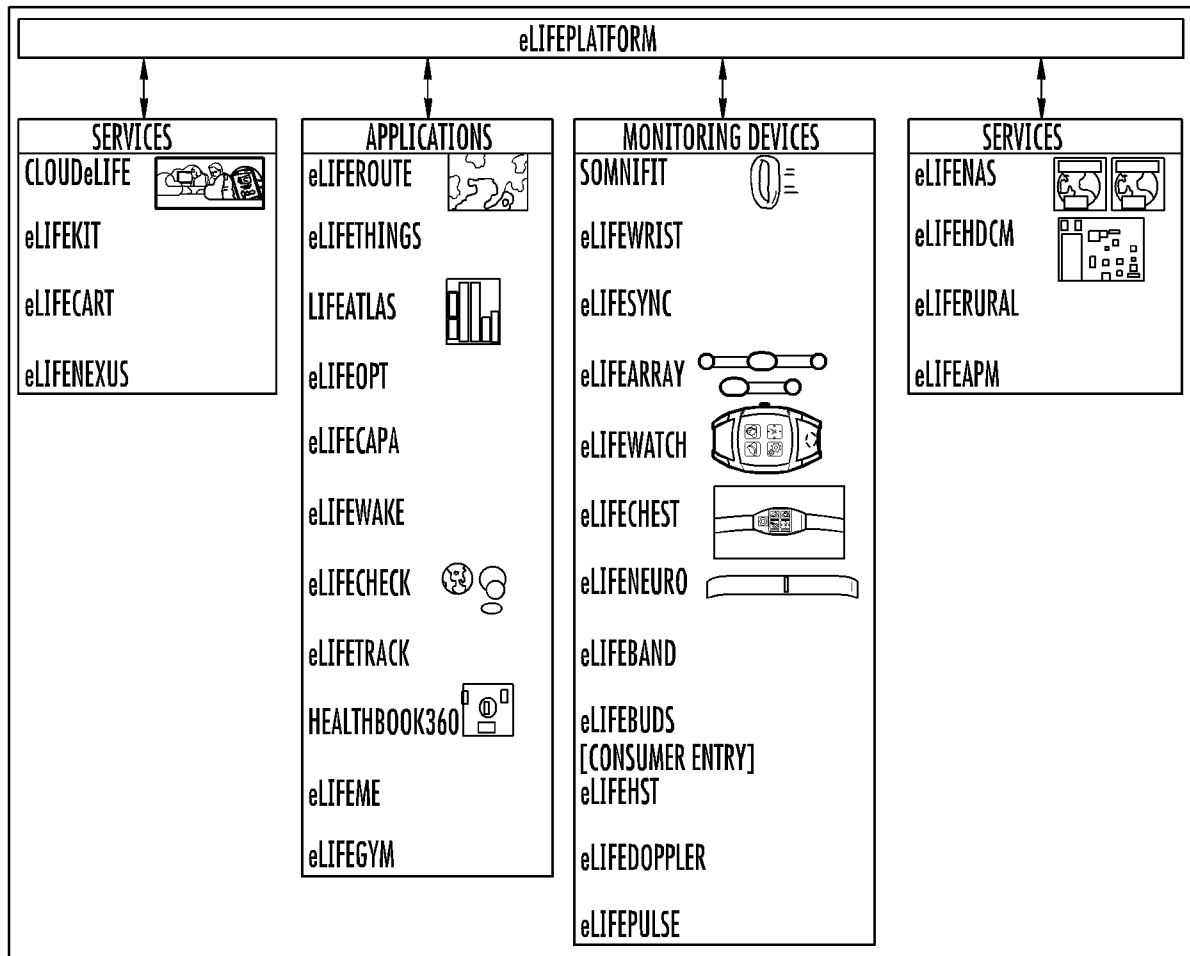


FIG. 27

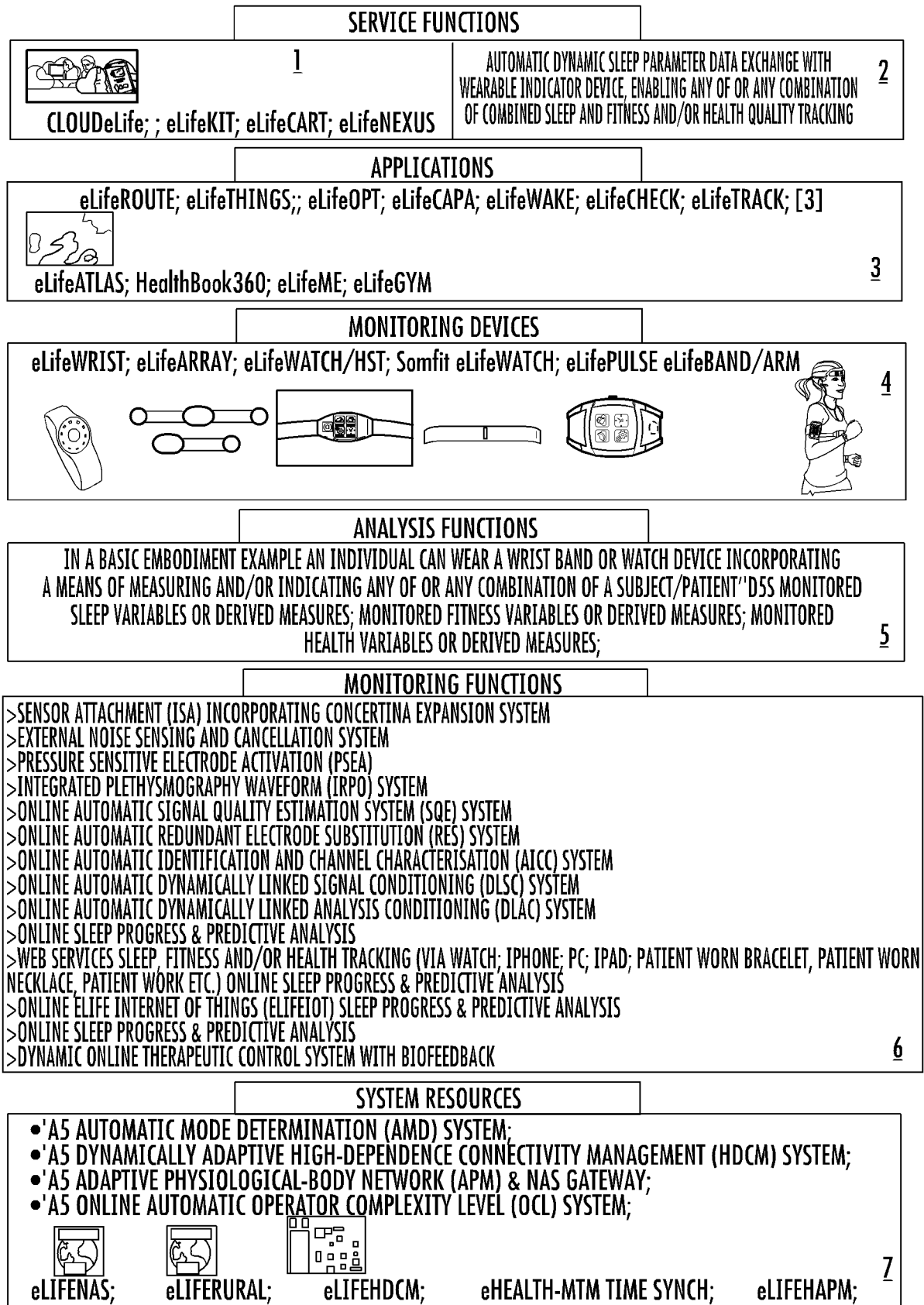


FIG. 28

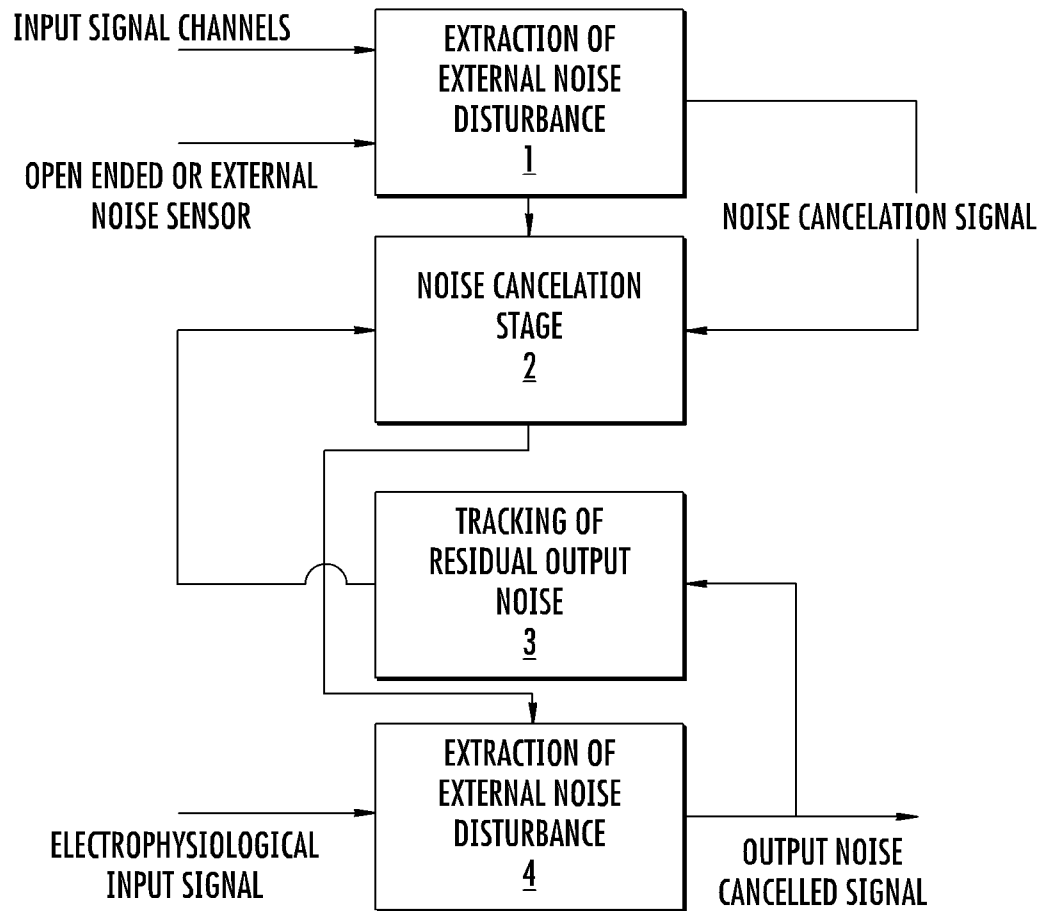


FIG. 29

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Title: MULTIPOINT TIME-SYNCH MONITORING (MTM) SYSTEM

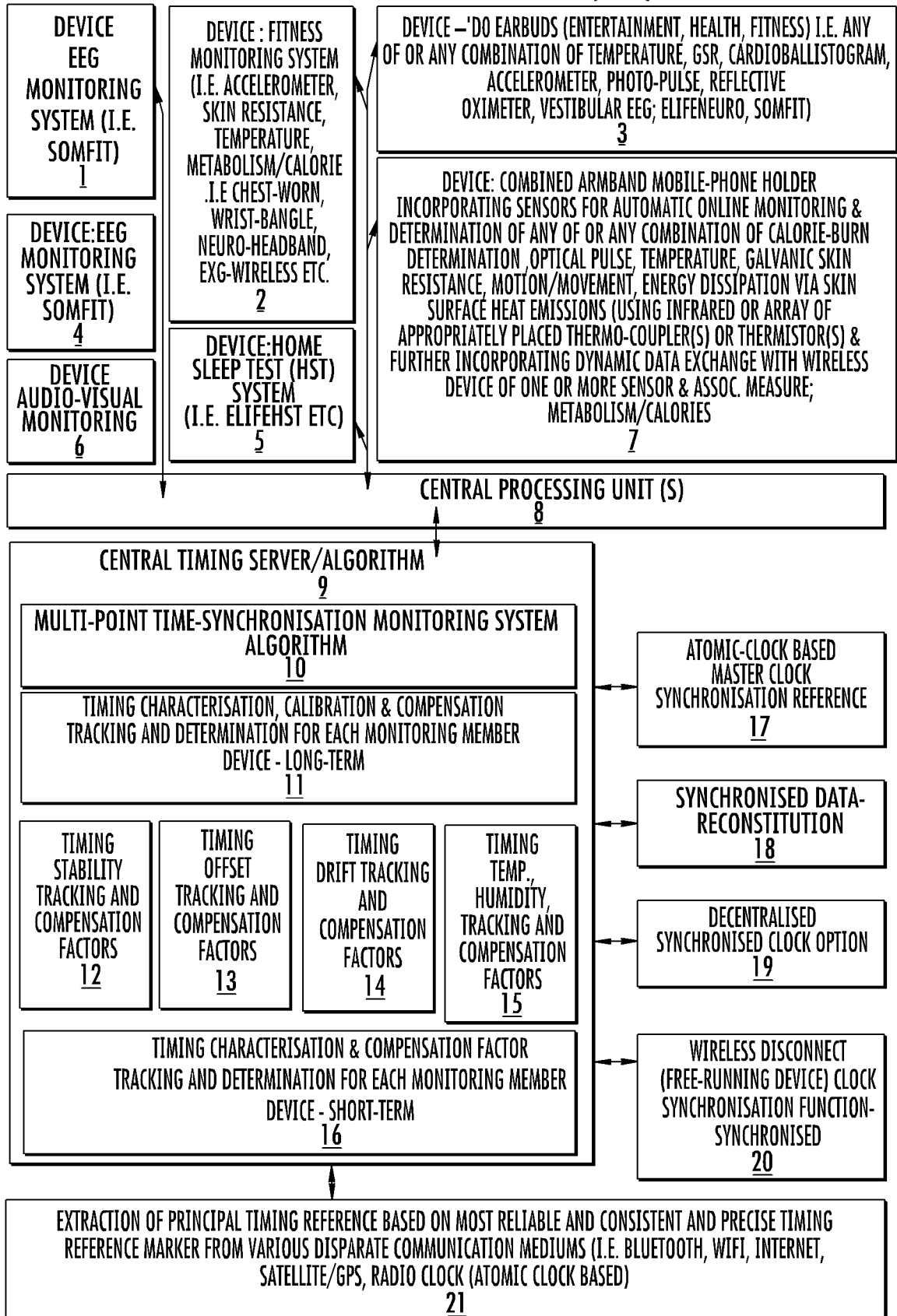
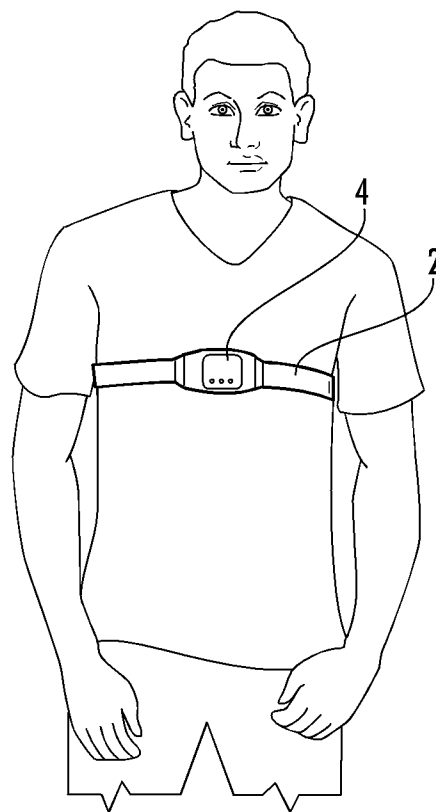
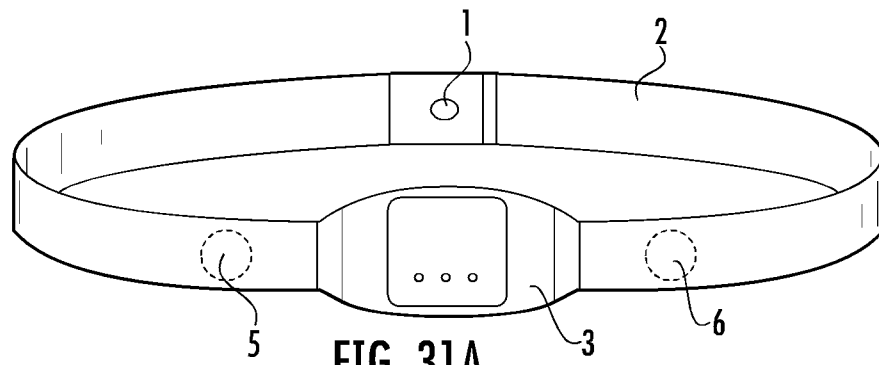
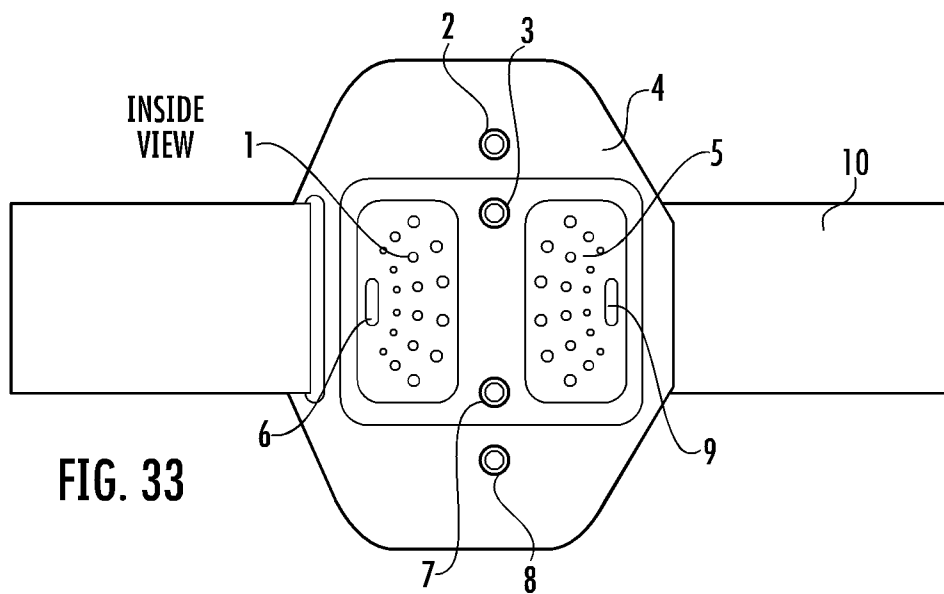
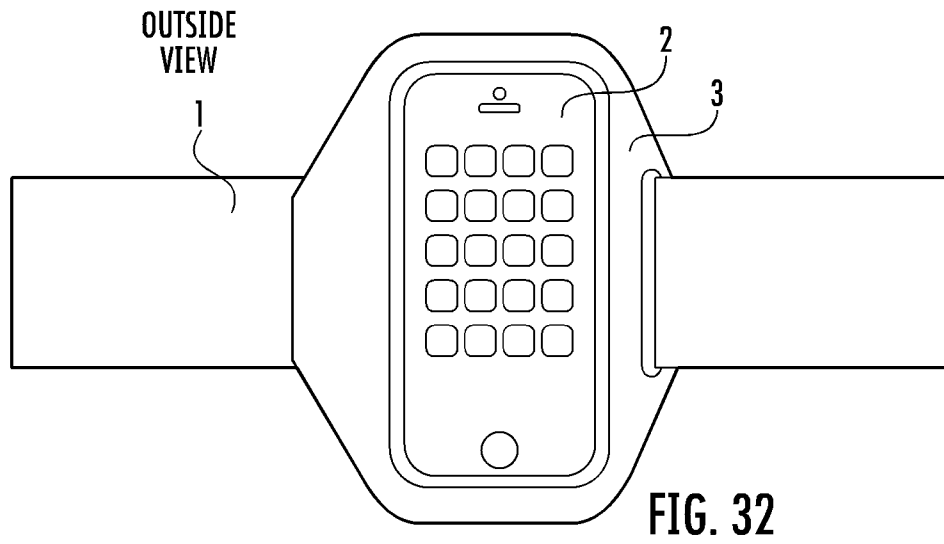


FIG. 30



eLIFEBAND (MOBILE DEVICE & INTEGRATED SENSOR ARMBAND)



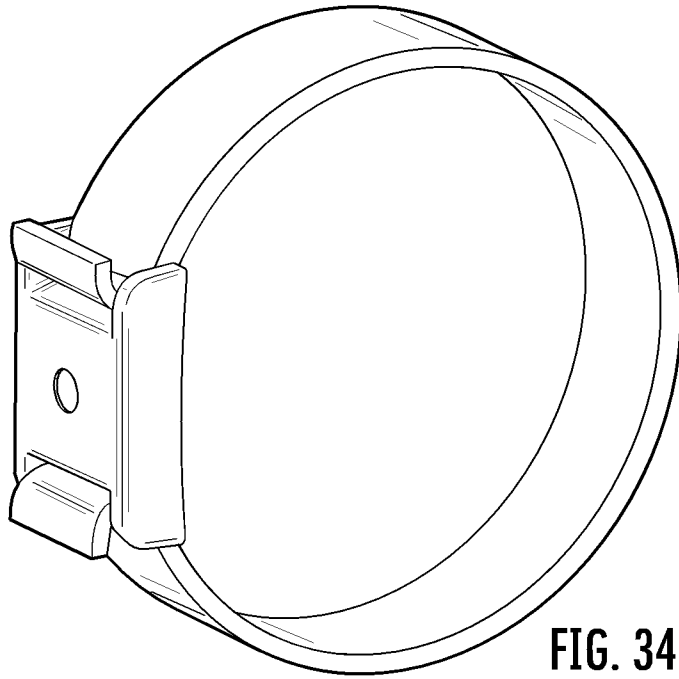


FIG. 34

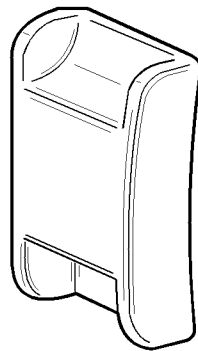


FIG. 35



FIG. 36

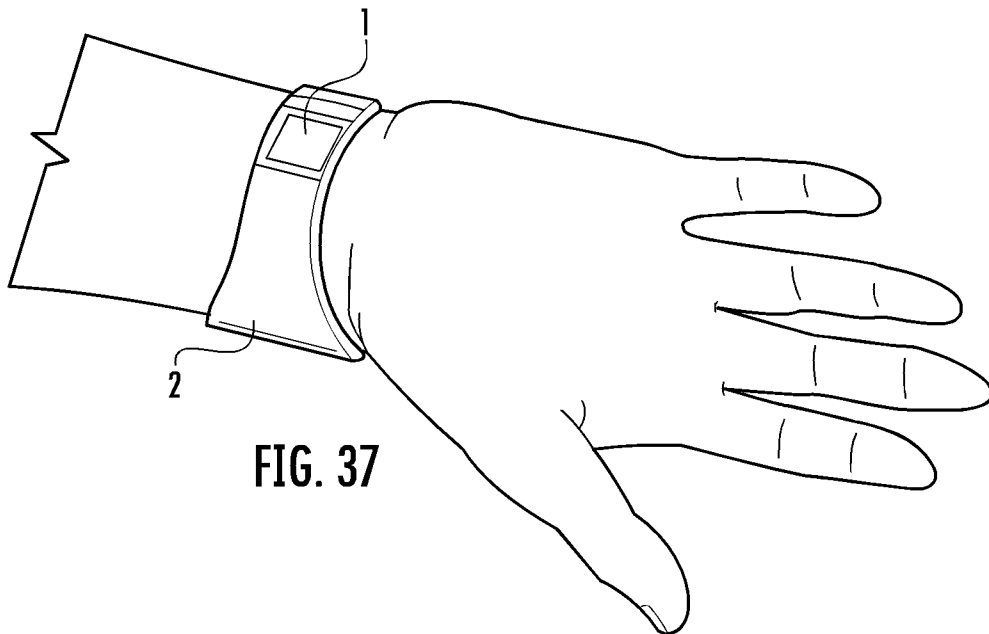


FIG. 37

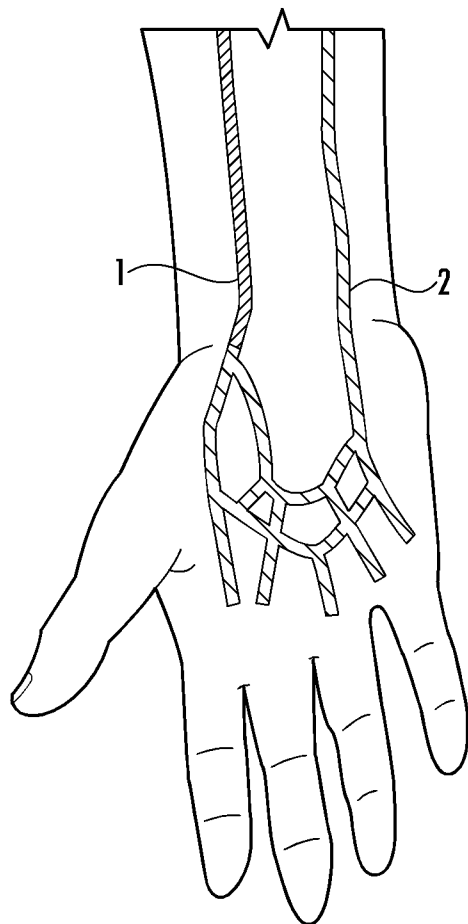
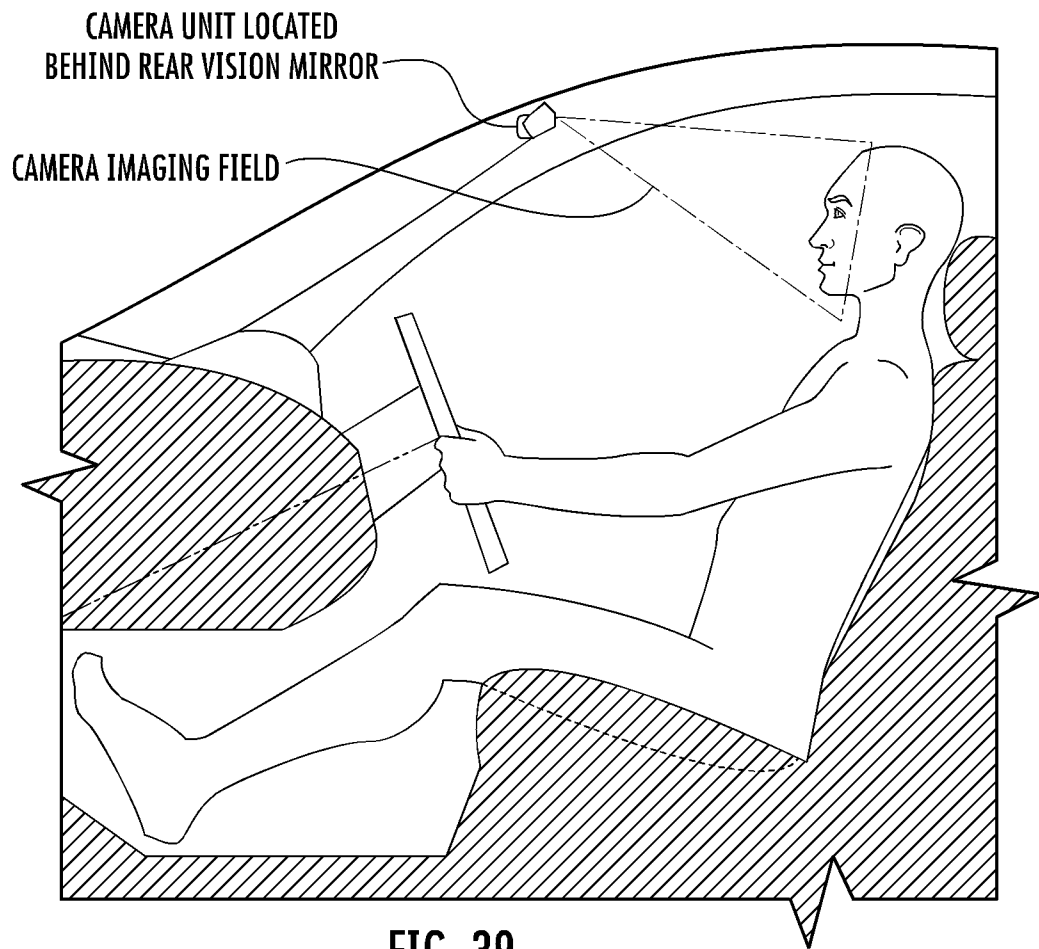


FIG. 38



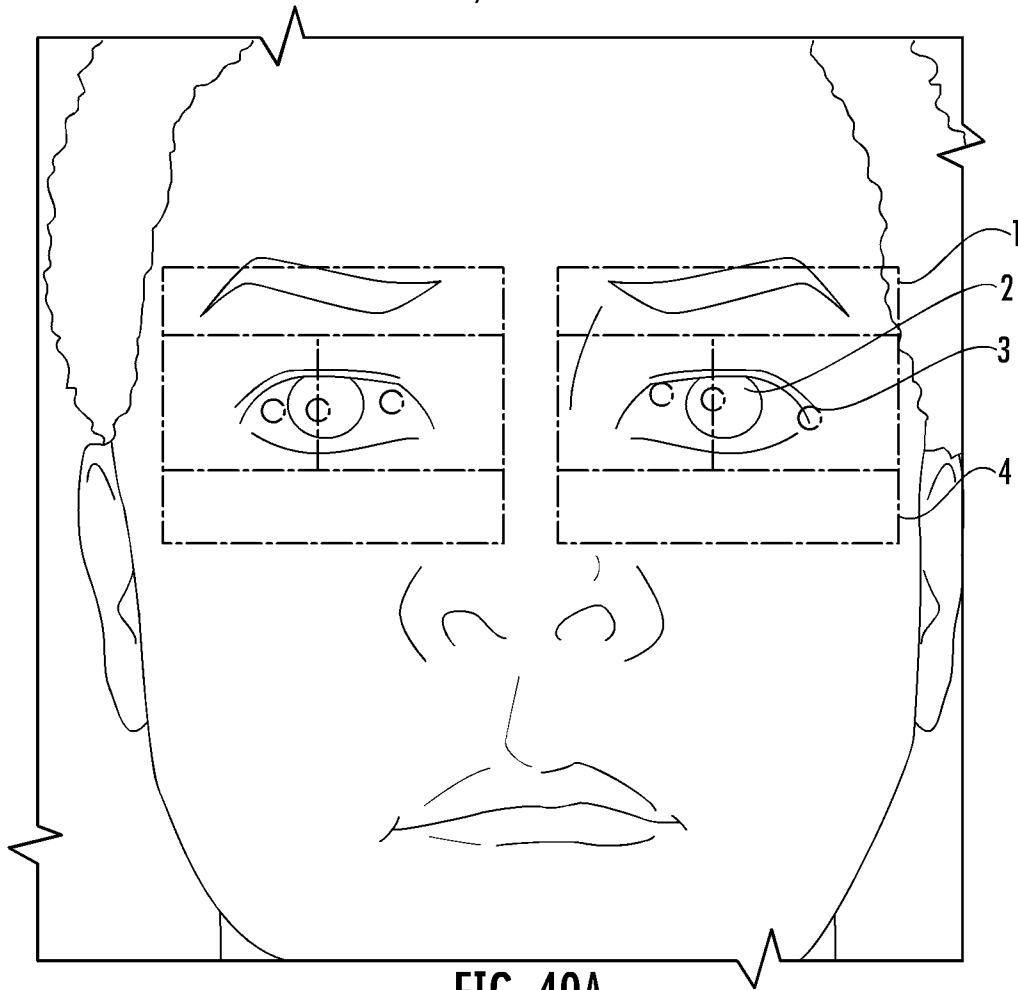


FIG. 40A

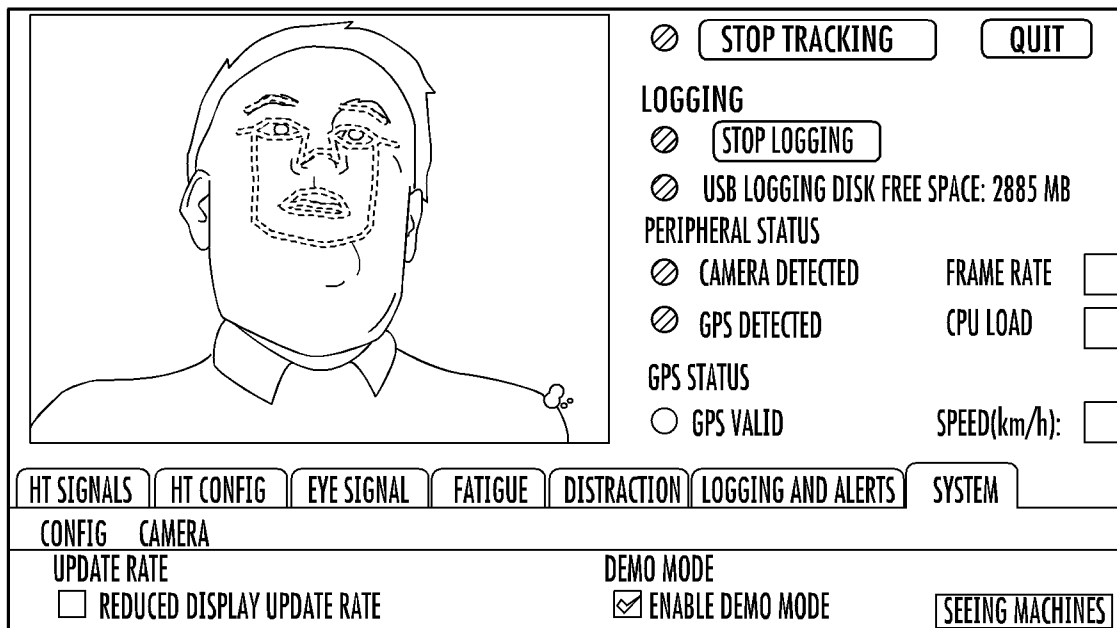


FIG. 40B



FIG. 41

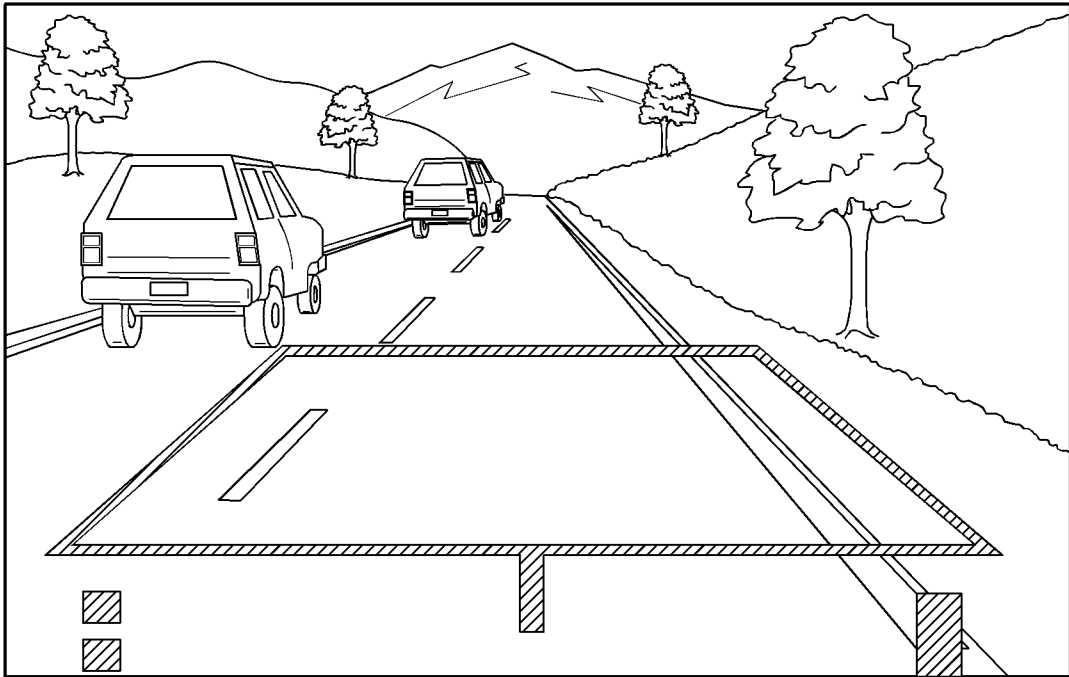


FIG. 42

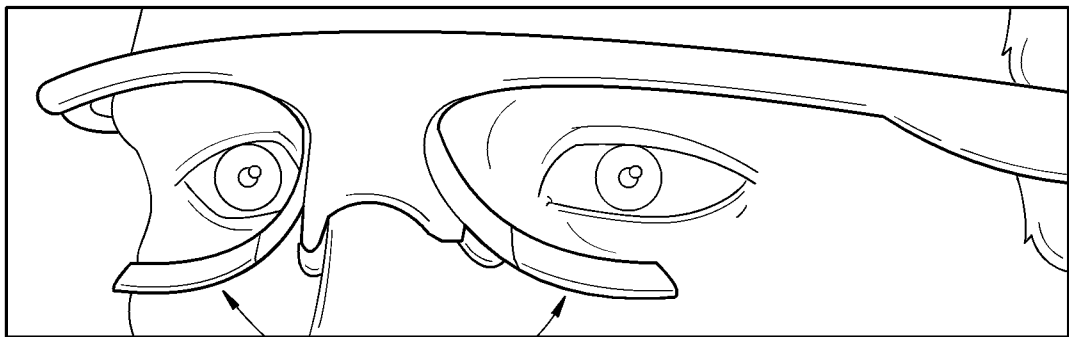
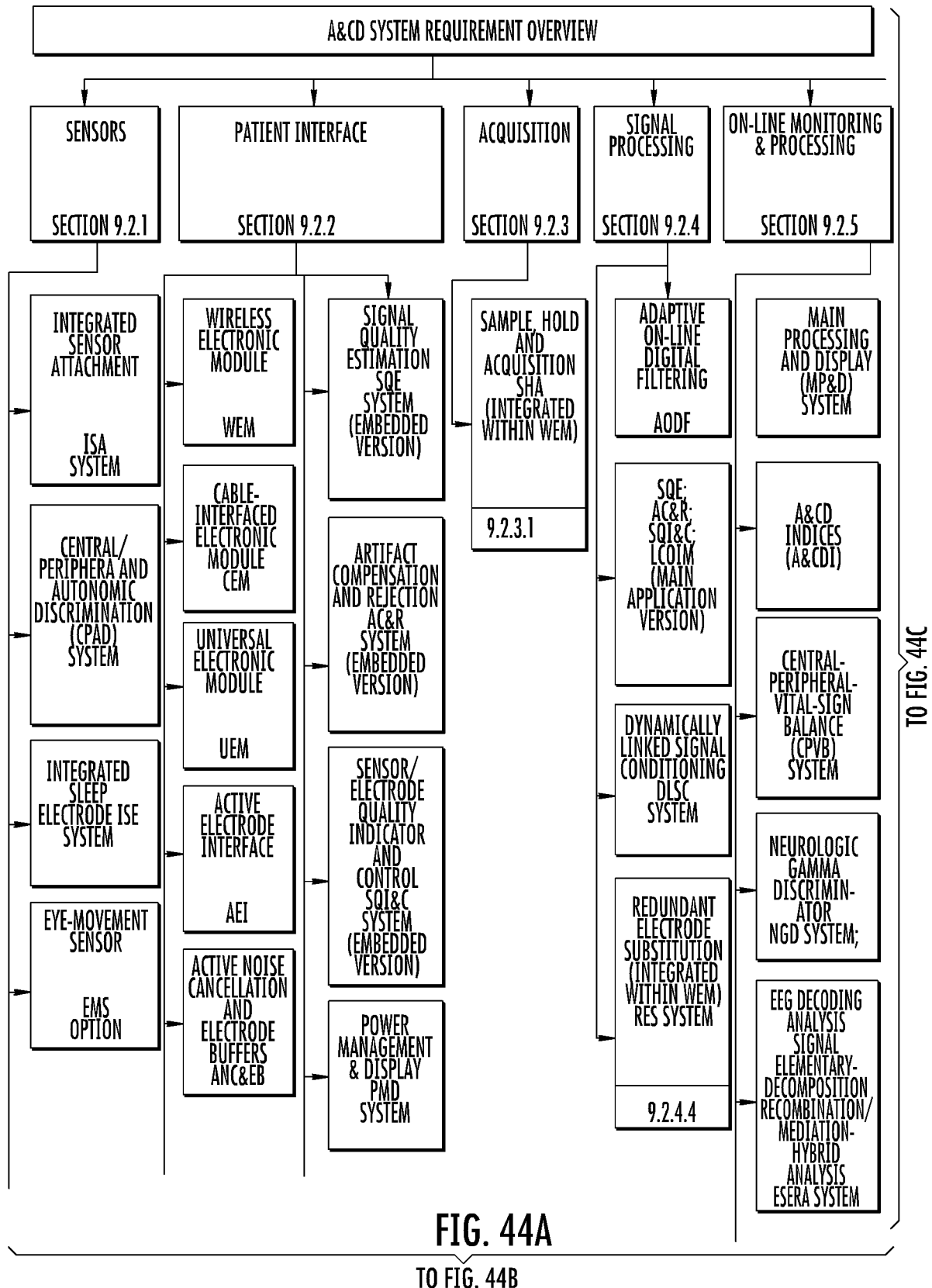


FIG. 43

TRANSCIVER UNITS



FROM FIG. 44A

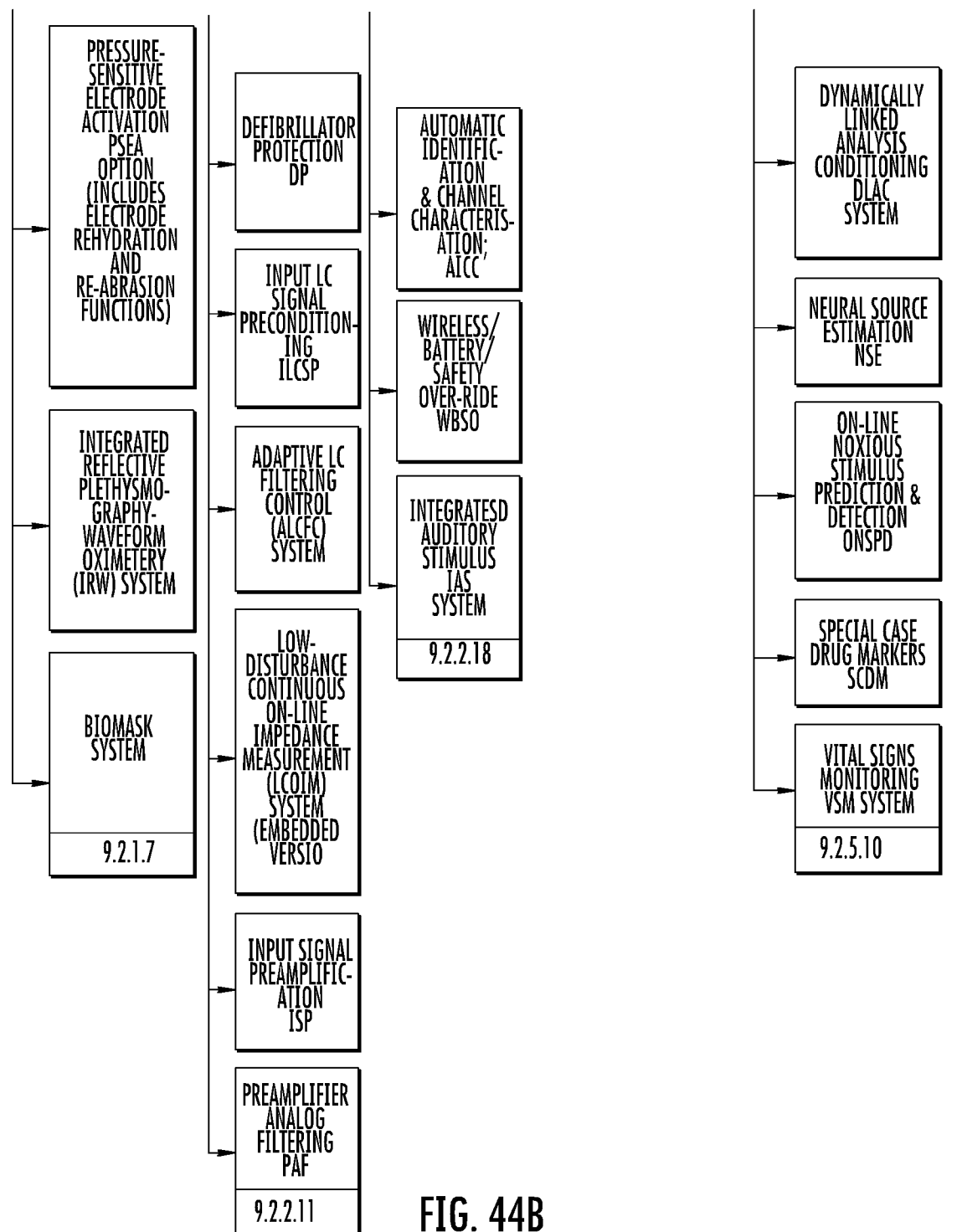
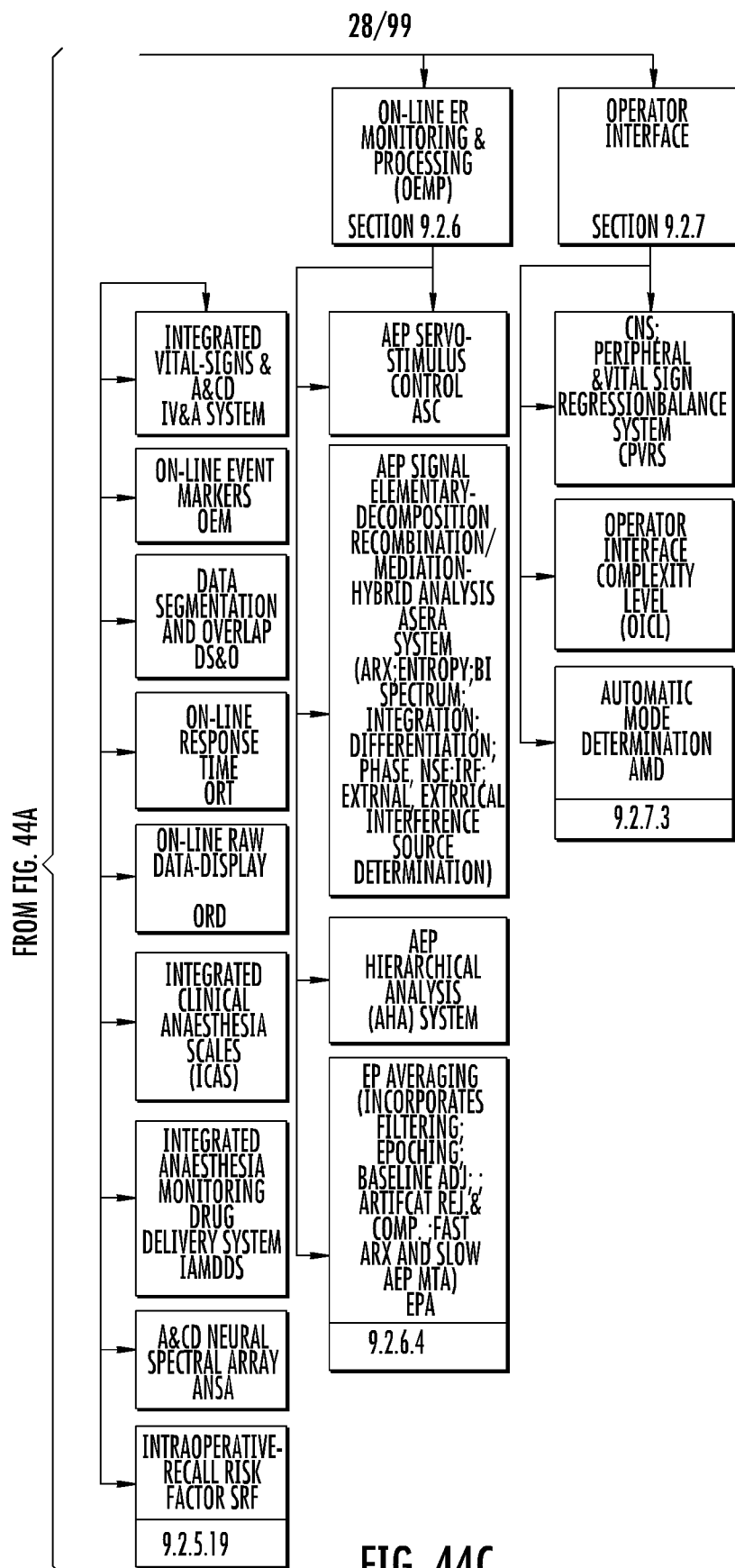


FIG. 44B



FIGURES NEURO PATENT PDF FILE
 TITLE: ELIFENEURO/SUBJECT-SPECIFIC EEG-MONITORING MINIMISATION. ADAPTATION-
 GENERIC PLUS TBI, AUTISM, DEPRESSION/STIM FEEDBACK, EPILEPSY HFO; AURA.

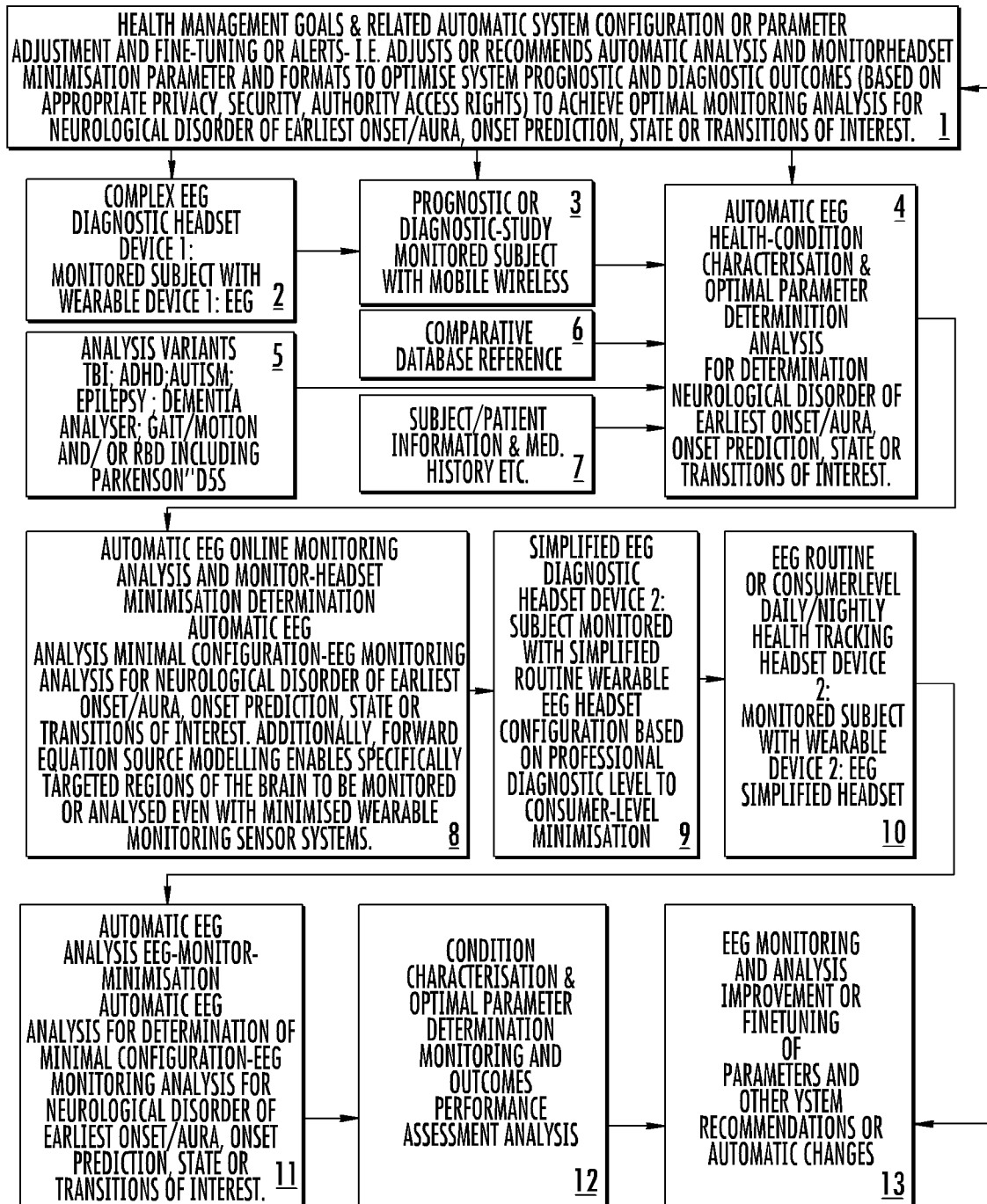


FIG. 45

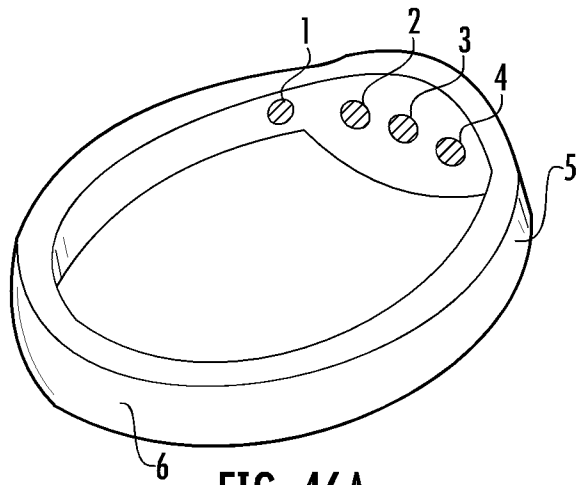


FIG. 46A

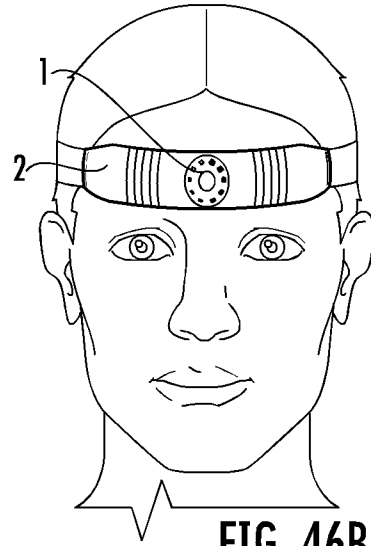


FIG. 46B

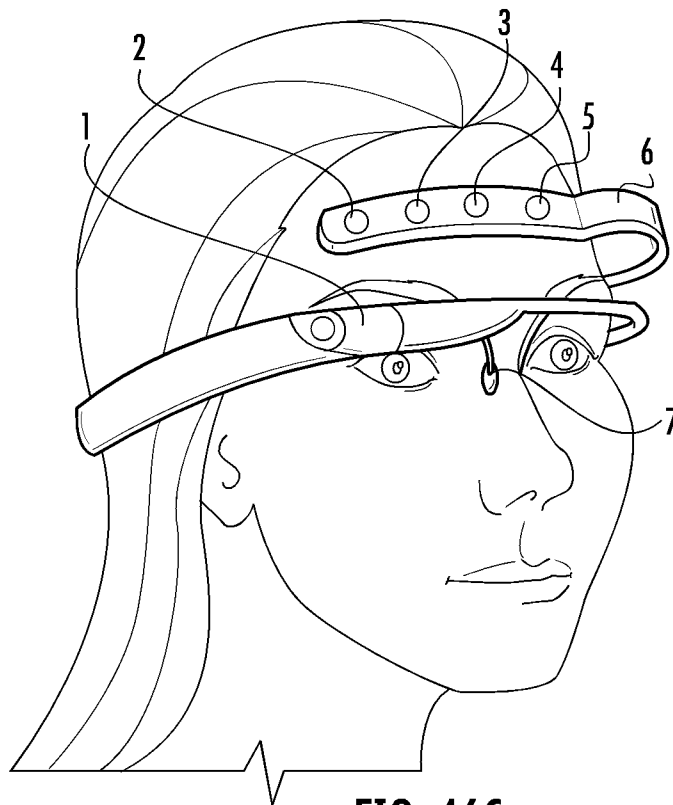


FIG. 46C

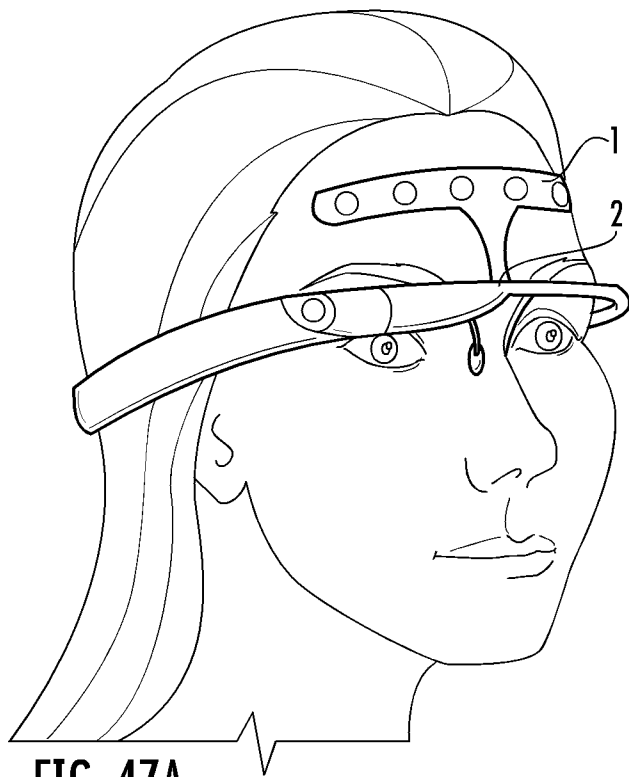


FIG. 47A

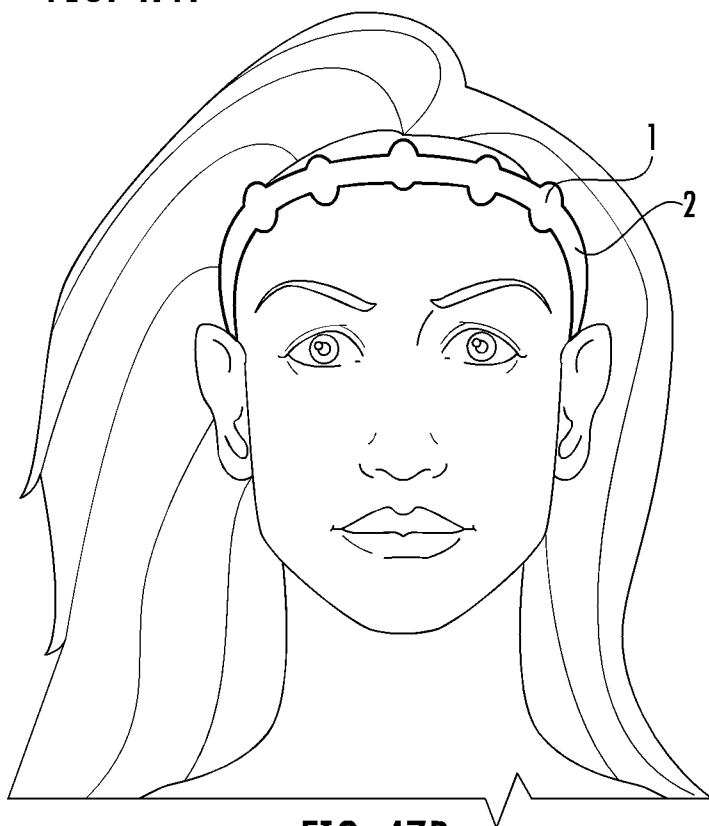


FIG. 47B

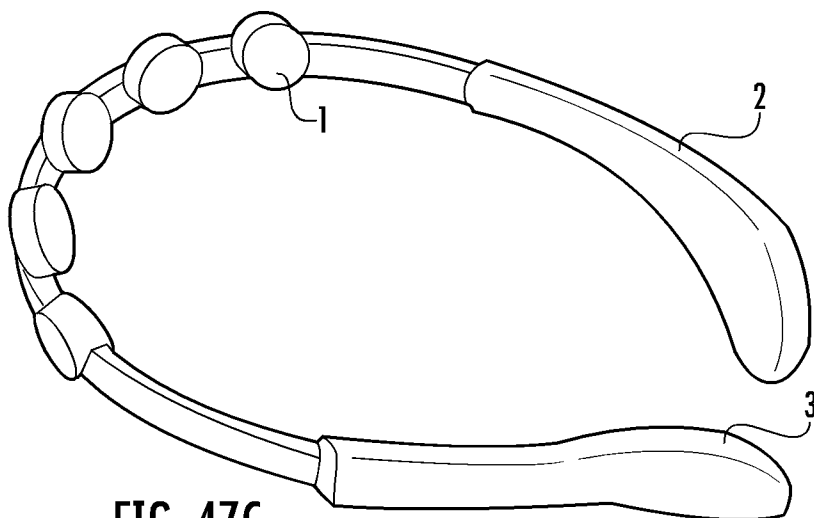


FIG. 47C

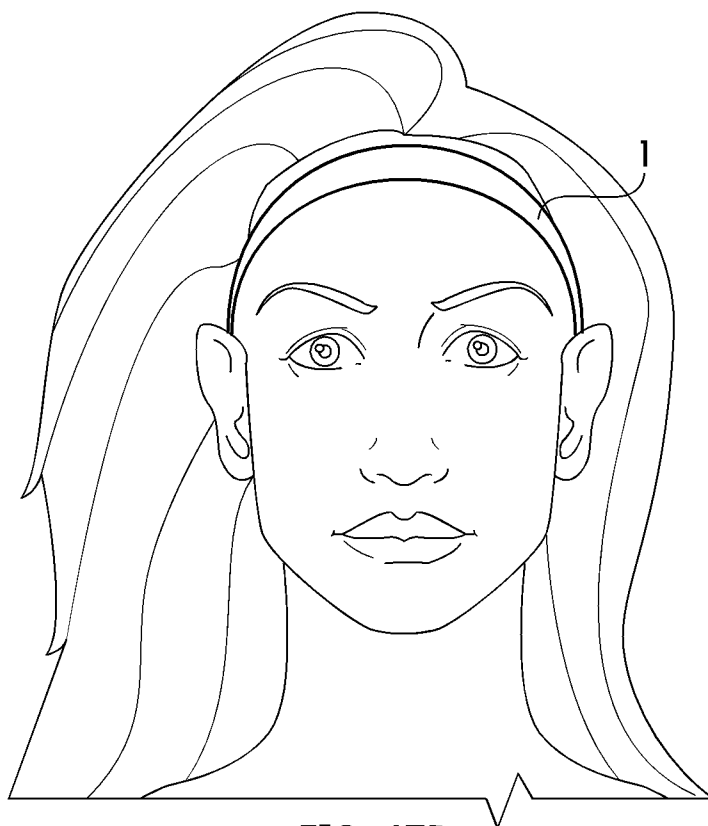


FIG. 47D

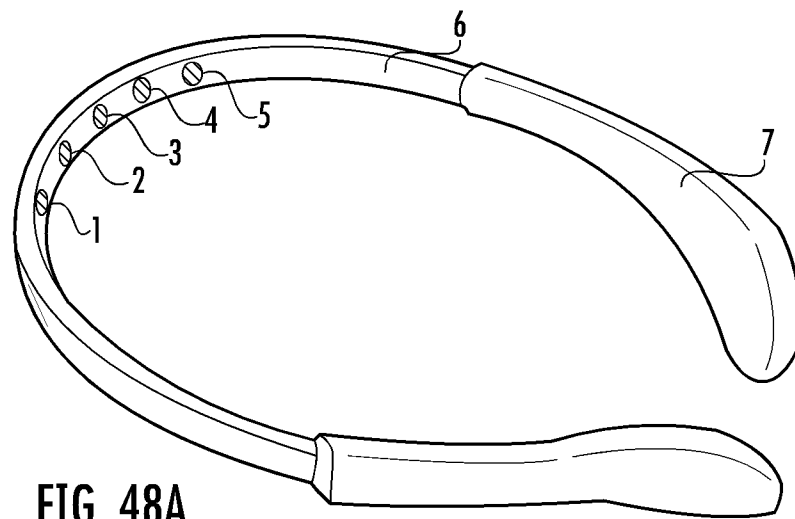


FIG. 48A

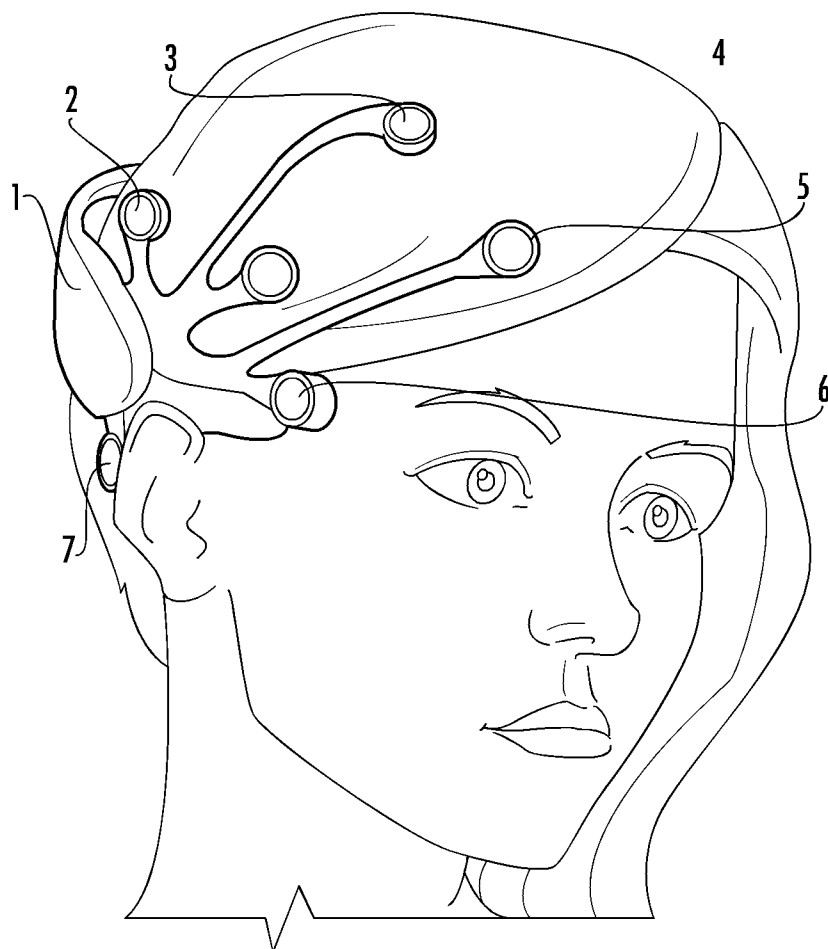


FIG. 48B

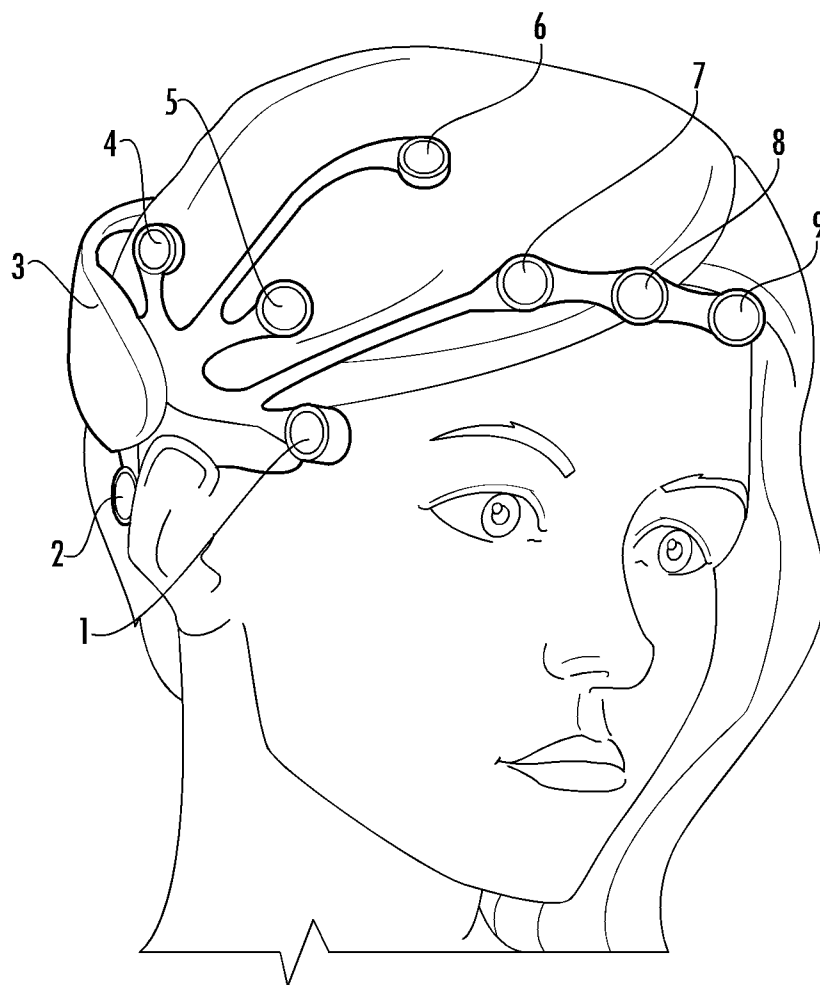


FIG. 49

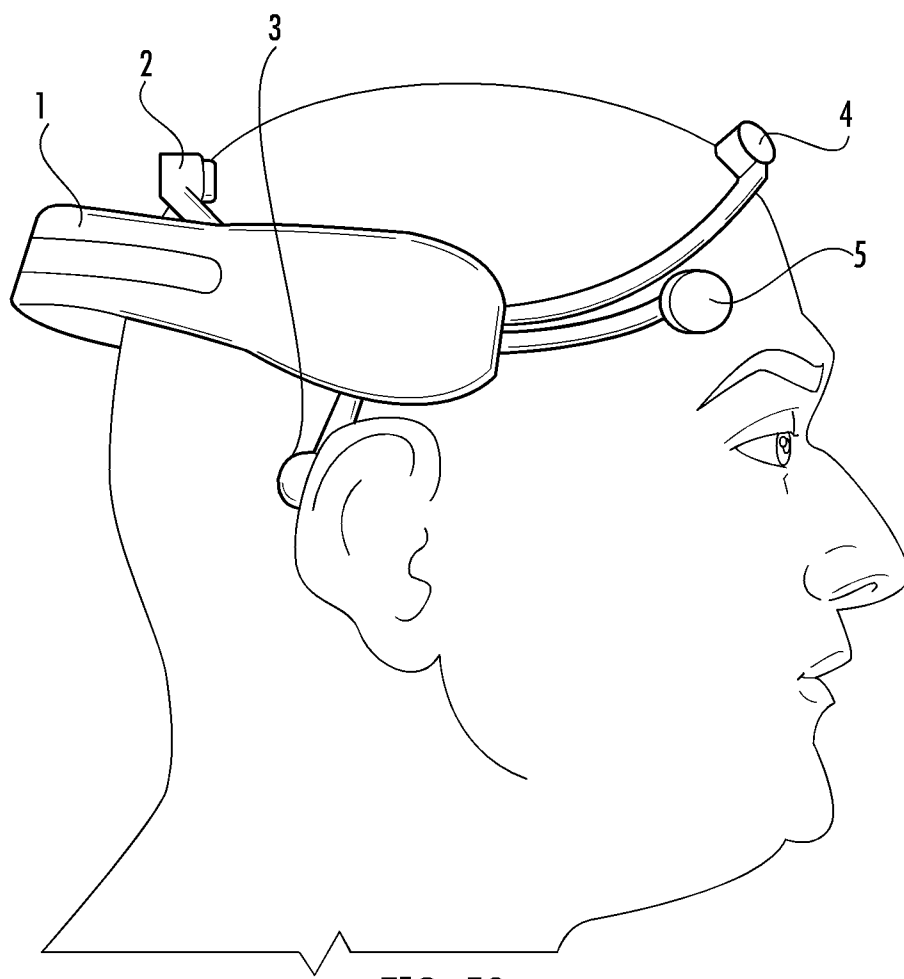


FIG. 50

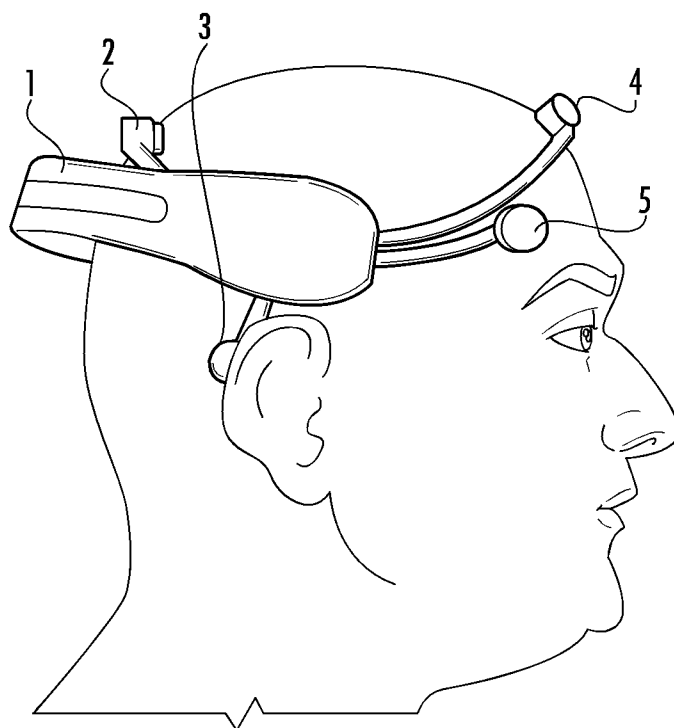


FIG. 51A

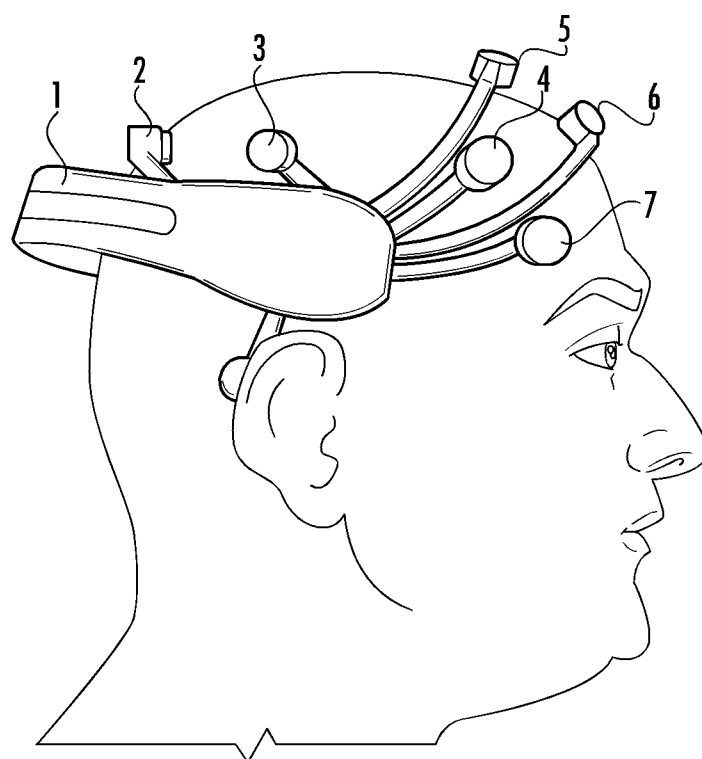
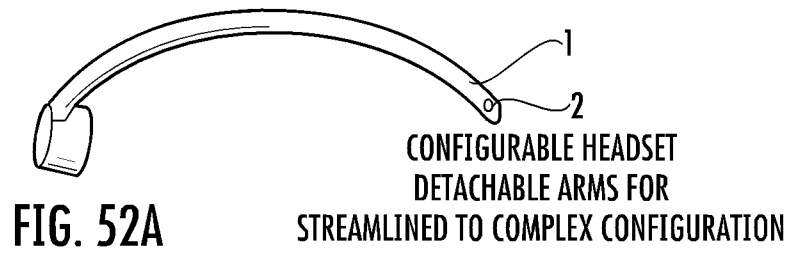
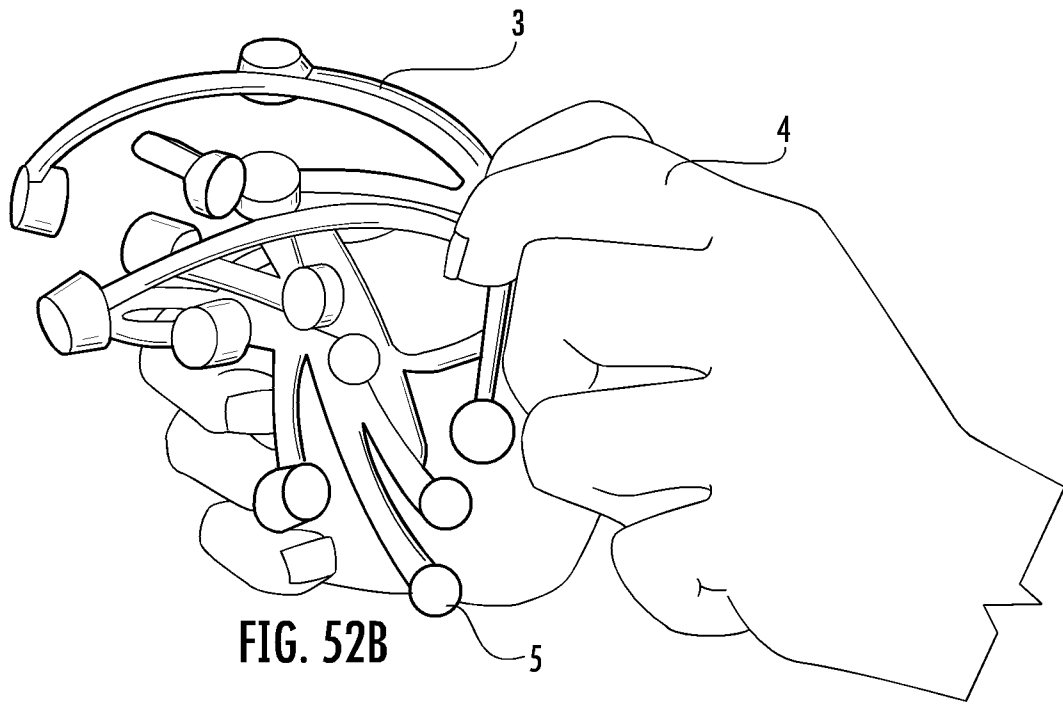


FIG. 51B



CONFIGURABLE HEADSET
DETACHABLE ARMS FOR
STREAMLINED TO COMPLEX CONFIGURATION



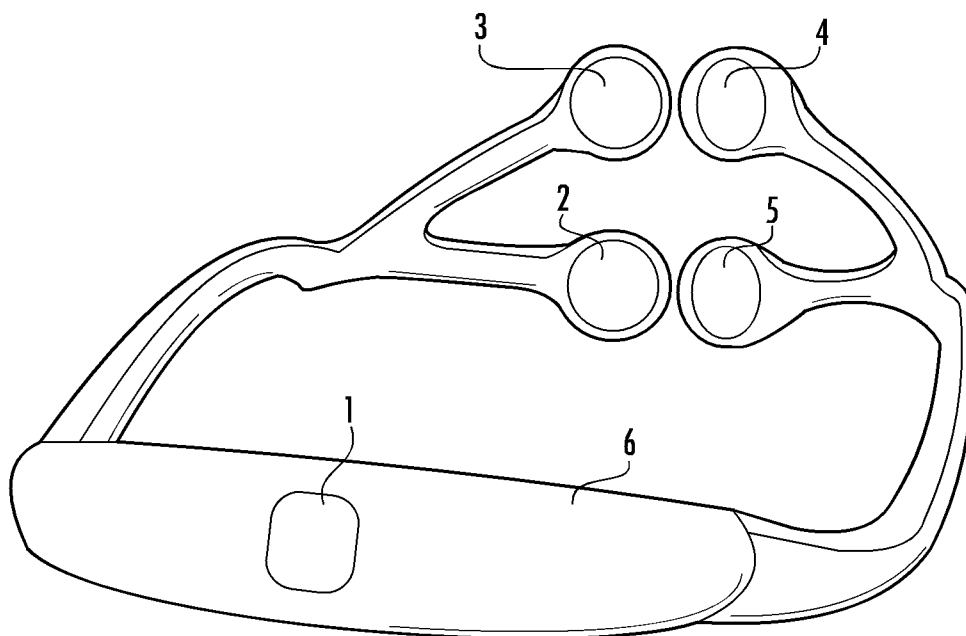
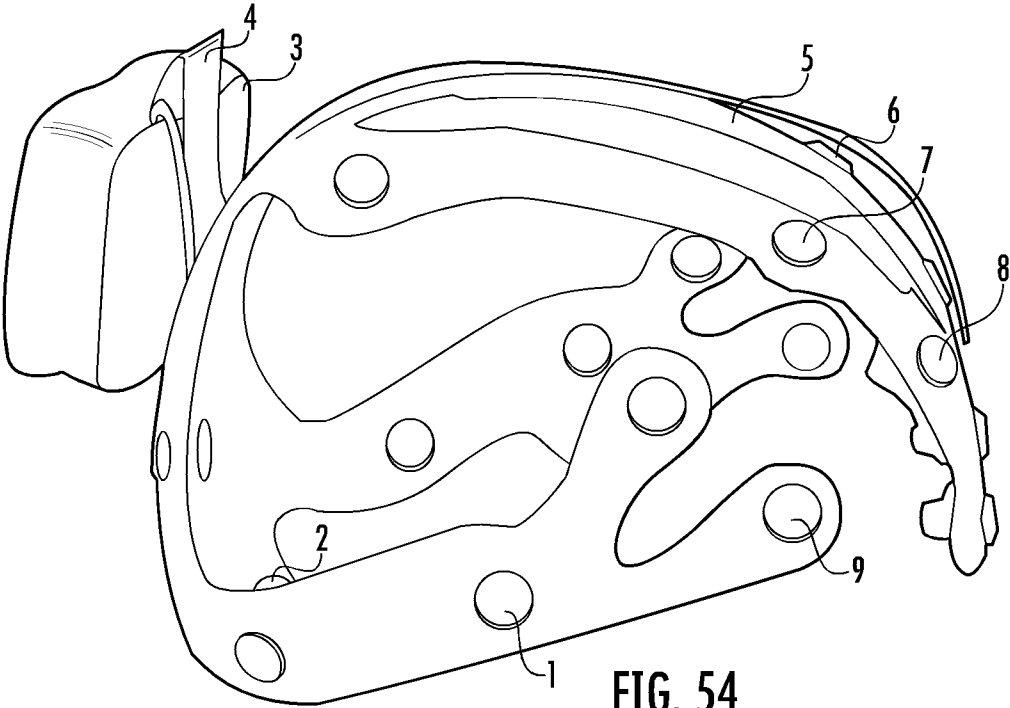


FIG. 53



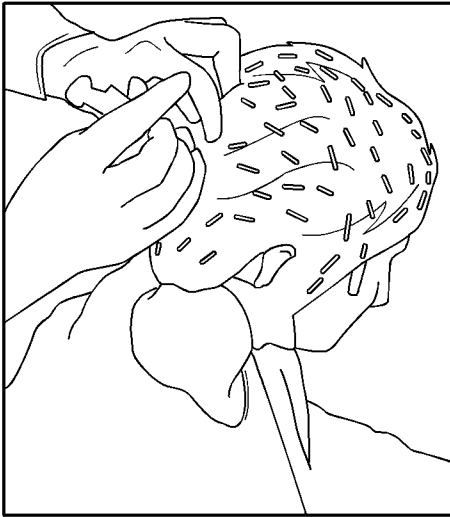


FIG. 55A

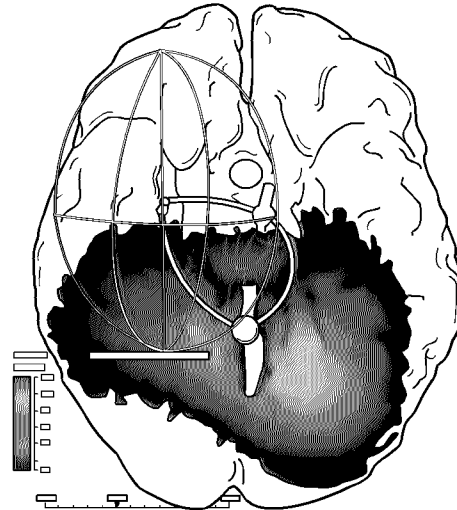


FIG. 55B

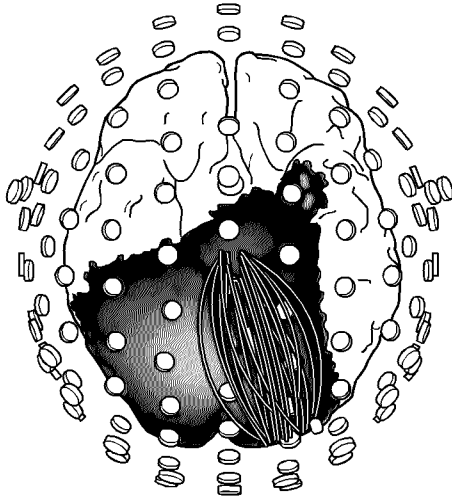


FIG. 55C

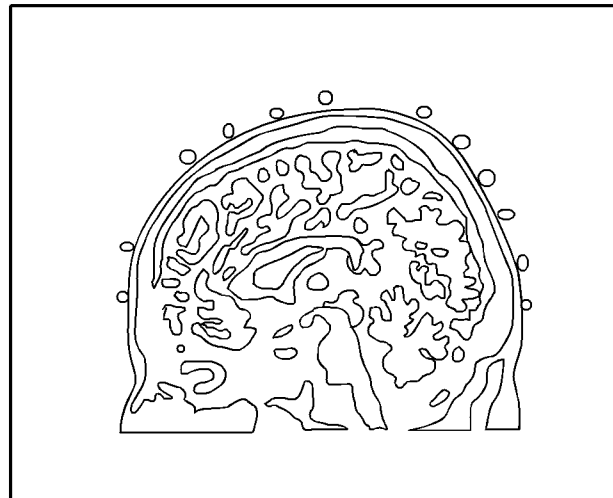


FIG. 55D

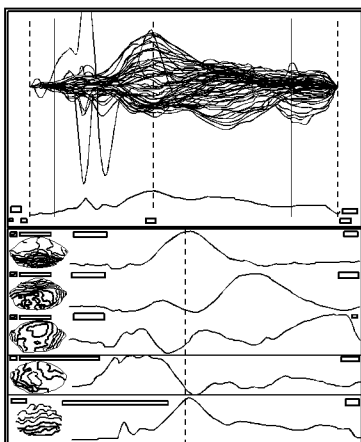


FIG. 55E

SOURCE COHERENCE (FIXED) FOR DIPPLES (3 FIXED MUSIC) (ALL AREAS): 2 ARCS, LAGS FROM, 7.5...120.0ms, MIN DISTANCE 5.0mm, CLIPPED AT 0.5

SOURCE COHERENCE (FIXED) FOR DIPPLES (3 FIXED MUSIC) ANALYSIS: NO. OF ARCS (LAGS FROM, 7.4...120.0ms, MIN DISTANCE 5.0mm, CLIPPED AT 0.5

BRAIN AREA	TOTAL	ANTERIOR	POSTERIOR	ANTERIOR-POSTERIOR	SUPERIOR-INFERIOR
BOTH HEMISPHERES	3	1	0	2	2
LEFT HEMISPHERE	0	0	0	0	0
RIGHT HEMISPHERE	1	0	0	1	1
MIDLINE	1	0	0	1	1
INTRA-HEMISPHERE	1	0	0	1	1
INTER-HEMISPHERE	2	1	0	1	1

SOURCE COHERENCE (FIXED) FOR DIPPLES (3 FIXED MUSIC) (ALL AREAS): 3 ARCS, LAGS FROM, 7.4...120.0ms, MIN DISTANCE 5.0mm, CLIPPED AT 0.5

FIG. 55F

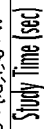
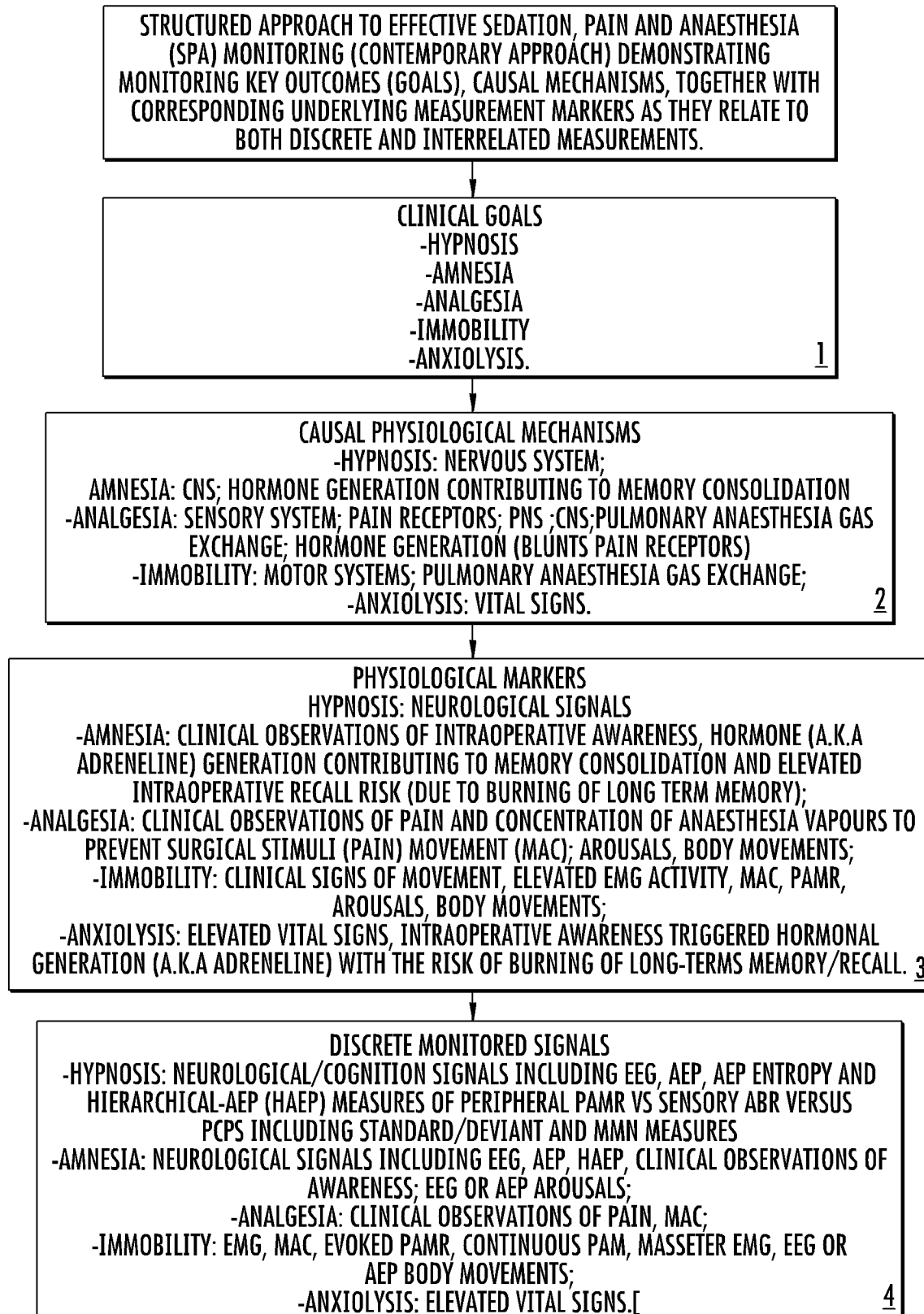


FIG. 56

**FIG. 57A**

TO FIG. 57B

FROM FIG. 57A

INTERRELATED SIGNALS

- HYPNOSIS: NEUROLOGICAL/COGNITION MEASURES OF HYPNOSIS ACCOMPANIED WITH ELEVATED EMG/PAMR SIGNALS, OR HYPNOSIS ACCOMPANIED WITH ELEVATED VITAL SIGNS SUCH AS DURING MUSCLE-SUPPRESSANT INDUCED PARALYSIS WITH AWARENESS;
- AMNESIA: NEUROLOGICAL/COGNITION MEASURES OF HYPNOSIS ACCOMPANIED WITH ELEVATED VITAL SIGNS SUCH AS DURING MUSCLE-SUPPRESSANT INDUCED PARALYSIS WITH AWARENESS;
- ANALGESIA: NEUROLOGICAL/COGNITION MEASURES OF HYPNOSIS ACCOMPANIED WITH EEG OR AEP AROUSALS (AR), BODY MOVEMENTS (BM), SURGICAL STIMULI TIME-ALIGNED AR AND/OR BM;
- IMMOBILITY: EMG, MAC, EVOKED PAMR, PAM EMG, MASSETER EMG, SURGICAL STIMULI EVENT-CORRELATED AR AND/OR BM;
- ANXIOLYSIS: ELEVATED VITAL SIGNS.

5

REF: STRUCTURED APPROACH TO SEDATION PAIN AND ANAESTHESIA MONITORING 12AUG10.VSD

SPECIFIC PHYSIOLOGICAL AND/OR COGNITIVE/PSYCHOLOGICAL SEDATION,
PAIN AND/OR ANAESTHESIA-SIGNAL MEASURES

ANAESTHESIA-SPECIFIC EVENTS AND EPISODES EPAWR DISCRIMINATORS OF MUSCLE SUPPRESSION; LINKAGES BETWEEN ANXIOLYSIS AND INTRUOPERATIVE RECALL-RISK; ONLINE MONITORIN REQUIRMENTS; A SERIES OF NEW ONLINE A&CD DISPLAY INDICES; SIMULTANEOUS PAWR, AUR, AND MLAEP MONITORING; NEUROL SOURCE ESTIMATION (NSE); AUTOMATED CLINICAL MARKERS OF SPA&CD; SEE NOTE FOR EXPANDED DETAILS

FIG. 57B

ANAESTHETIC EFFECTS	REF.CHAP.	PHYSIOLOGICAL VARIABLE	PHYSIOLOGICAL PARAMETER	INDICATOR MEASURE
HYPNOSIS	2-7	EEG; AEP	EEG; ENTROPY; MF-SKEW; BISPECTRUM AND OUTPUTS; MLAEP; PCP; MMN	A&CDI; AEP AWARENESS COTX (AEP CONSCIOUSNESS TRANSITION) AEP AWARENESS
AMNESIA	2-7	EEG; AEP	PCP; MMN	AROUSALS/NOXIOUS STIMULI
ANALGESIA	2-7	AEP	MLAEP DAS AND ENTROPY	EMG POWER AND ANAESTHETIC BALANCE
IMMOBILITY	2-7	EMG; PAMR	ENG POWER; PAMR INDEX	EMG POWER AND ANAESTHETIC BALANCE
ANXIOLYSIS	2-7	OXIMETER	HRV; PTT; ECG; BPV	SaO2; ECG; HRV; BPV; PAW; PTT
INTERRELATED ANAESTHETIC EFFECTS		PHYSIOLOGICAL VARIABLE	PHYSIOLOGICAL PARAMETER	INDICATOR MEASURE
ANXIOLYSIS AND HYPNOSIS	2-7	OXIMETER; EEG; AEP	HRV; PTT; ECG; BPV / EEG ENTROPY; MF-SKEW; BISPECTRUM AND PRODUCTS; MLAEP; PCP; N1-EFFECT; MMN	INTRAOPERATIVE RECALL FACTOR (IRF)
IMMOBILITY AND HYPNOSIS	2-7	EMG; PAMR; EEG; AEP	EEG; ENTROPY; MF-SKEW; BISPECTRUM AND PRODUCTS; MLAEP; PCP; N1-EFFECT; MMN / EMG POWER; PAMR INDEX	ANAESTHETIC BALANCE
AROUSALS AND MOVEMENT S		PHYSIOLOGICAL VARIABLE	PHYSIOLOGICAL PARAMETER	INDICATOR MEASURE
AROUSAL-NOXIOUS STIMULI	5-7	AEP; EEG; PTT; ECG; HRV	FREQUENCY SHIFT; SIGNAL MORPHOLOGY; CONTEXT	AROUSAL-NOXIOUS STIMULI EVENT AND INDEX
AROUSAL-CORTICAL (GENERAL)	5-7	PTT; ECG; HRV	FREQUENCY SHIFT; CONTEXT	AROUSAL-NOXIOUS STIMULI EVENT AND INDEX
AROUSAL-SUBCORTICAL (GENERAL)	5-7	PTT; ECG	SIGNAL MORPHOLOGY; CONTEXT	AROUSAL-CORTICAL EVENT AND INDEX
MICROAROUSAL	5-7	EEG	FREQUENCY SHIFT; CONTEXT	MICROAROUSAL EVENT AND INDEX
BODY MOVEMENT	5-7	EEG; EMG	BASELINE SHIFT AND SIGNAL MORPHOLOGY; CONTEXT	BODY MOVEMENT EVENT AND INDEX
MOVEMENT TIME	5-7	EMG; EEG; PTT	BASELINE SHIFT AND SIGNAL MORPHOLOGY; CONTEXT	MOVEMENT TIME EVENT AND INDEX
ARTIFACT		PHYSIOLOGICAL VARIABLE	PHYSIOLOGICAL PARAMETER	INDICATOR MEASURE

FIG. 58A

TO FIG. 58B

FROM FIG. 58A

EOG	2;3;4	EOG	LOW FREQUENCY; SIGNAL MORPHOLOGY	EOG EVENT AND INDEX
EYE-MOVEMENTS	2;3;4	EYE-MOVEMENT	LOW FREQUENCY; SIGNAL MORPHOLOGY	EYE-MOVEMENT EVENT AND INDEX
50/60 CYCLE OR RELATED	2;3;4;	ALL CHANNELS	FREQUENCY SPECTRUM THRESHOLDS	ALL CHANNELS EVENT AND INDEX
ELECTROSURGICAL DISTURBANCE	2;3;4-7	ALL CHANNELS	HIGH FREQUENCY SPECTRUM THRESHOLDS	ALL CHANNELS EVENT AND INDEX
EMG BURST	2;3; A1	EMG	BASELINE INCREASE	EMG EVENT AND INDEX
[CRUCIAL/CHARACTERISTIC PERIODS		PHYSIOLOGICAL VARIABLE		INDICATOR MEASURE
PHARMACODYNAMIC TRACKING	2; A1	EEG	EEG-ENTROPY;MF-SKEW;BISPECTRUM AND PRODUCTS;	DOSAGE GUIDANCE
ISO-ELECTRIC CORTICAL SILENCE	2; A1	EEG	SEF95; SIGNAL MORPHOLOGY; SKEW	ISO-ELECTRIC CORTICAL SILENCE EVENT
NEAR ISO-ELECTRIC CORTICAL SILENCE	2; A1	EEG	SEF95; SIGNAL MORPHOLOGY; SKEW	NEAR ISO-ELECTRIC CORTICAL SILENCE EVENT
BURST SUPPRESSION	2;A1	EEG	SEF95; SIGNAL MORPHOLOGY; SKEW	BURST SUPPRESSION INDEX
WAKE DISTURBANCE PERIODS	2;3;4-7	ALL CHANNELS	AROUSALS,ARTIFACT,EEG-SPECTRAL,BODY-MOVEMENT,MOVEMENT TIME	WAKE EVENT
GAMMA CONSC DISCRIMINATION	2	EEG	SPECTRAL-ENTROPY	GAMMA POWER
NEURAL SOURCE ESTIMATION	2;A2	EEG	SOURCE RECONSTRUCTION	LATERALISATION-ANTERIORISATION
SIGNAL QUALITY STATUS	2-7;A1	ALL CHANNELS	IMPEDANCE, CONTINUOUS TRACKING OF SIGNALS CHARACTERISTICS	SIGNAL QUALITY INDEX (SQI)
SIGNAL DROP-OUT	2-7;A1	ALL CHANNELS	IMPEDANCE, CONTINUOUS TRACKING OF SIGNALS CHARACTERISTICS	SIGNAL QUALITY INDEX (SQI)

FIG. 58B

EVENT TYPE	ABBREVIATION	CLASSIFICATION METHOD
CONVENTIONAL AROUSAL, MOVEMENT AND ARTIFACT EVENT CLASSIFICATIONS		
AROUSALS FROM SLEEP	AR	[98; 332; 332]
BODY MOVEMENT	BM	[372]
MOVEMENT TIME	MT	[372]
MICRO-AROUSAL	ARM	[266] (1.5-3 S DURATION)
CORTICAL AROUSAL	cAr	[45; 342; 344; 345]
SUBCORTICAL (AUTONOMIC) AROUSAL	sAr	[45; 342; 344; 345]
ARTIFACT		[456]
PROPOSED ANAESTHESIA-SPECIFIC AROUSAL, MOVEMENT AND ARTIFACT EVENT CLASSIFICATIONS		
NOXIOUS STIMULI EVENTS		
NOXIOUS STIMULI	Nx	NEW ANAESTHESIA-SPECIFIC EVENT;
NOXIOUS STIMULI AROUSAL (OVERALL)	ArNx	NEW ANAESTHESIA-SPECIFIC EVENT
NOXIOUS STIMULI CORTICAL AROUSAL	cArNx	NEW ANAESTHESIA-SPECIFIC EVENT
NOXIOUS STIMULI SUB-CORTICAL AROUSAL	sArNx	NEW ANAESTHESIA-SPECIFIC EVENT; [45; 342; 344; 345]
NOXIOUS STIMULI BODY MOVEMENT	BMNx	NEW ANAESTHESIA-SPECIFIC EVENT
AROUSAL EVENTS		
OVERALL ANAESTHESIA-SPECIFIC AROUSALS	AAr	COMBINATION OF CONVENTIONAL AND ANAESTHESIA-SPECIFIC AROUSALS
QUICK AROUSAL	Arq	PER CONVENTIONAL EXCEPT (0.25-3 S DURATION) AND SLEEP STATE SUBSTITUTED FOR UNCONSCIOUSNESS
QUICK CORTICAL AROUSAL	cArq	PER CONVENTIONAL EXCEPT (0.25-3 S DURATION) AND SLEEP STATE SUBSTITUTED FOR UNCONSCIOUSNESS
QUICK SUBCORTICAL AROUSAL	sArq	PER CONVENTIONAL EXCEPT (0.25-3 S DURATION) AND SLEEP STATE SUBSTITUTED FOR UNCONSCIOUSNESS
QUICK MICRO-AROUSAL	Armq	PER CONVENTIONAL EXCEPT (0.25-3 S DURATION), SLEEP STATE SUBSTITUTED FOR UNCONSCIOUSNESS, AND INCLUDES OVERALL CORTICAL AND SUBCORTICAL EVENTS

FIG. 59A

TO FIG. 59B

FROM FIG. 59A

QUICK MICRO-AROUSAL CORTICAL	cArm _q	PER CONVENTIONAL EXCEPT (0.25-3 S DURATION) AND SLEEP STATE SUBSTITUTED FOR UNCONSCIOUSNESS
QUICK MICRO-AROUSAL SUBCORTICAL	sArm _q	PER CONVENTIONAL EXCEPT (0.25-3 S DURATION) AND SLEEP STATE SUBSTITUTED FOR UNCONSCIOUSNESS
MOVEMENT EVENTS		
QUICK BODY MOVEMENT	BM _q	PER CONVENTIONAL EXCEPT (0.25-3 S DURATION) AND SLEEP STATE SUBSTITUTED FOR UNCONSCIOUSNESS
ARTIFACT		
ARTIFACT	AA _f	INCLUDES CONVENTIONAL AND ANAESTHESIA-SPECIFIC DEFINITIONS AND ALL SIGNAL BLACK OUT-PERIODS.
TOTAL ARTIFACT TIME	AA _f _t	TOTAL TIME OCCUPIED BY CONVENTIONAL AND ANAESTHESIASPECIFIC ARTIFACT DURING THE PRECEDING 60 S PERIOD (CONVENTIONAL DEFINITION INCLUDING ALL SIGNAL BLACK OUT-PERIODS.
RECOMMENDED AROUSAL, ARTIFACT AND NOXIOUS STIMULI ANAESTHESIA-SPECIFIC ONLINE INDICES		
OVERALL ANAESTHESIA- SPECIFIC AROUSAL INDEX	AA _r _i	RUNNING SCORE OF ALL CONVENTIONAL AND ANAESTHESIA- SPECIFIC AROUSALS DURING PRECEDING 60 S PERIOD
OVERALL ANAESTHESIA- SPECIFIC CORTICAL AROUSAL INDEX	AcA _r _i	RUNNING SCORE OF ALL CONVENTIONAL AND ANAESTHESIA- SPECIFIC CORTICAL AROUSALS DURING PRECEDING 60 S PERIOD
OVERALL ANAESTHESIA- SPECIFIC SUBCORTICAL AROUSAL INDEX	AsA _r _i	RUNNING SCORE OF ALL CONVENTIONAL AND ANAESTHESIA- SPECIFIC SUBCORTICAL AROUSALS DURING PRECEDING 60 S PERIOD
OVERALL ANAESTHESIA- SPECIFIC BODY MOVEMENT INDEX	ABM _i	RUNNING SCORE OF TOTAL SCORE OF CONVENTIONAL (BM) AND QUICK ANAESTHESIA-SPECIFIC (BMQ) EVENTS DURING THE PRECEDING 60 S PERIOD.

FIG. 59B

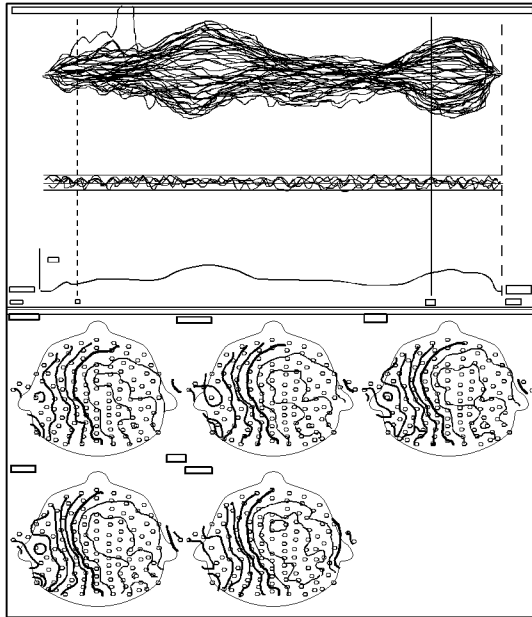


FIG. 60A

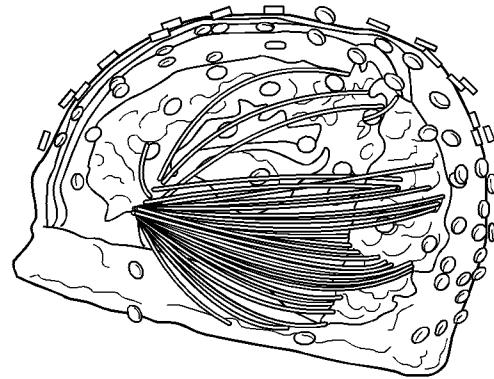


FIG. 60B

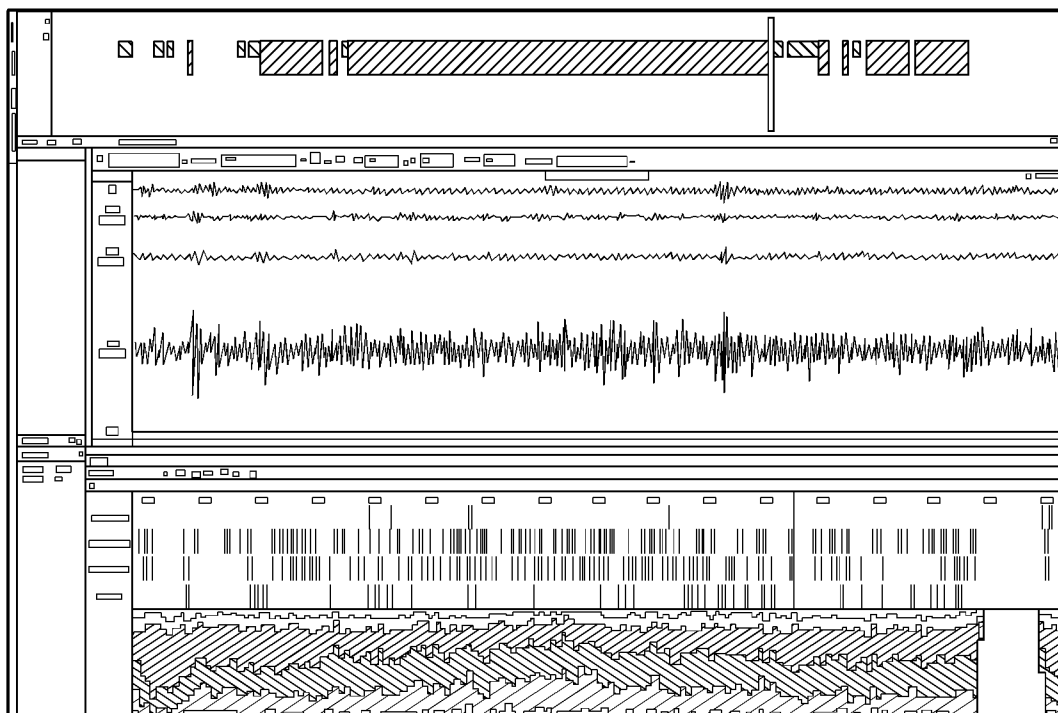


FIG. 60C

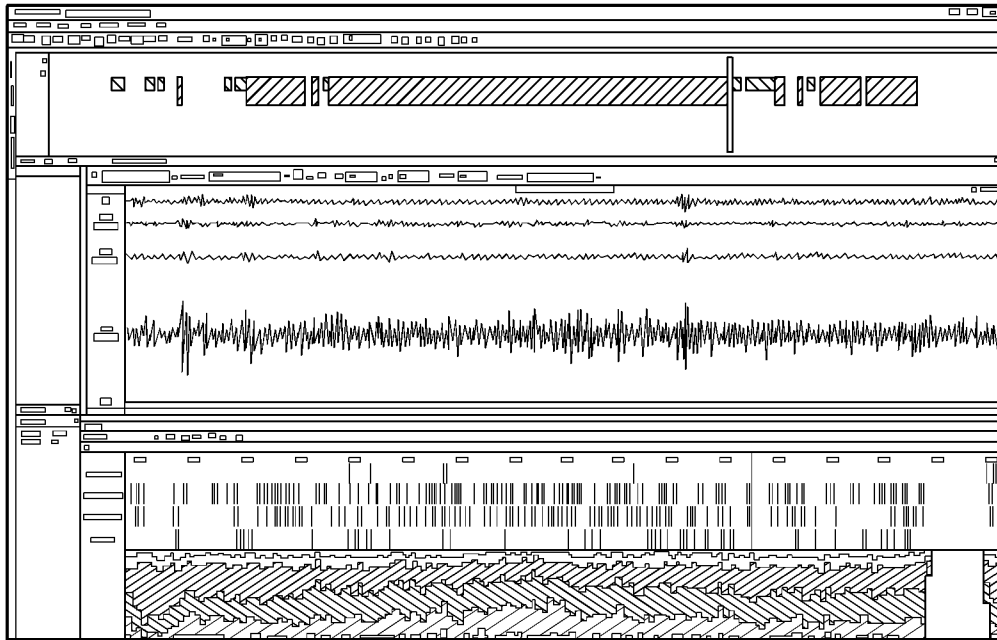


FIG. 61

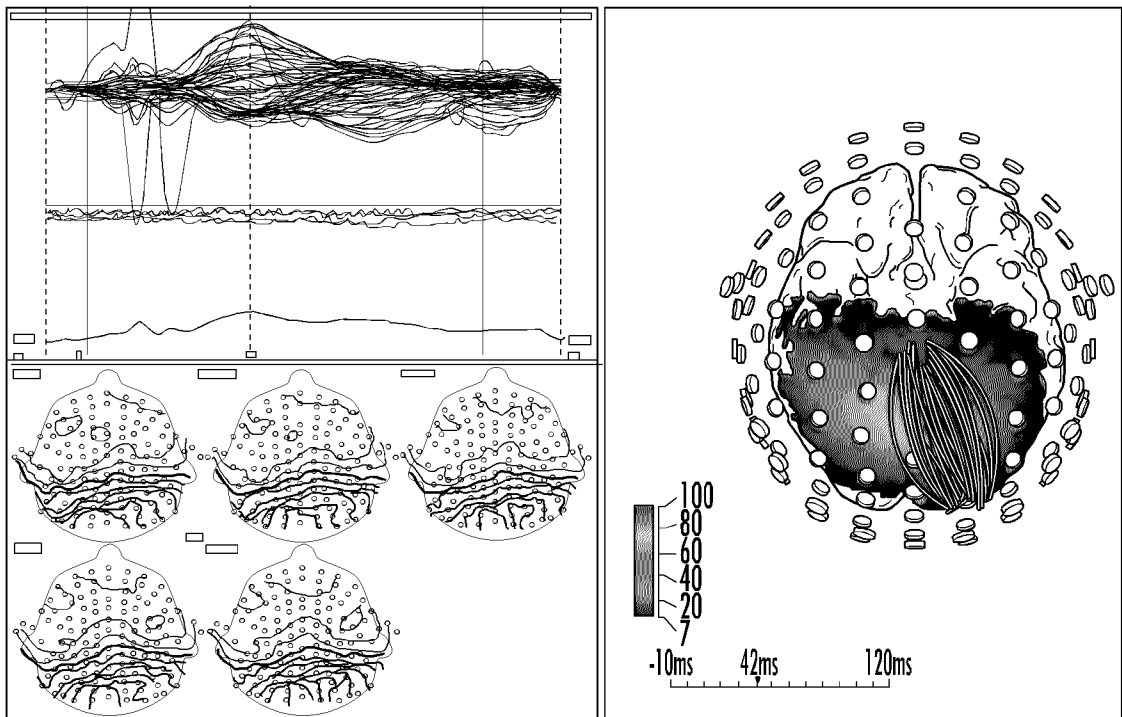
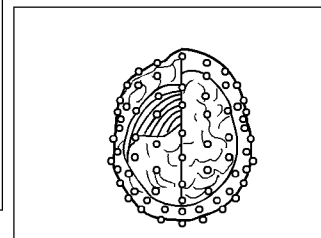
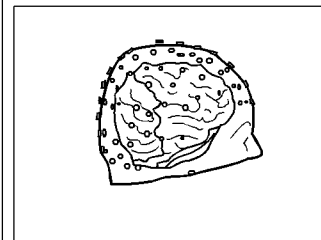
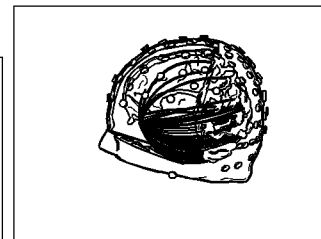
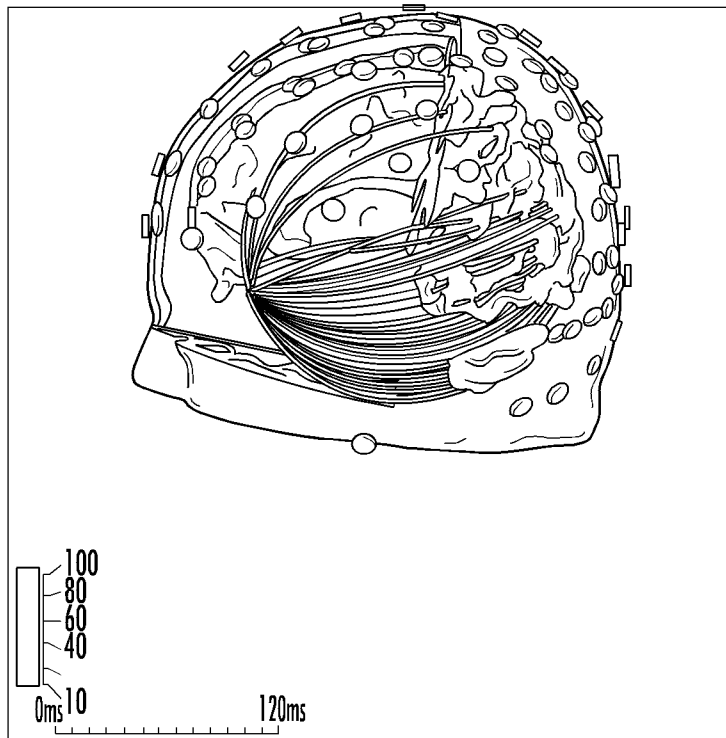
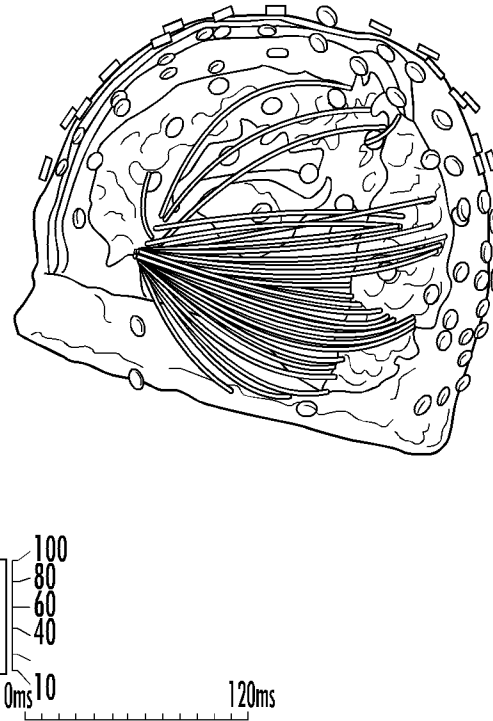
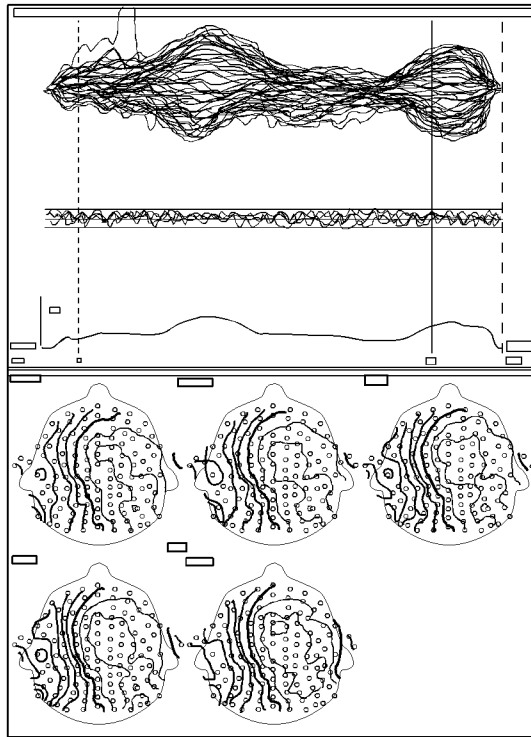


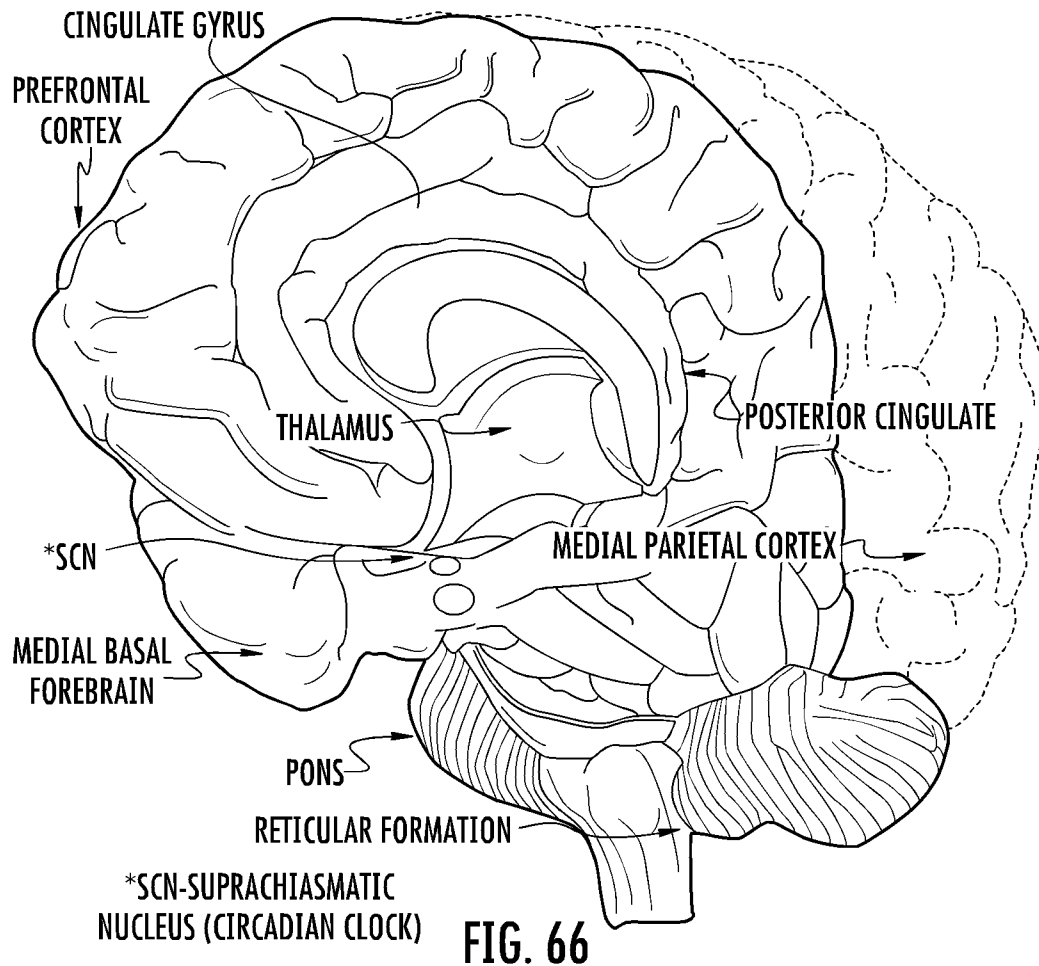
FIG. 62A

FIG. 62B



OUTPUT					
SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) (ALL AREAS): 0 ARCS, LAGS FROM 10.0..100.0ms, MIN. DISTANCE 5.0mm, CLIPPED AT 0.87					
SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) ANALYSIS: NO. OF ARCS (LAGS FROM 10.0..100.0ms, MIN DISTANCE 5.0mm, CLIPPED AT 0.86					
BRAIN AREA	TOTAL	ANTERIOR	POSTERIOR	ANTERIOR-POSTERIOR	SUPERIOR-INFERIOR
BOTH HEMISPHERES	569	0	0	569	569
LEFT HEMISPHERE	504	0	0	504	504
RIGHT HEMISPHERE	0	0	0	0	0
MIDLINE	81	0	0	81	81
INTRA-HEMISPHERIC	504	0	0	504	504
INTER-HEMISPHERIC	65	0	0	65	65
SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) (ALL AREAS): 569 ARCS, LAGS FROM 10.0..100.0ms, MIN. DISTANCE 5.0mm, CLIPPED AT 0.86					

FIG. 65



CHANGING MIN LAG TIMES TO
ADJUST ARCS — 3 ARCS

RESULTS: SLEEP (EV2 3M GM AVE);
STUDY 2; FD BP, MAPS, 3D VIEW: BOT;
COH OBJ CLIP < 50%; CDR PAR CLIP <
36%; MIN LAG 7.4MS; 120MS MAX LAG;
CDR TRANSP. 100%; ELECTR. TRANSP. 90%;
SRC COH (FIXED) FOR CDR (SLORETTA) OBJECT
ON
DIPOLES (3 FIXED MUSIC) OBJECT ON; DIPOLES
STRENGTH ICON ACTIVATED; AUTO NOISE EST

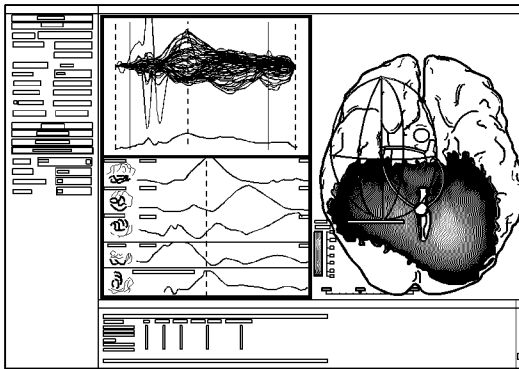


FIG. 67A

CHANGING MIN LAG TIMES TO
ADJUST ARCS — 2 ARCS (L GREEN R
HEM)

RESULTS: SLEEP (EV2 3M GM AVE);
STUDY 2; FD BP, MAPS, 3D VIEW: BOT;
COH OBJ CLIP < 50%; CDR PAR CLIP <
36%; MIN LAG 7.3MS; 120MS MAX LAG;
CDR TRANSP. 100%; ELECTR. TRANSP. 90%;
SRC COH (FIXED) FOR CDR (SLORETTA) OBJECT
ON
DIPOLES (3 FIXED MUSIC) OBJECT ON; DIPOLES
STRENGTH ICON ACTIVATED; AUTO NOISE EST

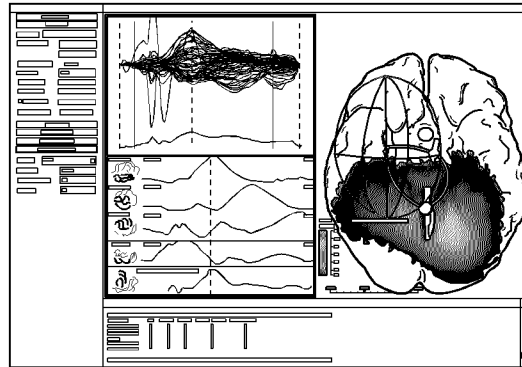


FIG. 67B

CHANGING MIN LAG TIMES TO
ADJUST ARCS — 1 ARC (BLUE R HEM)

RESULTS: SLEEP (EV2 3M GM AVE);
STUDY 2; FD BP, MAPS, 3D VIEW: BOT;
COH OBJ CLIP < 50%; CDR PAR CLIP <
36%; MIN LAG 40MS; 120MS MAX LAG;
CDR TRANSP. 100%; ELECTR. TRANSP. 90%;
SRC COH (FIXED) FOR CDR (SLORETTA) OBJECT
ON
DIPOLES (3 FIXED MUSIC) OBJECT ON; DIPOLES
STRENGTH ICON ACTIVATED; AUTO NOISE EST

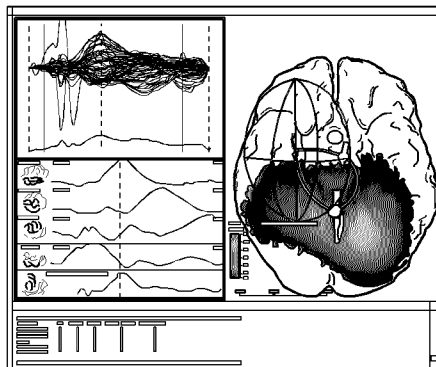


FIG. 67C

CHANGING MIN LAG TIMES TO
ADJUST ARCS — 1 ARC (DARKER
BLUE R HEM)

RESULTS: SLEEP (EV2 3M GM AVE);
STUDY 2; FD BP, MAPS, 3D VIEW: BOT;
COH OBJ CLIP < 50%; CDR PAR CLIP <
36%; MIN LAG 45MS; 120MS MAX LAG;
CDR TRANSP. 100%; ELECTR. TRANSP. 90%;
SRC COH (FIXED) FOR CDR (SLORETTA) OBJECT
ON
DIPOLES (3 FIXED MUSIC) OBJECT ON; DIPOLES
STRENGTH ICON ACTIVATED; AUTO NOISE EST

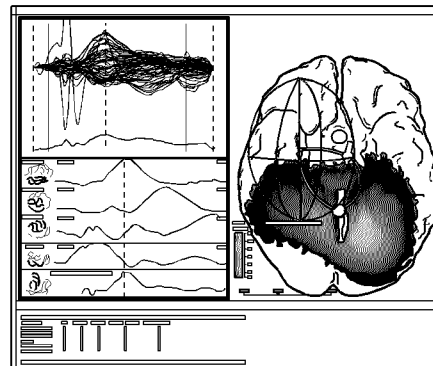
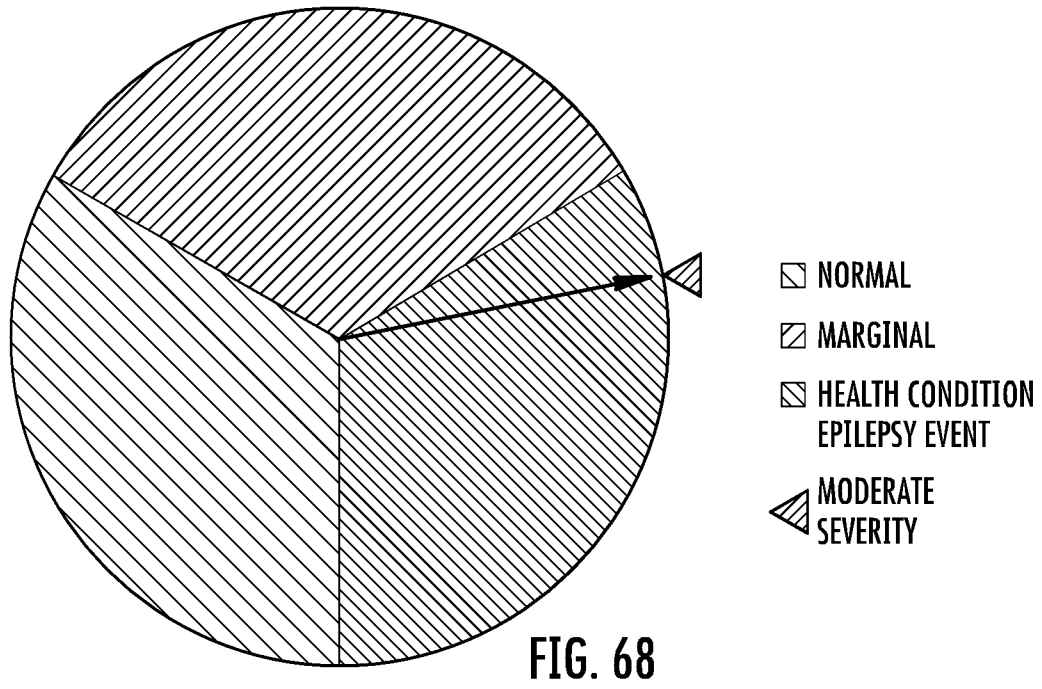


FIG. 67D



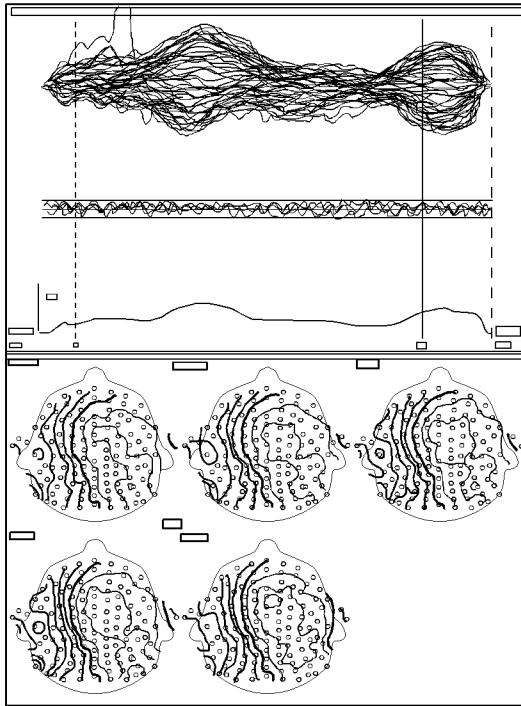


FIG. 69A

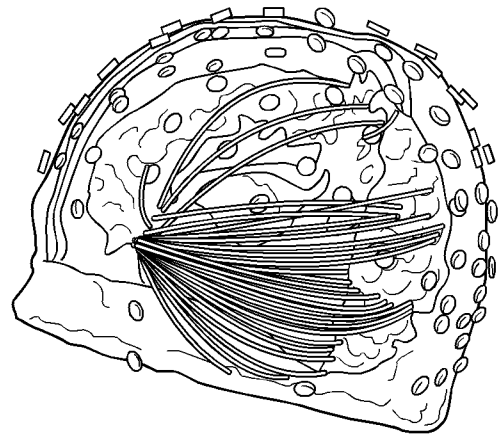


FIG. 69B

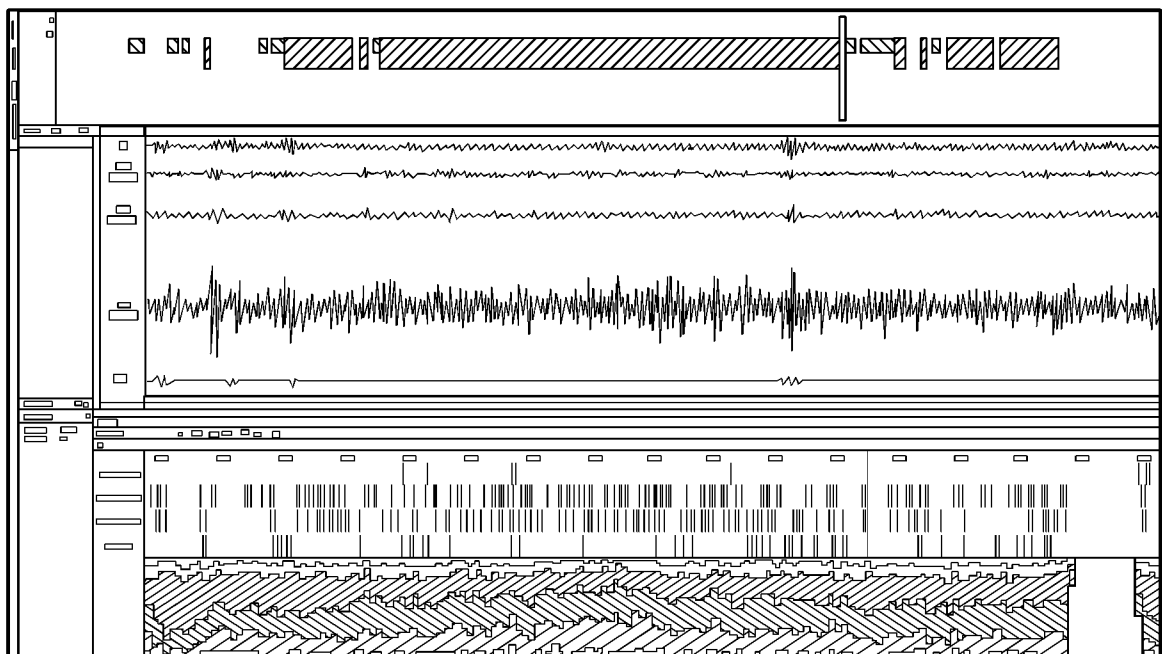


FIG. 69C

PHYSIOLOGICAL STATUS		PSYCHOLOGICAL STATUS		NEUROLOGIC STATUS		EVENT STATUS		MULTIVARIATE/COMBIN.ANALYSIS		HEALTH CONDITION	
ARRHYTHMIA ONSET	AO ▽	REM	REM	PARKINSON ONSET	PO	EEG SPIKES	SK ▽	MMDA-GABA	NG	PARKINSON'S	PK
ARRHYTHMIA DETECTION	AD	WAKE	WAKE	ALZHEIMER ONSET	AO	EEG SPINDLES	SD	VITAL-SIGN INCREASE-JUNCO	VU	ALZHEIMER'S	AZ
VITAL SIGN NORMAL (N) VS ABNORMAL	VN	STAGE 1	S1	SEIZURE ONSET	SO	EEGK-COMPLEXES	EK	EPILEPSY ONSET CLUSTER - EEG	EOE	SLEEP BEHAV. DISORDER	SB
(A) OPERATING RANGE TRACKING	VA	STAGE 2	S2	EPILEPSY ONSET	EO	EEG HFOS	EH	SLEEP BEHAV. DISORDER+TREMOR	SBT	CARDIAC ARREST	CA
PALPITATIONS DETECTION	PD	STAGE 3	S3			EEG RIPPLES	ER			RESPIRATORY ARREST	RA
VIBR-LEV-CARDIOBALL EARBUD	VE	STAGE 4	S4			EEG AROUSALS	EA				
TEMPERATURE EARBUD	TE	ATTENTIVE	AT			EEG MICRO AROUSAL	EM				
OXIMETRY PULSE HR EARBUD	OE	TREMOR	TR			EEG EVENT CLUSTERS	EC				
OXIMETRY PTT EARBUD	OP	SHAKE	SH			EEG ENSEMBLE	EE				
OXIMETRY PAW/PWA EARBUD	PA					APNOEA	AP				
OXIMETRY BP VARIATION	OB					SNORING	SN				
OXIMETRY HRW	OH ▽					HYPOXIA	HX ▽				
GO TO SETUP		GO TO SETUP		GO TO SETUP		GO TO SETUP		GO TO SETUP		GO TO SETUP	

FIG. 69D

ACTIVE HEALTH MANAGEMENT ATTRIBUTES (CLICK/TAP TO ILLUMINATE; DOUBLE CLICK/TAP TO GO TO ANY DISPLAYED EVENTS)						
PHYSIOLOGICAL STATUS		PSYCHOLOGICAL STATUS	NEUROLOGIC STATUS	EVENT STATUS		MULTIVARIATE/COMBIN.ANALYSIS
ARRHYTHMIA ONSET	AO	REM	PARKINSON ONSET	EEG SPIKES	SK	NG
ARRHYTHMIA DETECTION	AD	WAKE	ALZHEIMER ONSET	EEG SPINDLES	SD	VU
VITAL SIGN NORMAL (N) VS ABNORMAL	VN	STAGE 1	SEIZURE ONSET	EEG COMPLEXES	EK	EOE
(A) OPERATING RANGE TRACKING	VA	STAGE 2	EPILEPSY ONSET	EEG HFOS	EH	SBT
PALPITATIONS DETECTION	PD	STAGE 3		EEG RIPPLES	ER	CA
VIBR-LEV-CARDIOBALL EARBUD	VE	STAGE 4		EEG AROUSALS	EA	RA
TEMPERATURE EARBUD	TE	ATTENTIVE		EEG MICRO AROUSAL	EM	
OXIMETRY PULSE HR EARBUD	OE	TREMOR		EEG EVENT CLUSTERS	EC	
OXIMETRY PTT EARBUD	OP	SHAKE		EEG ENSEMBLE	EE	
OXIMETRY PAW/PWA EARBUD	PA			APNOEA	AP	
OXIMETRY BP VARIATION	OB			SHORING	SN	
OXIMETRY HRW	OH			HYPOXIA	HX	
GO TO SETUP		GO TO SETUP	GO TO SETUP	GO TO SETUP		GO TO SETUP
GO TO SETUP		GO TO SETUP	GO TO SETUP	GO TO SETUP		GO TO SETUP

FIG. 70

SIGNAL QUALITY USER ALERT:

DEPRESS SENSOR DEVICE PRESSURE PAD 3 TO STRENGTHEN CONNECTION

1

VIEW MODE

SIGNAL QUALITY : 80%

LOG EVENT ☐30JUN09
09:32:45

1 2

AEP CO

AEP UNCO

200-500Hz

WAKE

COGNITION

110-199 Hz

RESPONSE

70-109 Hz

EMG

WAKE

47-69 Hz

INTERFERENCE

32-46 Hz

GAMMA

ANAESTHESIA

12-31 Hz

BETA

SLEEP

8-11 Hz

ALPHA

SLEEP

DC-7 Hz

ARTIFACT/ WAKE

A&CD SPECTRAL NEURAL ARRAY 12MCH09.VSD

AEP CO

CO1x

AEP UNCO

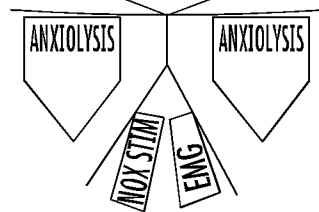
ARTIFACT BLACKOUT

BURST SUPPRESSION

A&CDi
37

SIGNAL DIST: MDi:35m; ADi:15m

ANAESTHETIC BAL[EEG/SEMG/VS]:30%

AEP PCP
AWARENESS

SAO2: 97%

SAO2: ECG HR: 65 BPM HRV: 15%

ECG: BP VARIATION : + 10 % BL

BPV: PAT: 70% PTT: 32 USEC

RESPIRATION RATE: 25 CPM

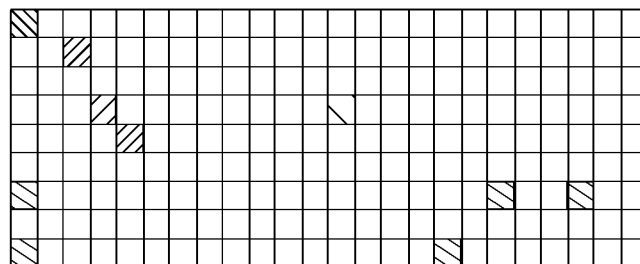
RESP:

RECALL RISK FACTOR IRF: 30%

PCP AEP AWARENESS:30%

EMG/MUSCLE MSi: 20%

EEG BSi: 20%

CRITICAL
EVENTSOTHER
EVENTS

AWARENESS	SENSORS
(NOXIOUS STIMULI)	[1] FP1
EMG BURST	[2] FP2
BODY MOVEMENT	[3] FPZ
SIGNAL DROPOUT	[4] MASSETER EMG
AROUSAL	[5] IZ
EYE MOVEMENT	[6] AT-PAMR
ELECTROSURGICAL INT	[7] A2
MAINS NOISE	NZ [F7]
	[9] F7
	[10] F8
	[11] AEP

SDA MODE AEP EEG FFT AMP √AMP AMP² ENTROPY MF BETA RATIO AMP SKEW DIFF INTEG KURTO SIS SKEWNESS BISPE REAL BICOHER EMG SEF95 BURST CTRUM TRIPLE P ENCE POWER SUP63

FIG. 71

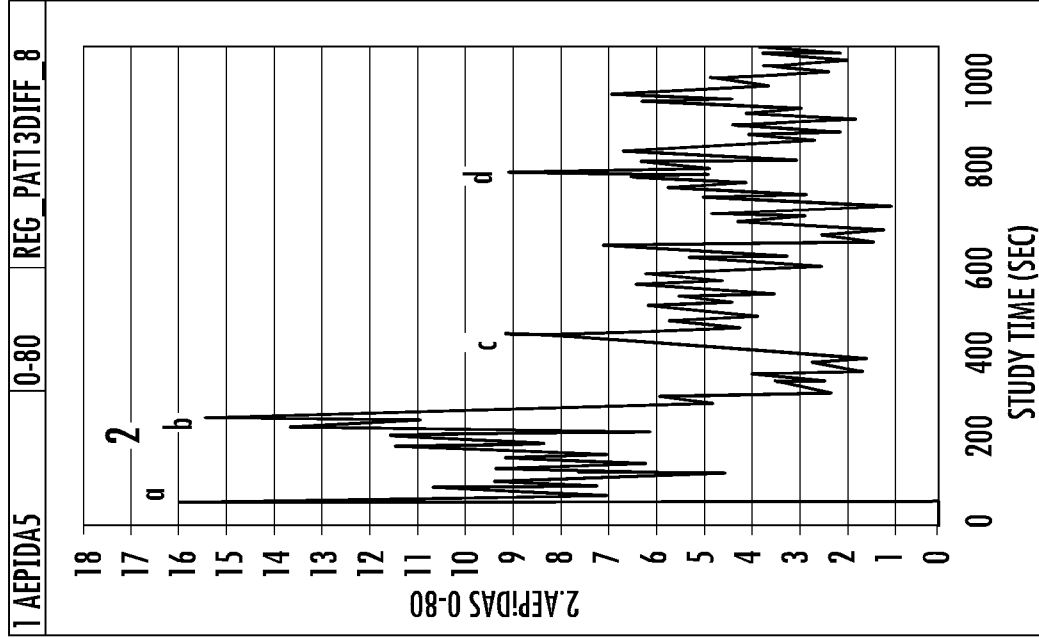


FIG. 72B

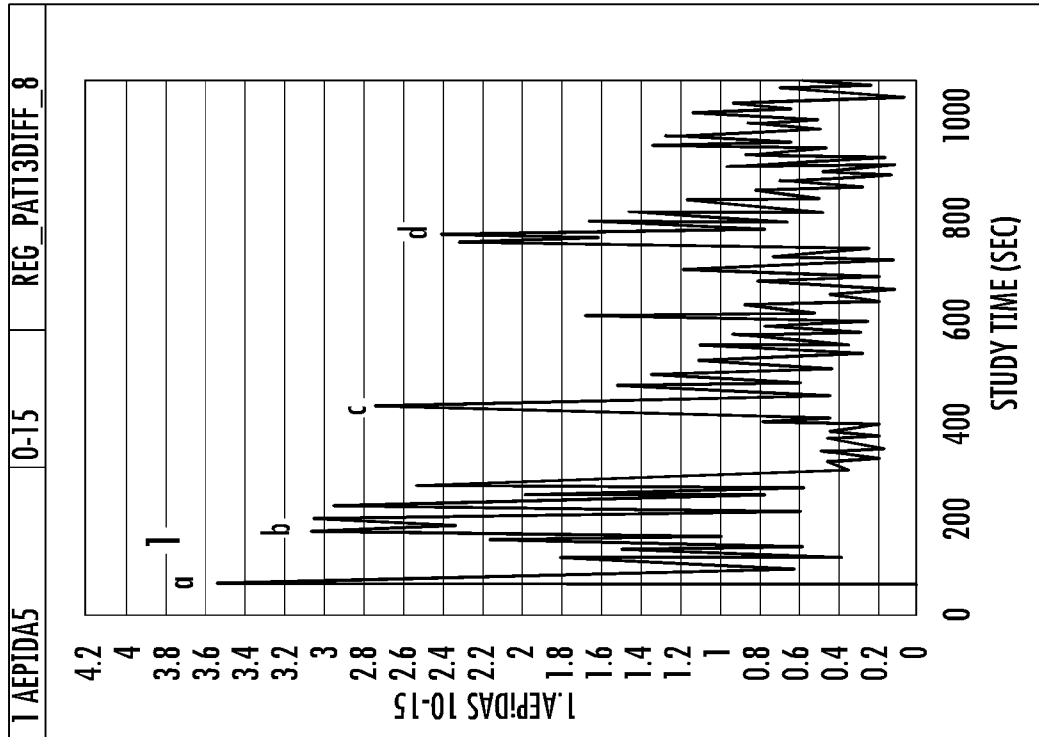


FIG. 72A

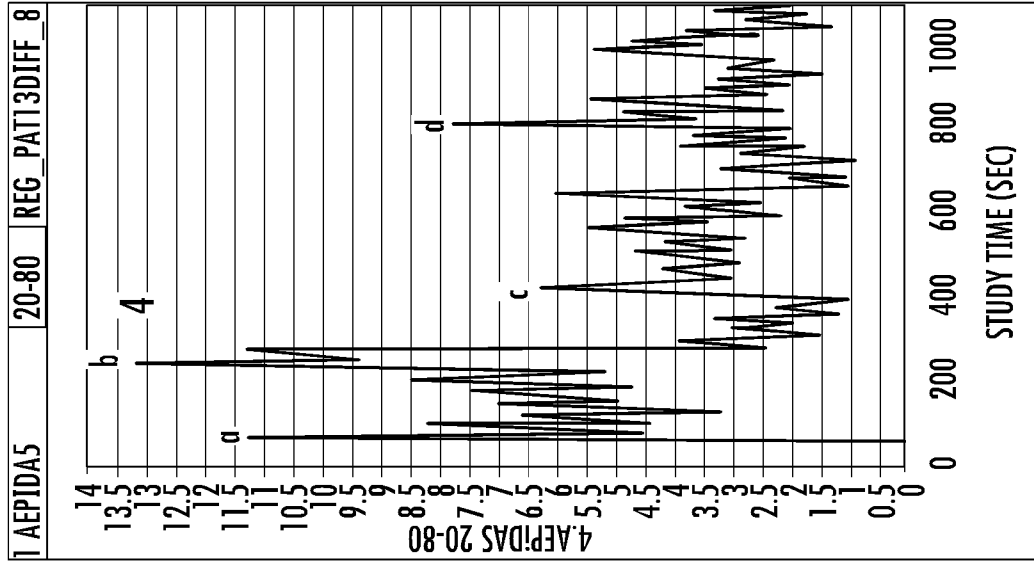


FIG. 72D

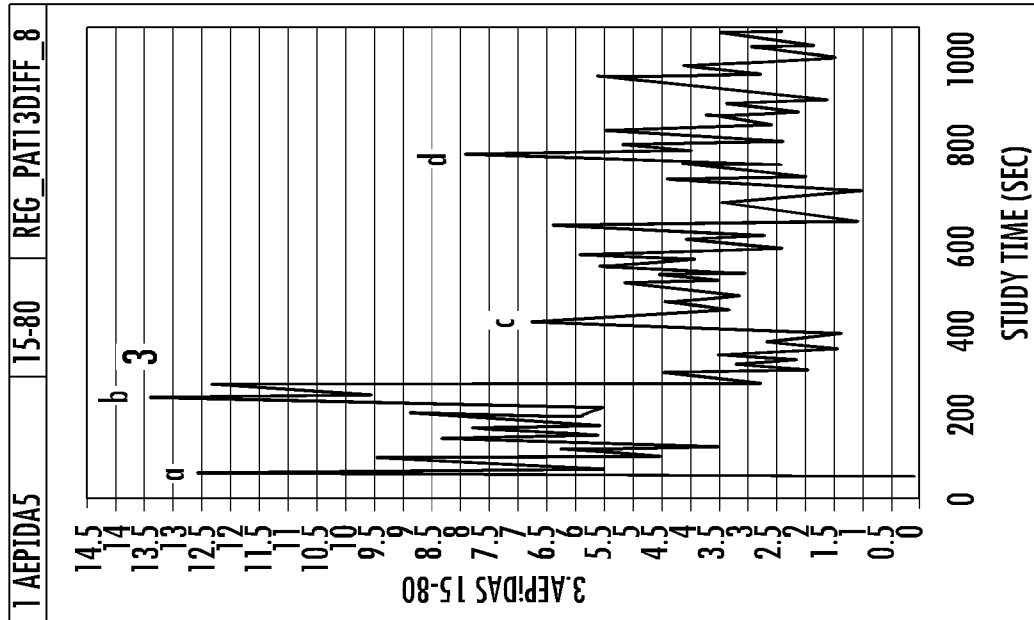


FIG. 72C

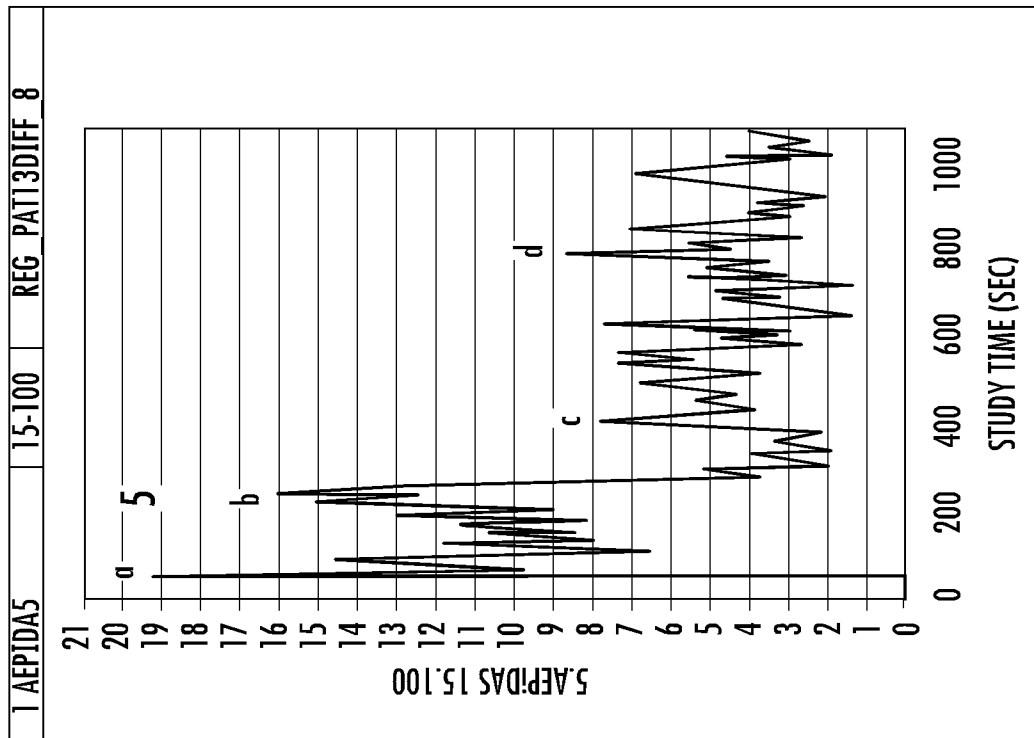


FIG. 72E

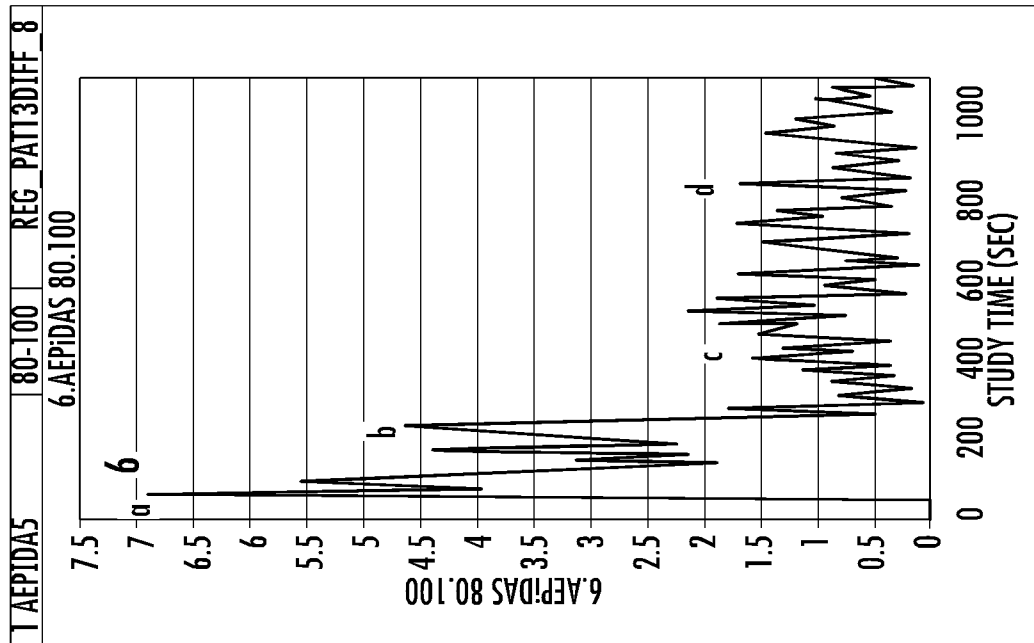


FIG. 72F

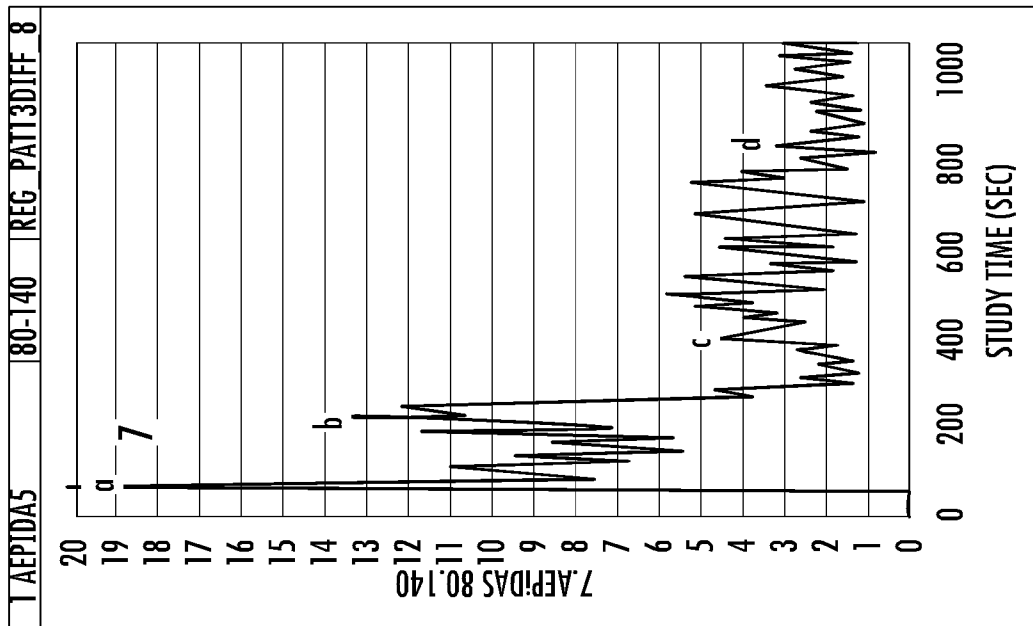


FIG. 72G

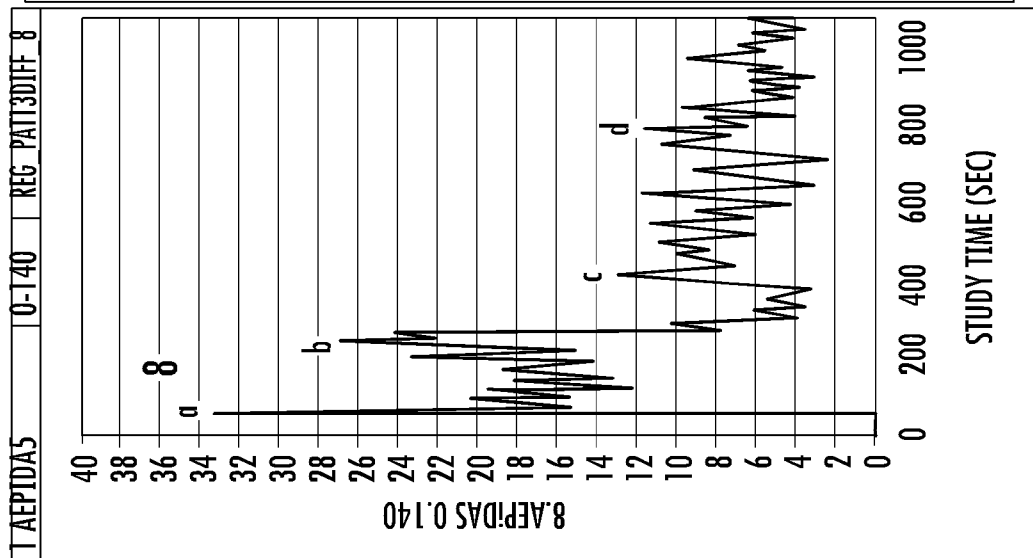


FIG. 72H

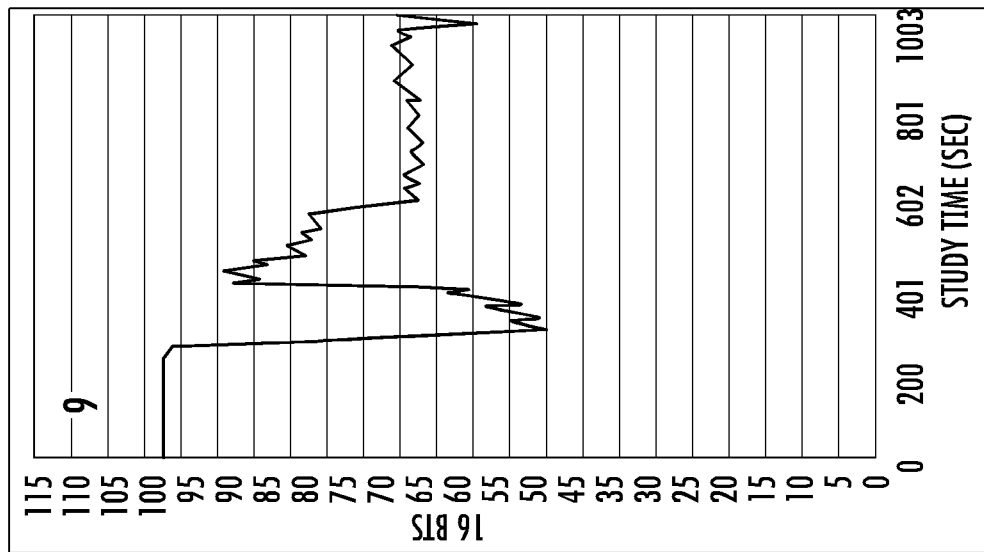


FIG. 72I

62/99

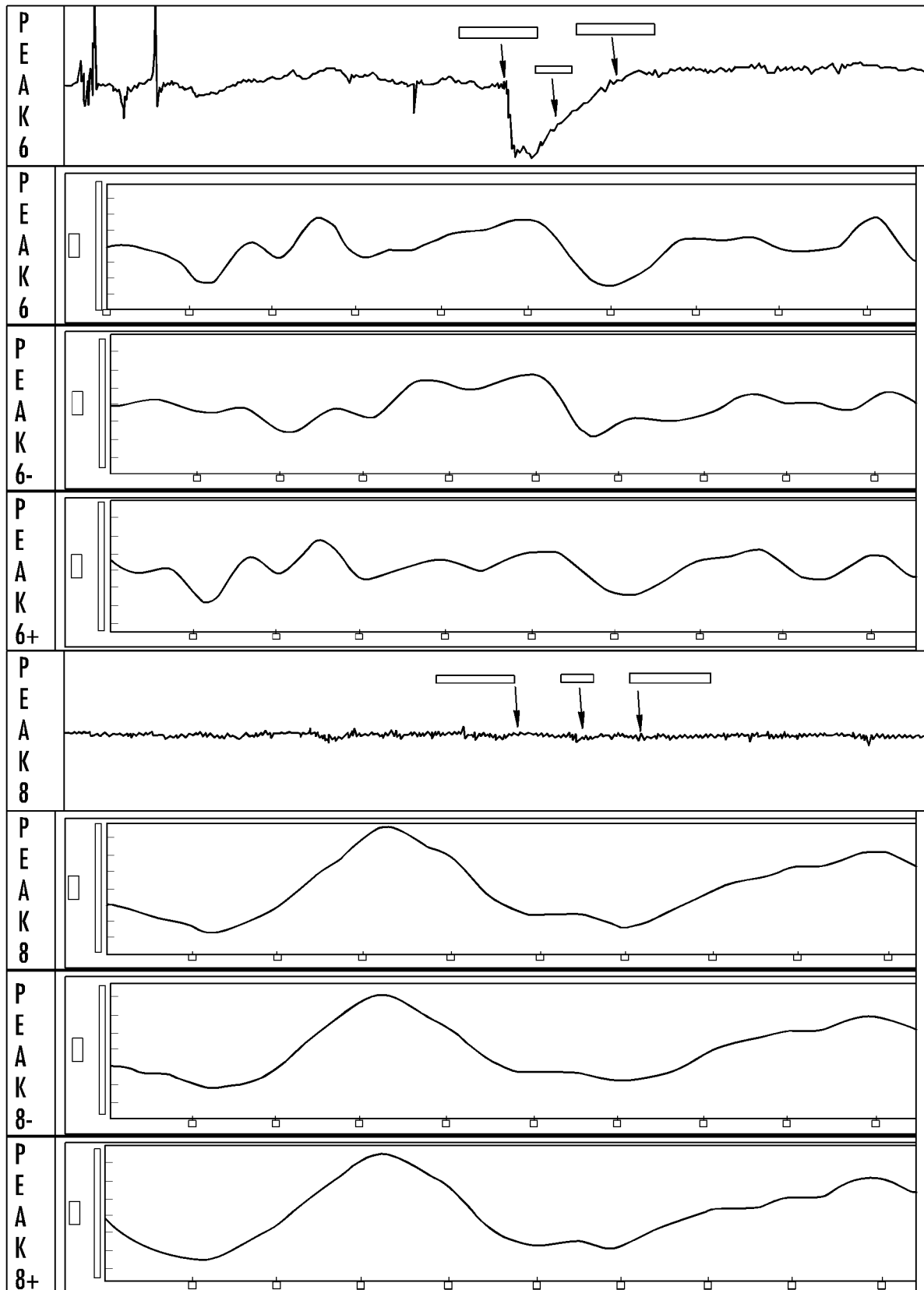
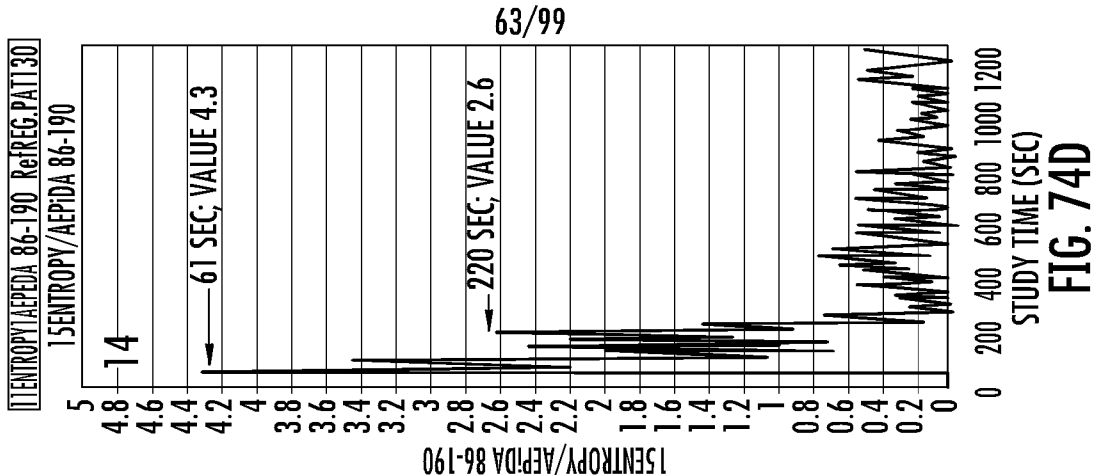
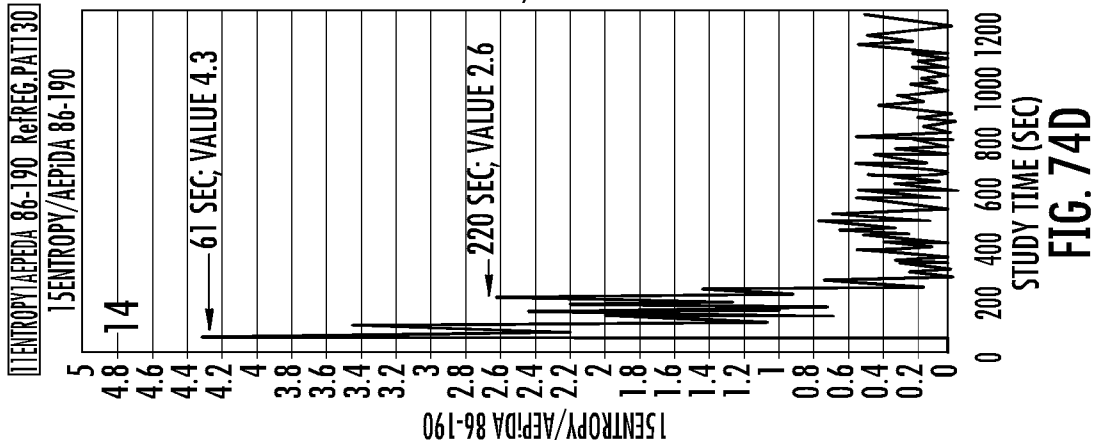
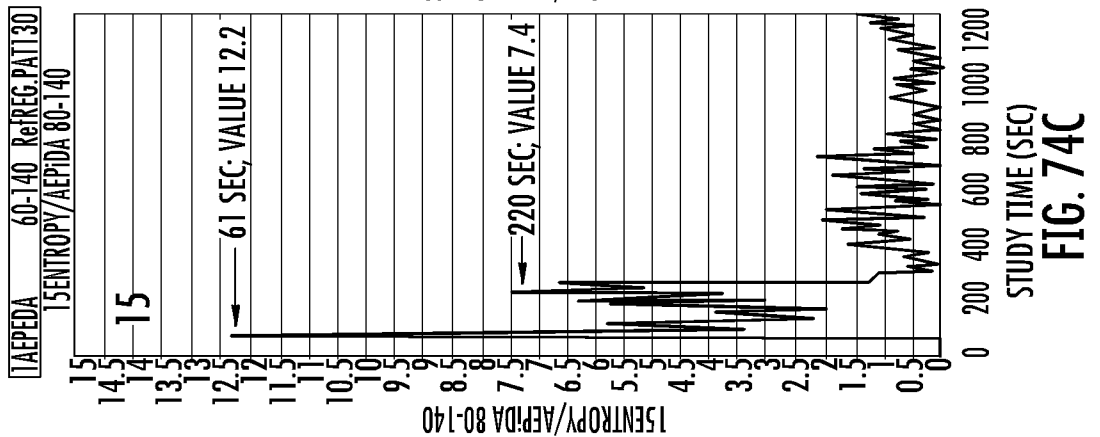
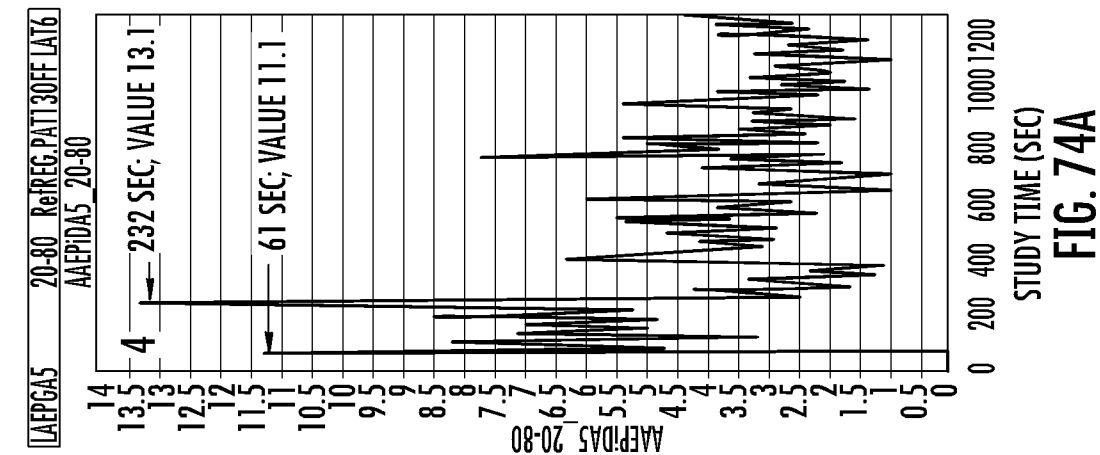
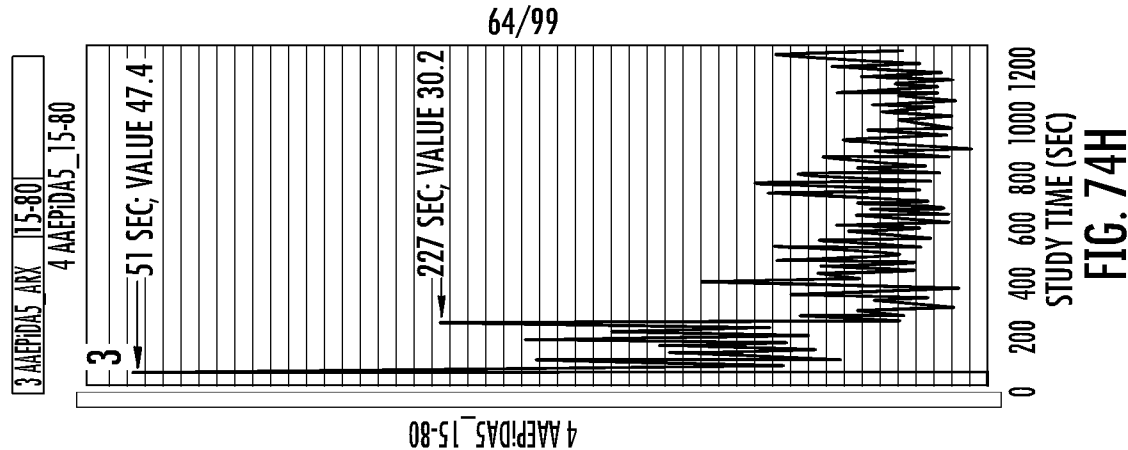
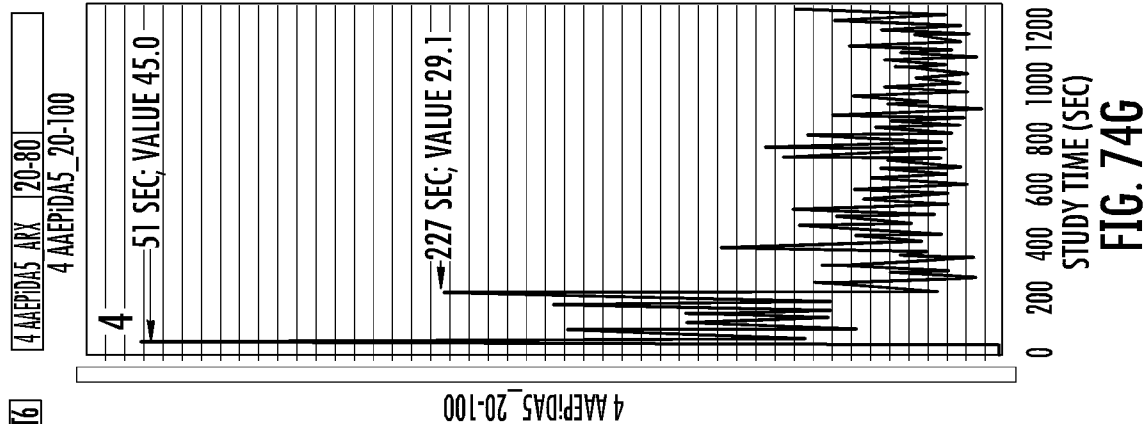
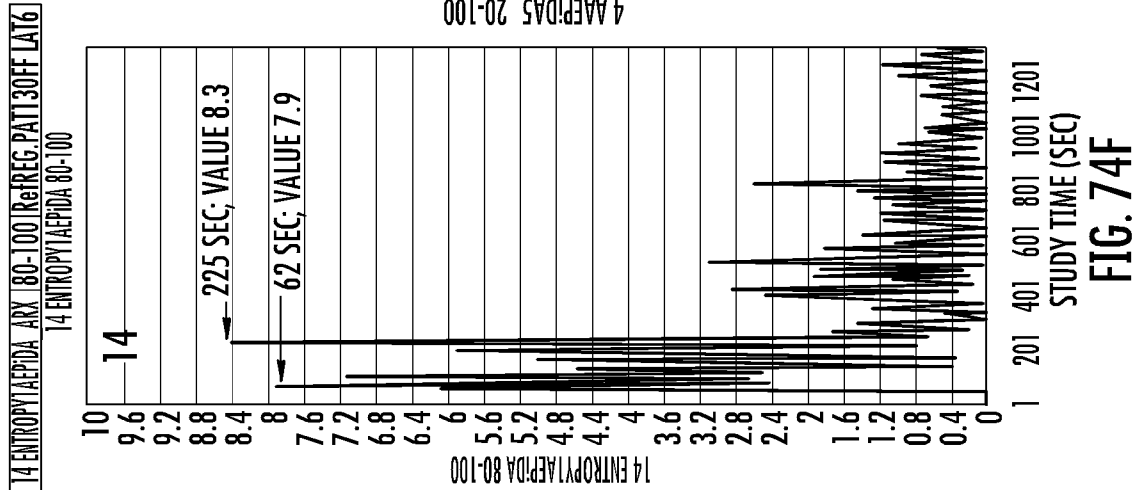
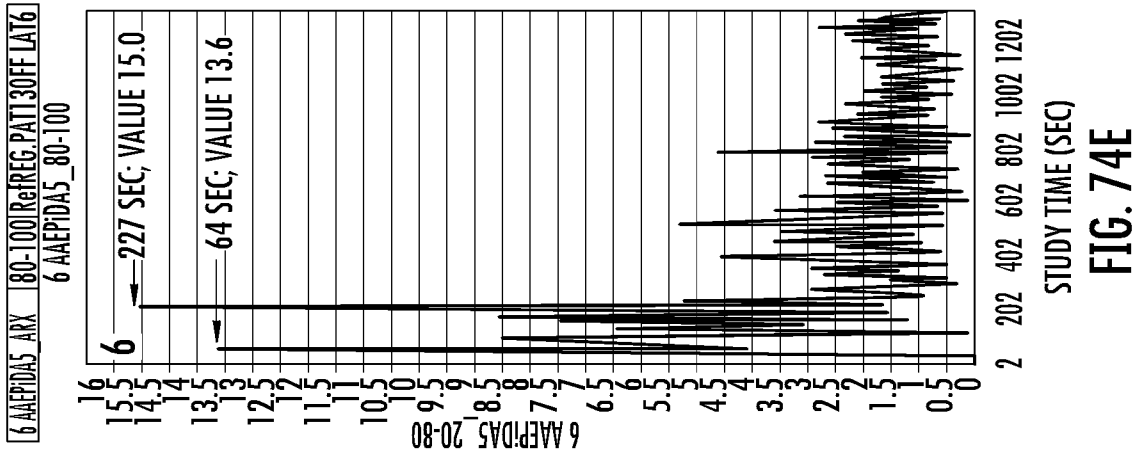


FIG. 73





HMS WITH AUTOMATIC TRACKING OF EOI:

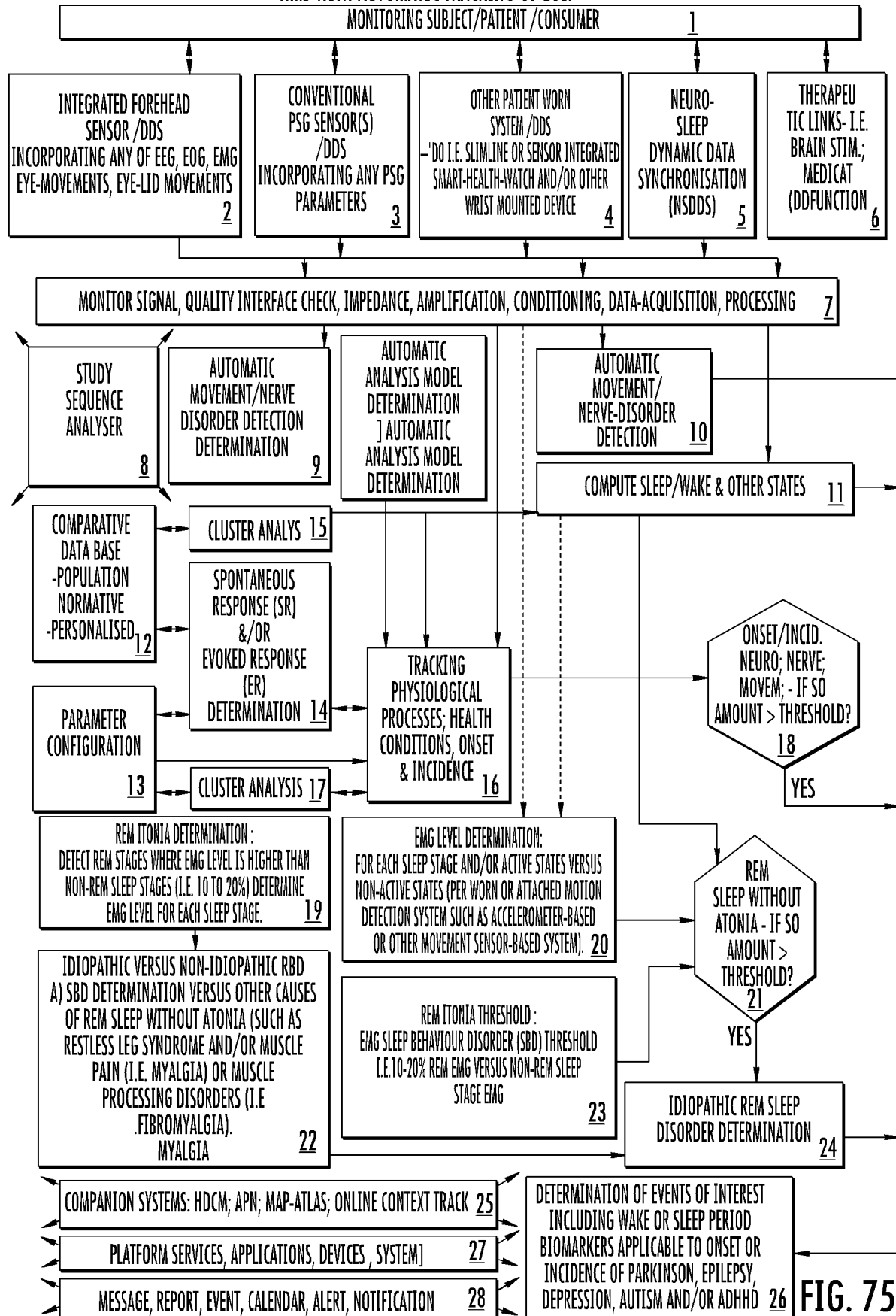


FIG. 75

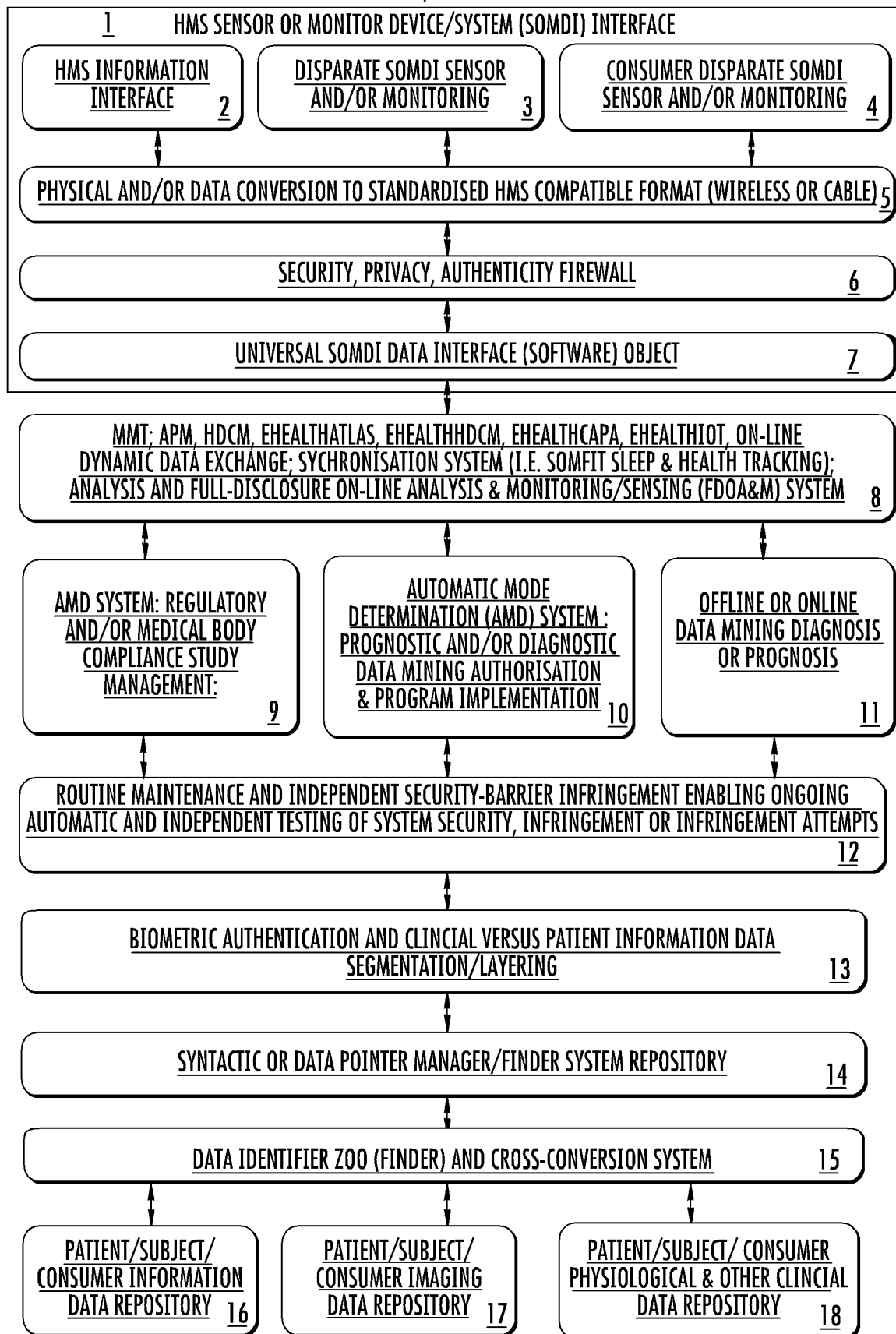
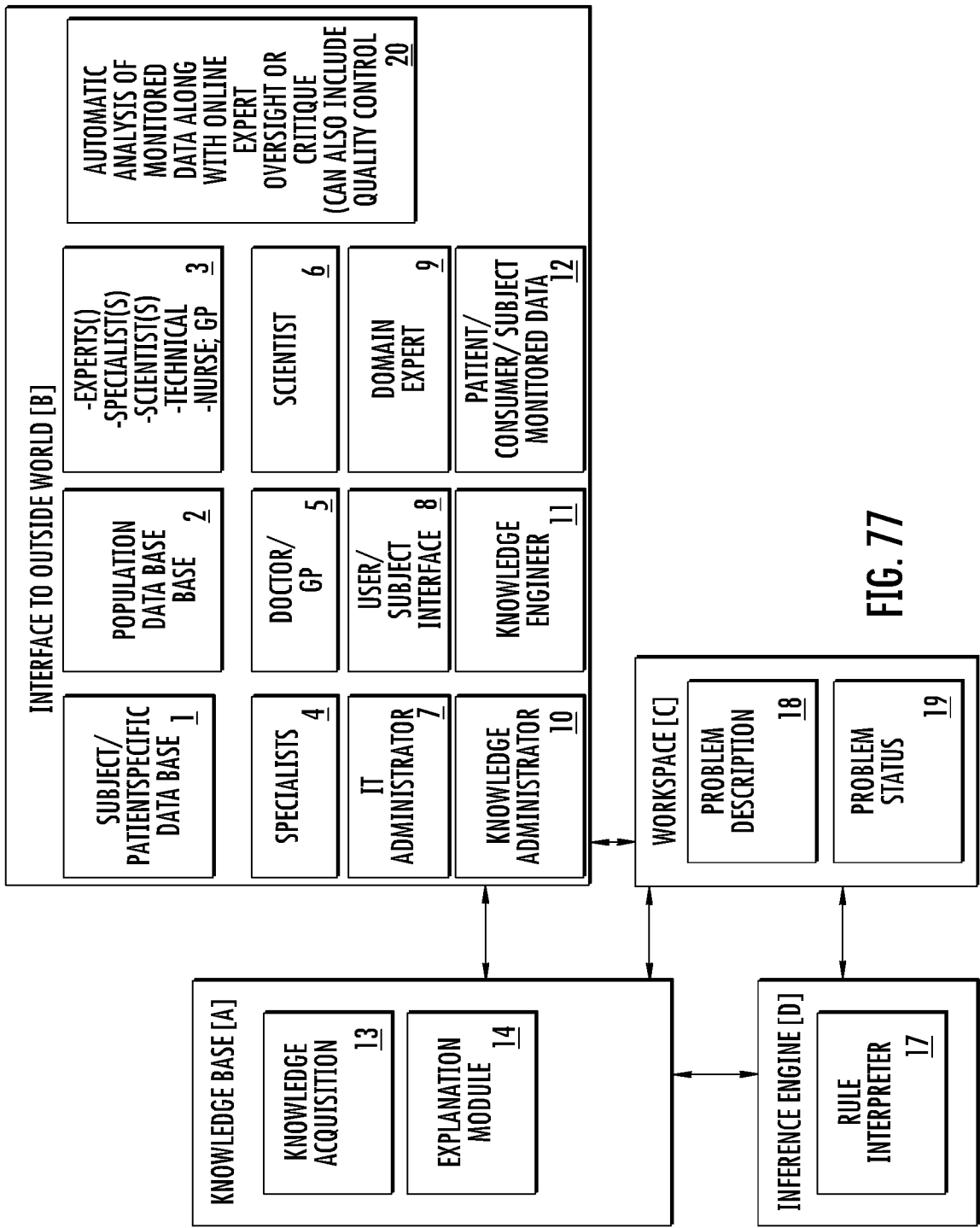


FIG. 76



HEALTH MANAGEMENT SYSTEM EXPERT SYSTEM INFORMATION TO KNOWLEDGE TRANSFORMATION METHOD

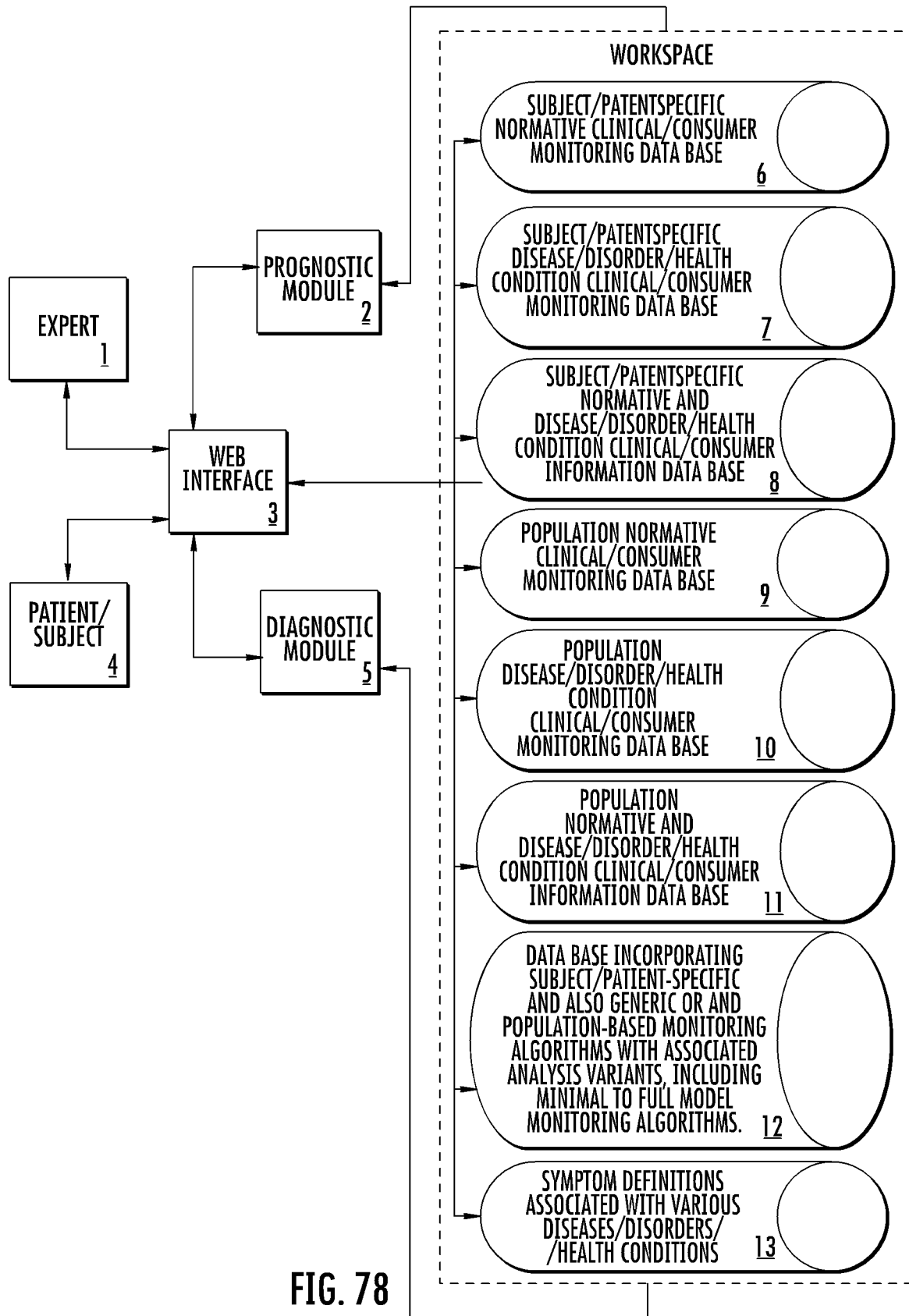


FIG. 78

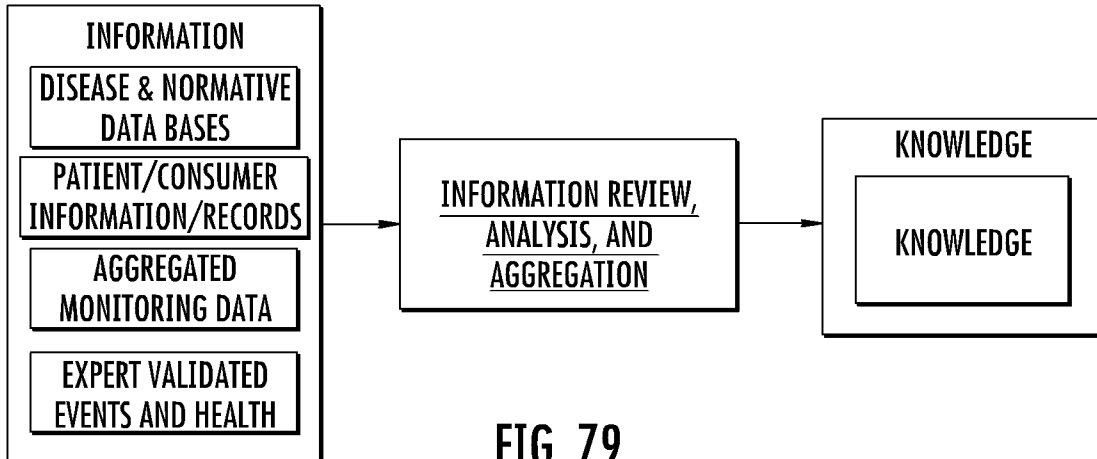


FIG. 79

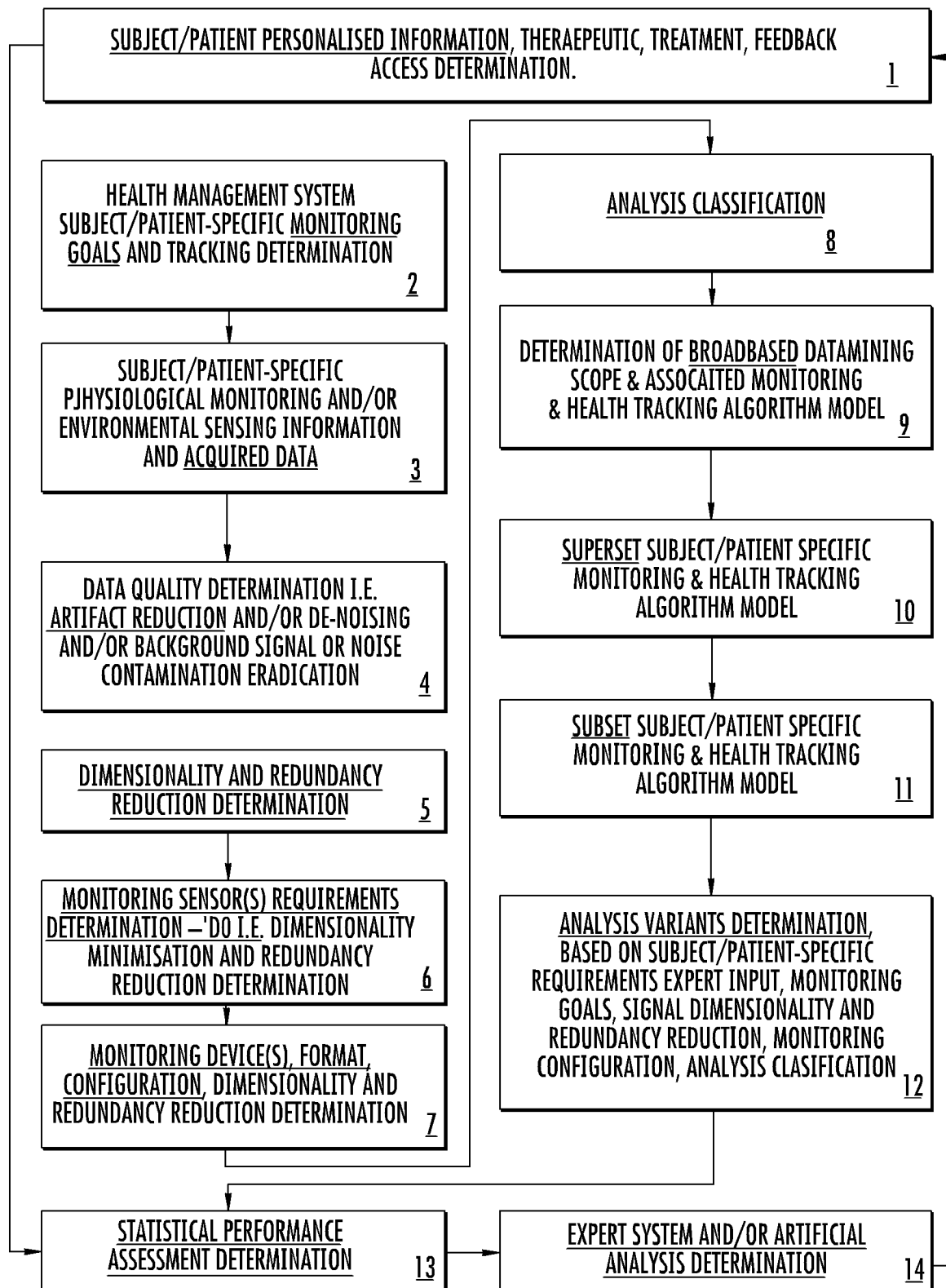


FIG. 80

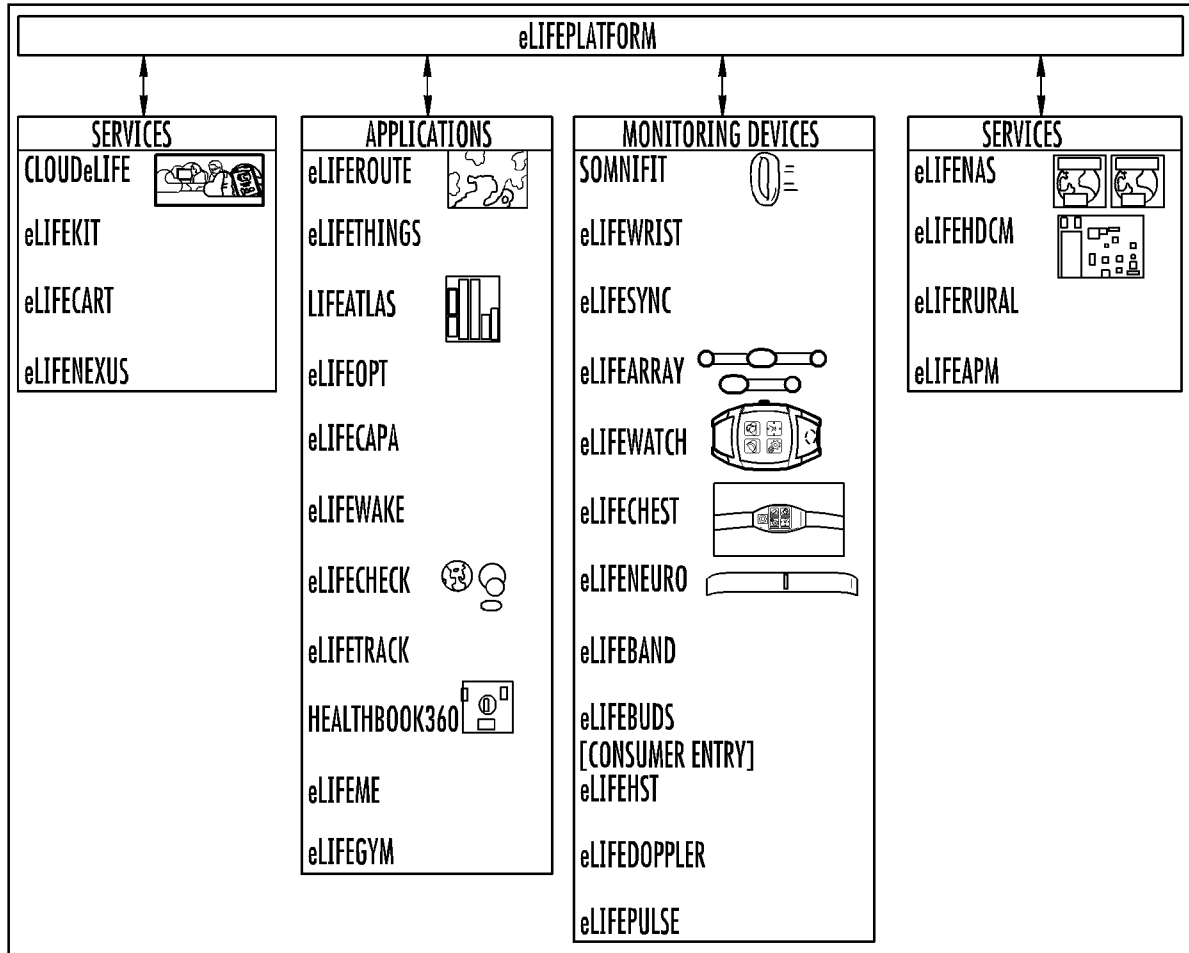


FIG. 81

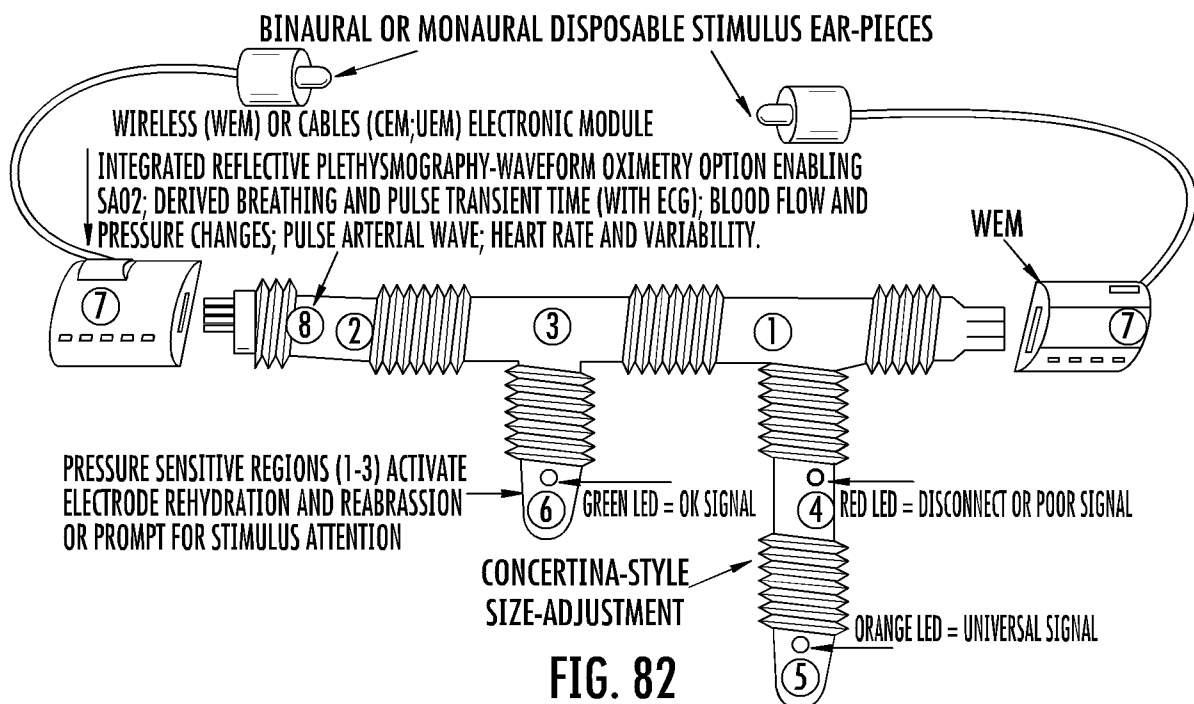


FIG. 82

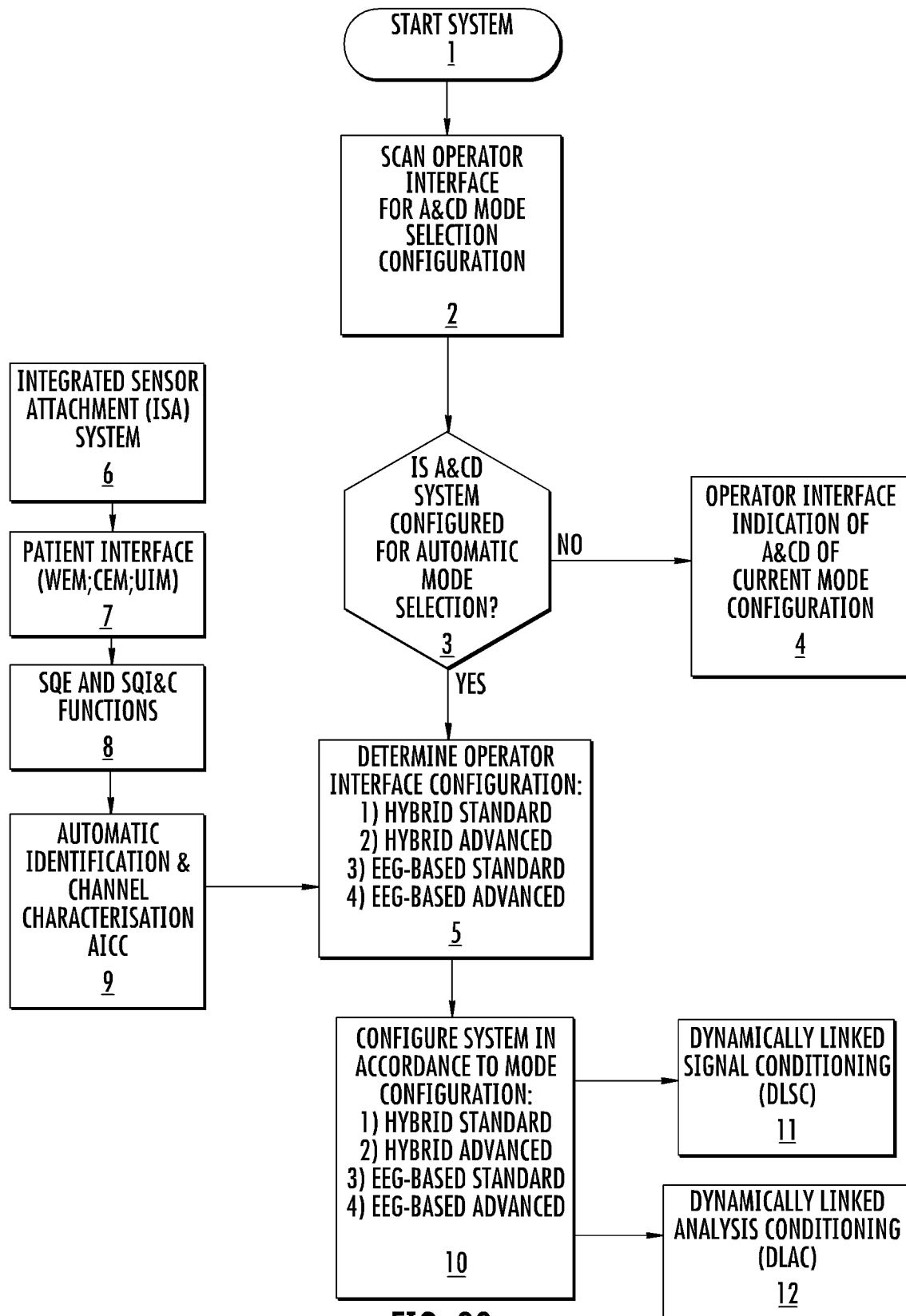


FIG. 83

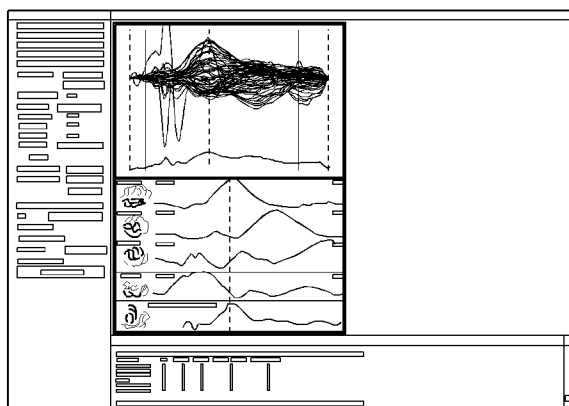


FIG. 84A

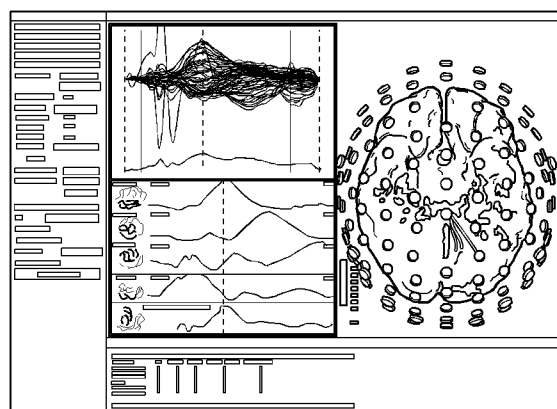


FIG. 84B

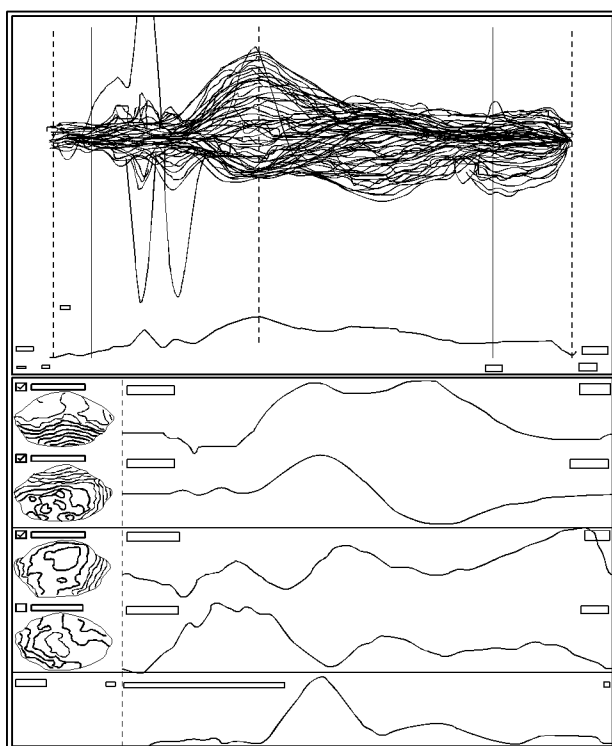


FIG. 85C

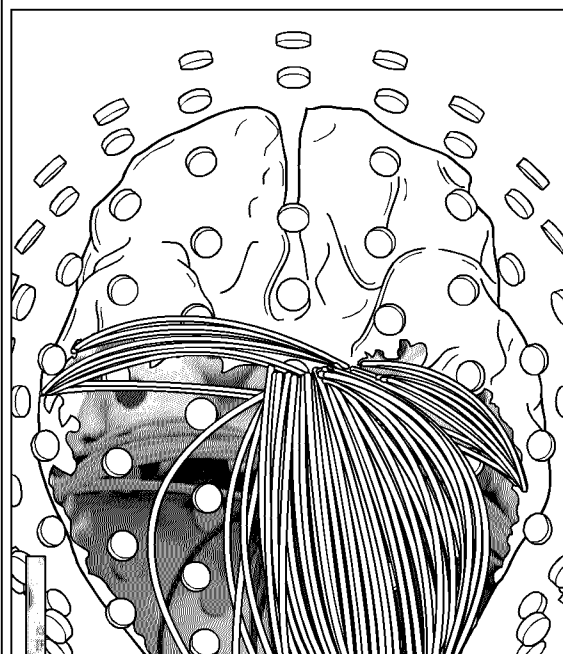


FIG. 85D

OUTPUT					
SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) ANALYSIS: NO. OF ARCS (LAGS FROM, 5.0..100.0ms, MIN DISTANCE 5.0mm, CLIPPED AT 0.5					
BRAIN AREA	TOTAL	ANTERIOR	POSTERIOR	ANTERIOR-POSTERIOR	SUPERIOR-INFERIOR
BOTH HEMISPHERES	540	2	722	218	200
LEFT HEMISPHERE	645	0	403	188	460
RIGHT HEMISPHERE	9	0	6	3	6
MIDLINE	240	0	120	23	110
INTRA-HEMISPHERIC	653	0	461	423	402
INTER-HEMISPHERIC	289	2	341	44	342
SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) (ALL AREAS): 569 ARCS, LAGS FROM 10.0..100.0ms, MIN. DISTANCE 5.0mm, CLIPPED AT 0.86					

FIG. 85E

- ☒ ☐ **SOURCE RESULTS**
☒ ☒ **ELECTRODES (80%)**
☐ ☒ **HEAD MODEL**
☐ ☒ **MAPS**
☐ ☒ **SOURCE LOCATIONS**
☐ ☒ **LEADFIELD**
☒ ☒ **CDR (eLORETA) (100%)**
☒ ☒ **SOURCE COHERENCE (FIXED) FOR sLORETA)**
☒ ☒ **DIPOLES (4 FIXED MUSIC)**

SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) PROPERTIES:	
COLOR	 DIPOLE COLORS 2
DISPLAY AS	TORUS
DISPLAY	ALL AREAS
CLIP BELOW	50%
MIN LAG	6.0ms
MAX LAG	100.0ms
MIN DISTANCE	5
LIMIT SYMBOLS	ON
LINE WIDTH	3
DIPOLARS (4 FIXED MUSIC) PROPERTIES	
COLOR	 DIPOLE COLORS 1
COLOR CODING	AUTO
COLOR RANGE	FULL
SCALING	AUTO (TIME RANGE)
SCALE	4 uA
SYMBOL SIZE	15.0ms
CLIP BELOW	0%
TIME RANGE	TRACE
SHAPE	POLE
LINE WIDTH	1
MATERIALS	SHINY
ELIPSOIDS	OFF
ELIPSOID WIDTH	1

SOURCE COHERENCE	
COHERENCE:	FIXED ▾
RESULT TYPE:	CURRENTS ▾
ZERO-LAG REMOVAL:	OFF ▾
CLIP BELOW:	42 % 

DIPOLE FIT	
DIPOLE TYPE:	FIXED MUSIC ▾
NUMBER OF DIPOLARS:	4 ▾
	ADVANCED ▾
☐ TEST DIPOLAR	☐ MIRRORRED
SPEED MODE:	AUTO ▾
SPEED DIST. [mm]:	200.0 
MIN DIST. [mm]:	20.0 
☐ REGULARIZATION	1.0 
CROSS-VALIDATION	SAVE DATA
SCAN METHODS	
CURRENT DENSITY	
SOURCE LOCATIONS	
SOURCE COHERENCE	
COHERENCE:	FIXED ▾
RESULT TYPE:	CURRENTS ▾
ZERO-LAG REMOVAL:	OFF ▾
CLIP BELOW:	42 % 

FIG. 86A

CURRENT DENSITY	SOURCE LOCATIONS
CDR TYPE: sLORETA ▾	USE: NEW COLIN 7AUG13 BEM 3/ ▾
CDR DIPOLE TYPE: OFF ▾	GRID SPACING [mm]: 7.0 ▴ ▾
ADVANCED ▾	☐ EXCLUDE STOP MARKERS
COMPONENT BASED: ☐ ON	SOURCE TYPE: ROTATING ▾
REGULARIZATION: AUTO (TIME RANGE) ▾	SOURCE EXTENSION [mm]: 0 ▴ ▾
RELATIVE DEVIATION: 100% ▴ ▾	
USED LAMBDA: 8470 ▴ ▾	
FITTED LAMBDA: 8470 ▴ ▾	
fMRI HOTSPOTS: <OFF> ▾	
WEIGHTING: 140% ▴ ▾	
LP NORM MODEL, DATA: 2.00 ▴ ▾ 2.00 ▴ ▾	
L1 NORM LIMIT (0=OFF): 0% ▴ ▾	
RESTART	

FIG. 86B

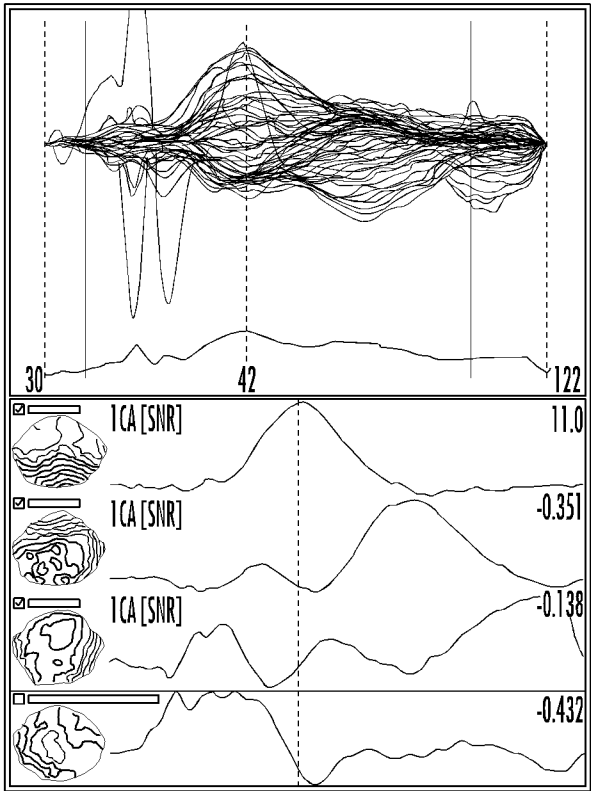


FIG. 87A

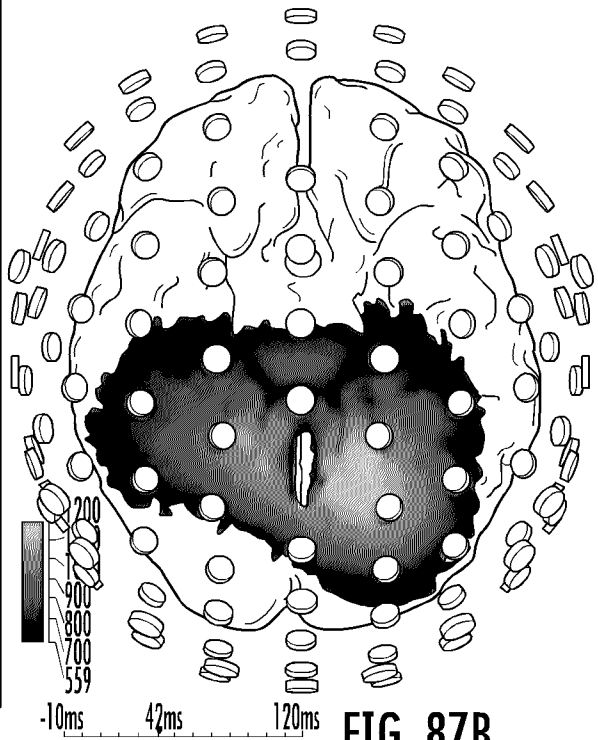


FIG. 87B

OUTPUT					
COHERENCE (FIXED) OF CDR (sLORETA) FOR 131 SAMPLES AND 2125 OF 12033 LOCATIONS, LAGS FROM 0.0 TO 60.0mm AND 100.00% AT 0.0mm					
SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) ANALYTIC NO. OF ARC LAGS FROM 10.0...300.0ms, MIN DISTANCE 3.0mm, CLIPPED AT 0.0mm					
BRAIN AREA	TOTAL	ANTERIOR	POSTERIOR	ANTERIOR-POSTERIOR	SUPERIOR-INFERIOR
BOTH HEMISPHERES	29149	0	28149	0	6582
LEFT HEMISPHERE	11201	0	13141	0	3425
RIGHT HEMISPHERE	600	0	680	0	221
MIDLINE	3725	0	3725	0	1618
INTRA-HEMISPHERE	23141	0	13741	0	3629
INTER-HEMISPHERE	34355	0	14306	0	2955
SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) (ALL AREAS) 6077 ARC LAGS FROM 10.0ms MIN DISTANCE 3.0mm, CLIPPED AT 0.3492 (INVERT)					

FIG. 87C

NOISE ESTIMATION		
METHOD:	AUTO ▼	
TIME RANGE [ms]:		
-10 ▲▼	0 ▲▼	GET
EEF [uv]	NOISE: 0.0870 ▲▼	SNR: 8.00
ADVANCED ▼		

FIG. 88A

OPTIONS	
MAX. DISPL. CHANNELS:	132 ▲▼
START LATENCY [ms]:	-10 ▲▼
CURSOR LATENCY [ms]:	42 ▲▼
END LATENCY [ms]:	120 ▲▼
INTERLEAVE [SAMPLES]:	1 ▲▼
TIMERANGE [S]:	0.130 ▲▼
TIMETICKS EVERY [S]:	0.1 ▲▼
SENSITIVITY / SCALING	
EEG [uVmm]:	0.06 ▲▼
MONTAGES	
☒ EEG	<NONE> ▼
☐ SHOW DESELECTED GROUPS	
☐ SHOW OTHER CHANNELS	
☒ SHOW DESELECTED CHANNELS	
☒ BUTTERFLY PLOT	☐ DISPLAY TIME
☐ MAXIMUM PEAKS	☐ MINIMUM PEAKS
☐ PLUS IS UP	☒ MGFP

FIG. 88B

CURRENT DENSITY	MAPS/PCA	SOURCE COHERENCE
CDR TYPE: sLORETA	PARAMETERS	COHERENCE: FIXED
CDR DIPOLE TYPE: OFF	SPHERE PARAMETERS	RESULT TYPE: CURRENTS
ADVANCED	☐ FIT SPHERE TO ACTIVE SENSORS	ZERO-LAG REMOVAL: OFF
COMPONENT BASED: ☐ ON	SPHERE/PROJ.CENTER [mm]: RADIUS [MM]:	CLIP BELOW: 43 %
REGULARIZATION: AUTO (TIME RANGE)	-0.4 3.5 58.9 96.6	
RELATIVE DEVIATION: 100%	MODE	
USED LAMBDA: 48.5	☐ THUMBNAILS LAPLACIAN 5	
FITTED LAMBDA: 48.5	☐ POS. PLOT HORI. ZOOM 1	
fMRI HOTSPOTS: <OFF>	☐ COHERENCE ☐ ACROSS GROUPS	
WEIGHTING: 140%	THRESHOLD [%] 80	
LP NORM MODEL, DATA: 2.00 2.00	MIN. DISTANCE [mm]: 50	
L1 NORM LIMIT (0=OFF): 0%	MINIMUM LAG [ms]: 2.0	
RESTART	MAXIMUM LAG [ms]: 5.0	
	TIME-COURSES	
	☐ MGFP ☐ FILTERED	
	☐ DIPOLES ☐ SCAN ☒ CDR ☐ STATS	
	☐ STRENGTH ☐ DEVIATION BUTTERFLY	
	MAPS/CONTOUR LINES	
	☒ CONTOUR ☒ MAPS 1	
	☐ COMBINE GRADIOMETERS ☒ AUTO	
	EEG [uV] 0.24	
	PCA/ICA SETTINGS	
	☐ PCA ☒ ICA 3	
	DISPLAYED COMPONENTS: 4	
	☒ APPLY PCA/ICA-FILTER	
	4: PCA 6.29% SNR: 3.88	
	PCA/ICA WEIGHTS	

☐ SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) PROPERTIES:

COLOR	mm DIPOLE COLORS 2
DISPLAY AS	TORUS
DISPLAY	ALL AREAS
CLIP BELOW	50%
MIN LAG	10.0ms
MAX LAG	100.0ms
MIN DISTANCE	5
LIMIT SYMBOLS	ON
LINE WIDTH	3

FIG. 89

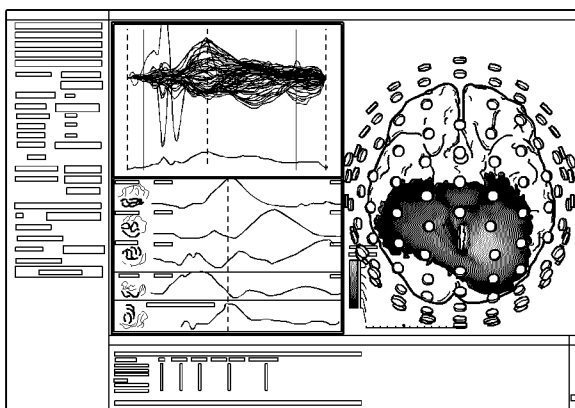


FIG. 90A

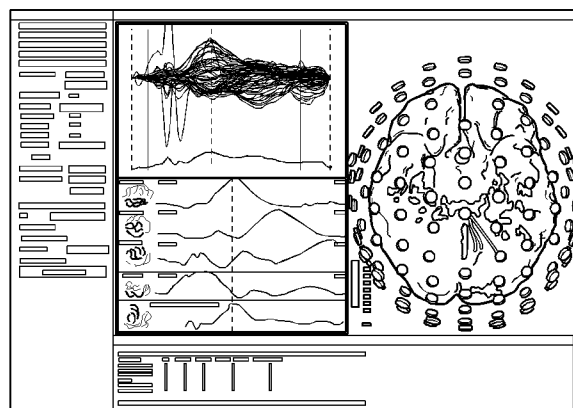


FIG. 90B

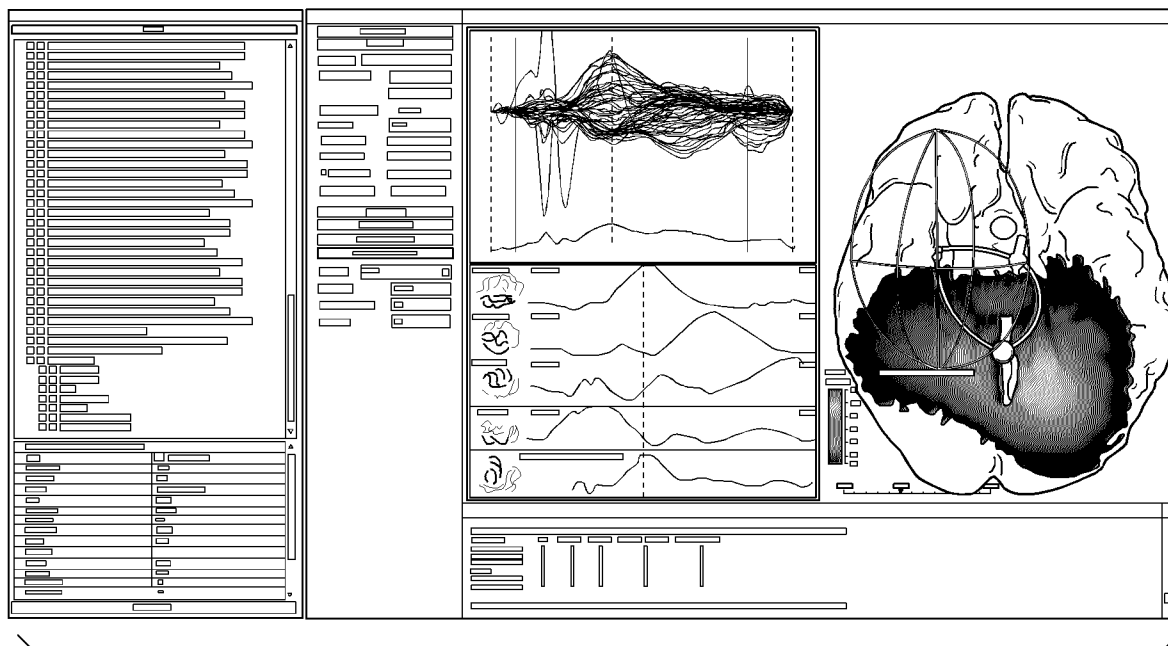


FIG. 91

NOISE ESTIMATION

METHOD: **AUTO**

TIME RANGE [ms]:

-10 0 GET

NOISE: SNR:

EEF [uv] 0.0870 8.00

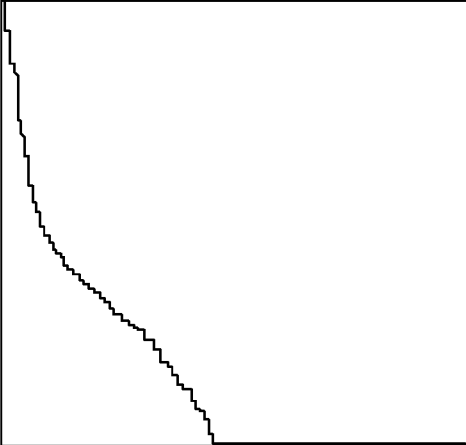
ADVANCED

REGULARIZATION (SVD-COMP.): 20

☐ USE NOISE COVARIANCES ☒ SVD

☒ SHOW DATA COVARIANCES ☒ LOG-SCALE

DATA SVD: SV103: 0.000uV²



- ☒ ☐ **SOURCE RESULTS**
- ☐ ELECTRODES
 - ☐ HEAD MODEL
 - ☐ MAPS
 - ☐ SOURCE LOCATIONS
 - ☐ LEADFIELD
 - ☒ CDR (sLORETA) (100%)
 - ☒ DIPOLES (3 FIXED MUSIC)
 - ☒ SOURCE COHERENCE (FIXED) FOR DIPOLES (3 FIXED MUSIC)

SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) PROPERTIES:

COLOR	DIPOLE COLORS 2
DISPLAY AS	TORUS
DISPLAY	ALL AREAS
CLIP BELOW	50%
MIN LAG	6.0ms
MAX LAG	120.0ms
MIN DISTANCE	5
LIMIT SYMBOLS	ON
LINE WIDTH	3

- ☒ ☐ **SOURCE RESULTS**
- ☐ ELECTRODES
 - ☐ HEAD MODEL
 - ☐ MAPS
 - ☐ SOURCE LOCATIONS
 - ☐ LEADFIELD
 - ☒ CDR (sLORETA) (100%)
 - ☒ DIPOLES (3 FIXED MUSIC)
 - ☒ SOURCE COHERENCE (FIXED) FOR DIPOLES (2 FIXED MUSIC)

DIPOLES (4 FIXED MUSIC) PROPERTIES

COLOR	DIPOLE COLORS 1
COLOR CODING	AUTO
COLOR RANGE	FULL
SCALING	AUTO (TIME RANGE)
SCALE	4 uA
SYMBOL SIZE	15.0ms
CLIP BELOW	0%
TIME RANGE	TRACE
SHAPE	POLE
LINE WIDTH	1
MATERIALS	SHINY
ELIPSOIDS	OFF
ELIPSOD WIDTH	1

FIG. 92

DIPOLE FIT DIPOLE TYPE: FIXED MUSIC NUMBER OF DIPOLES: 3 ☐ TEST DIPOLE ☐ MIRRORED SPEED MODE: AUTO SPEED DIST. [mm]: 200.0 MIN DIST. [mm]: 20.0 ☐ REGULARIZATION 1.0 CROSS-VALIDATION SAVE DATA		DIPOLE FIT DIPOLE TYPE: FIXED MUSIC NUMBER OF DIPOLES: 3 ☐ TEST DIPOLE ☐ MIRRORED SPEED MODE: AUTO SPEED DIST. [mm]: 200.0 MIN DIST. [mm]: 20.0 ☐ REGULARIZATION 1.0 CROSS-VALIDATION SAVE DATA	
SCAN METHODS CURRENT DENSITY SOURCE LOCATIONS SOURCE COHERENCE		SCAN METHODS CURRENT DENSITY SOURCE LOCATIONS SOURCE COHERENCE	
COHERENCE: FIXED RESULT TYPE: DIPOLES ZERO-LAG REMOVAL: OFF CLIP BELOW: 0 %		USE: NEW COLIN 7AUG13 BEM 3 / GRID SPACING [mm]: 7.0 ☐ EXCLUDE STOP MARKERS SOURCE TYPE: ROTATING SOURCE EXTENSION [mm]: 0	

CURRENT DENSITY CDR TYPE: sLORETA CDR DIPOLE TYPE: OFF ☐ ADVANCED ☐ ION REGULARIZATION: AUTO (TIME RANGE) RELATIVE DEVIATION: 100% USED LAMBDA: 1740 FITTED LAMBDA: 1740 fMRI HOTSPOTS: <OFF> WEIGHTING: 140% LP NORM MODEL, DATA: 2.00 2.00 L1 NORM LIMIT (0=OFF): 0% ○ RESTART SOURCE LOCATIONS SOURCE COHERENCE	
---	--

FIG. 93

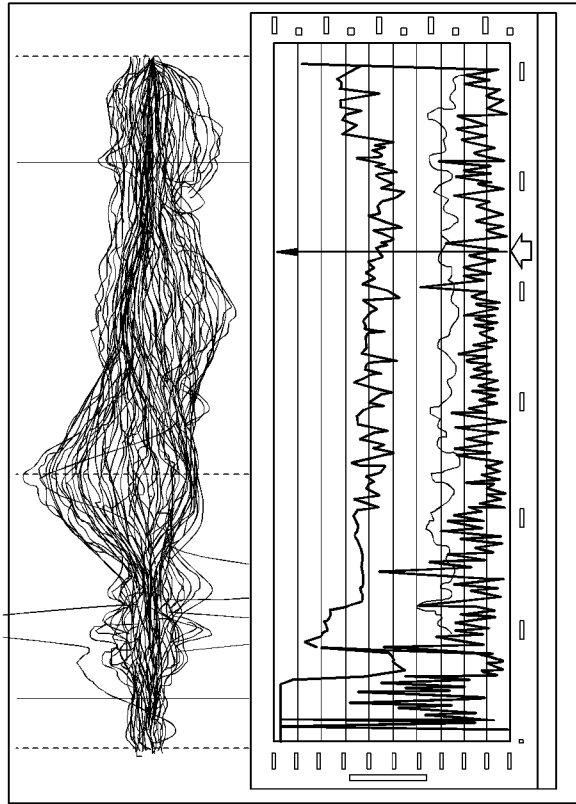


FIG. 94A

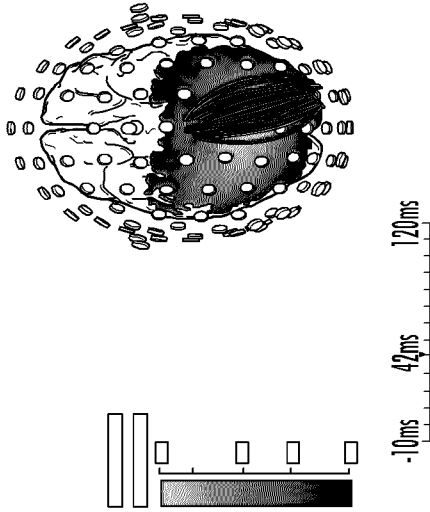


FIG. 94B

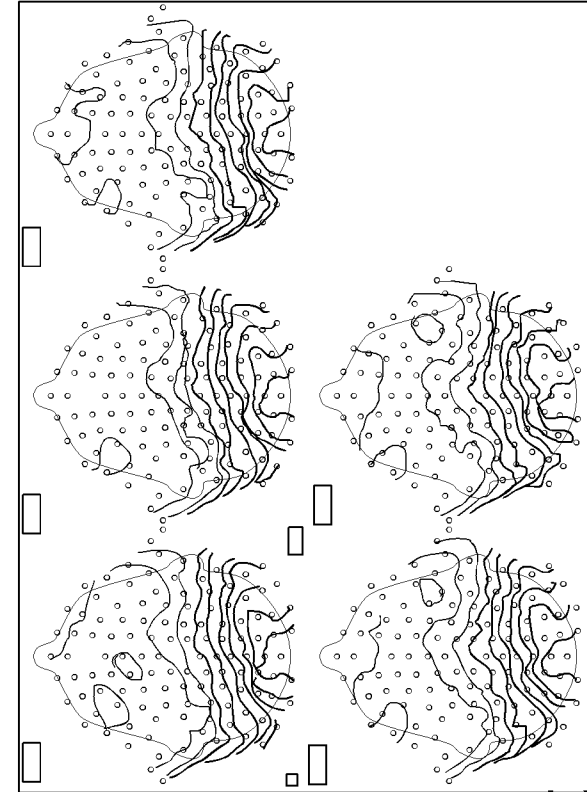


FIG. 94C

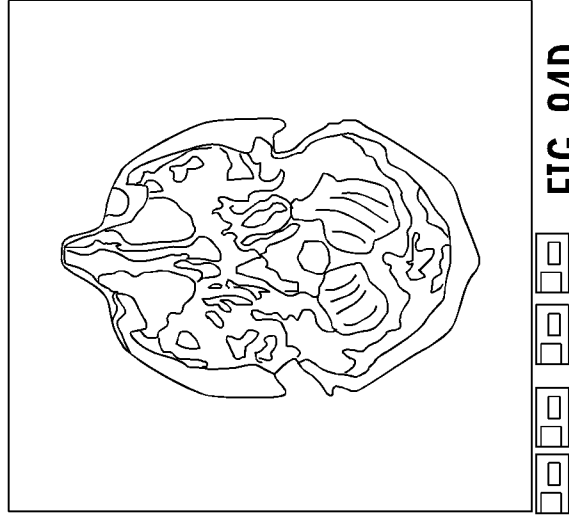
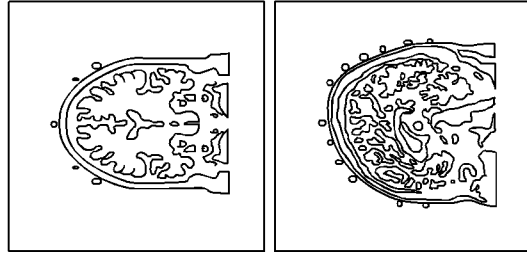


FIG. 94D



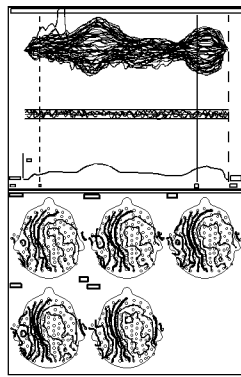


FIG. 95A

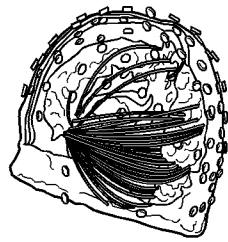


FIG. 95B

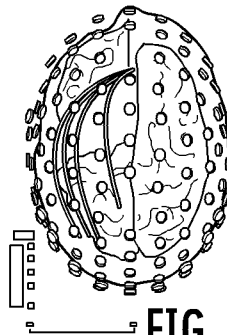


FIG. 95C

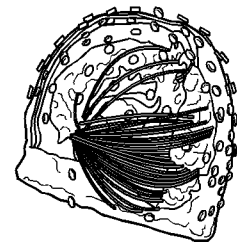


FIG. 95D

OUTPUT

SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) (ALL AREAS): 0 ARCS, LAGS FROM 10.0..100.0ms, MIN. DISTANCE 5.0mm, CLIPPED AT 0.87

SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) ANALYSIS: NO. OF ARCS (LAGS FROM, 10.0..100.0ms, MIN DISTANCE 5.0mm, CLIPPED AT 0.86

BRAIN AREA	TOTAL	ANTERIOR	POSTERIOR	ANTERIOR-POSTERIOR	SUPERIOR-INFERIOR
BOTH HEMISPHERES	569	0	0	569	569
LEFT HEMISPHERE	504	0	0	504	504
RIGHT HEMISPHERE	0	0	0	0	0
MIDLINE	81	0	0	81	81
INTRA-HEMISPHERIC	504	0	0	504	504
INTER-HEMISPHERIC	65	0	0	65	65

SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) (ALL AREAS): 569 ARCS, LAGS FROM 10.0..100.0ms, MIN. DISTANCE 5.0mm, CLIPPED AT 0.86

FIG. 95E

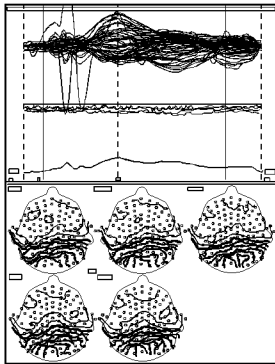


FIG. 95F

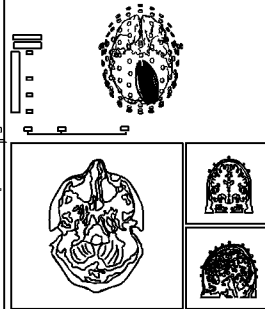


FIG. 95G

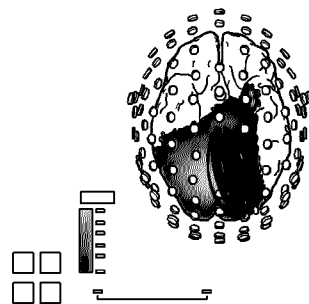


FIG. 95H

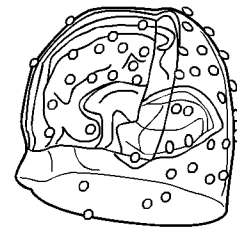


FIG. 95I

OUTPUT

SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) ANALYSIS: NO. OF ARCS (LAGS FROM, 5.0..100.0ms, MIN DISTANCE 5.0mm, CLIPPED AT 0.5

BRAIN AREA	TOTAL	ANTERIOR	POSTERIOR	ANTERIOR-POSTERIOR	SUPERIOR-INFERIOR
BOTH HEMISPHERES	58	0	58	0	56
LEFT HEMISPHERE	43	0	43	0	41
RIGHT HEMISPHERE	0	0	0	0	0
MIDLINE	0	0	0	0	0
INTRA-HEMISPHERIC	43	0	43	0	41
INTER-HEMISPHERIC	15	0	15	0	15

SOURCE COHERENCE (FIXED) FOR CDR (sLORETA) (ALL AREAS): 569 ARCS, LAGS FROM 10.0..100.0ms, MIN. DISTANCE 5.0mm, CLIPPED AT 0.86

FIG. 95J

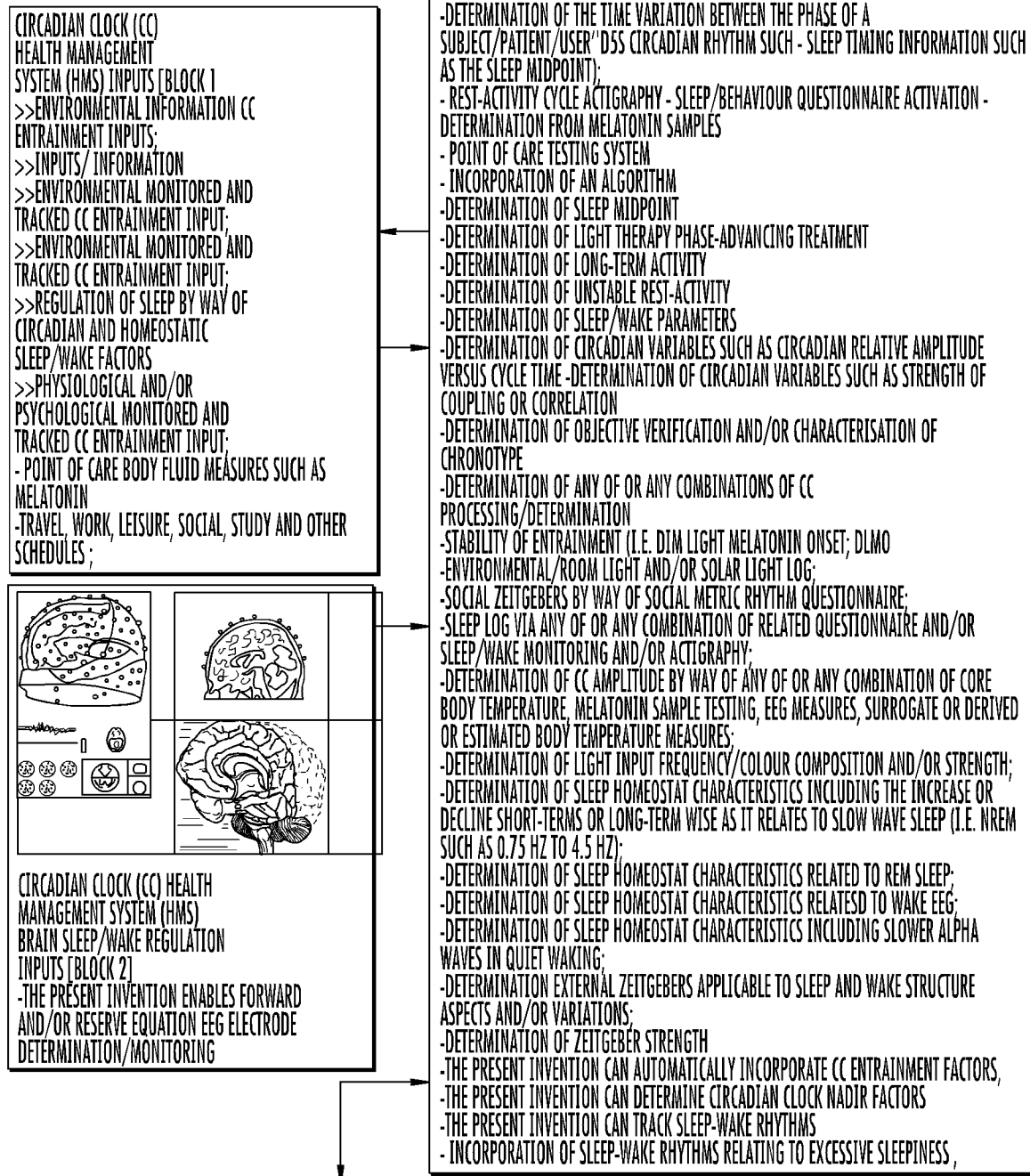


FIG. 96A



FIG. 96B

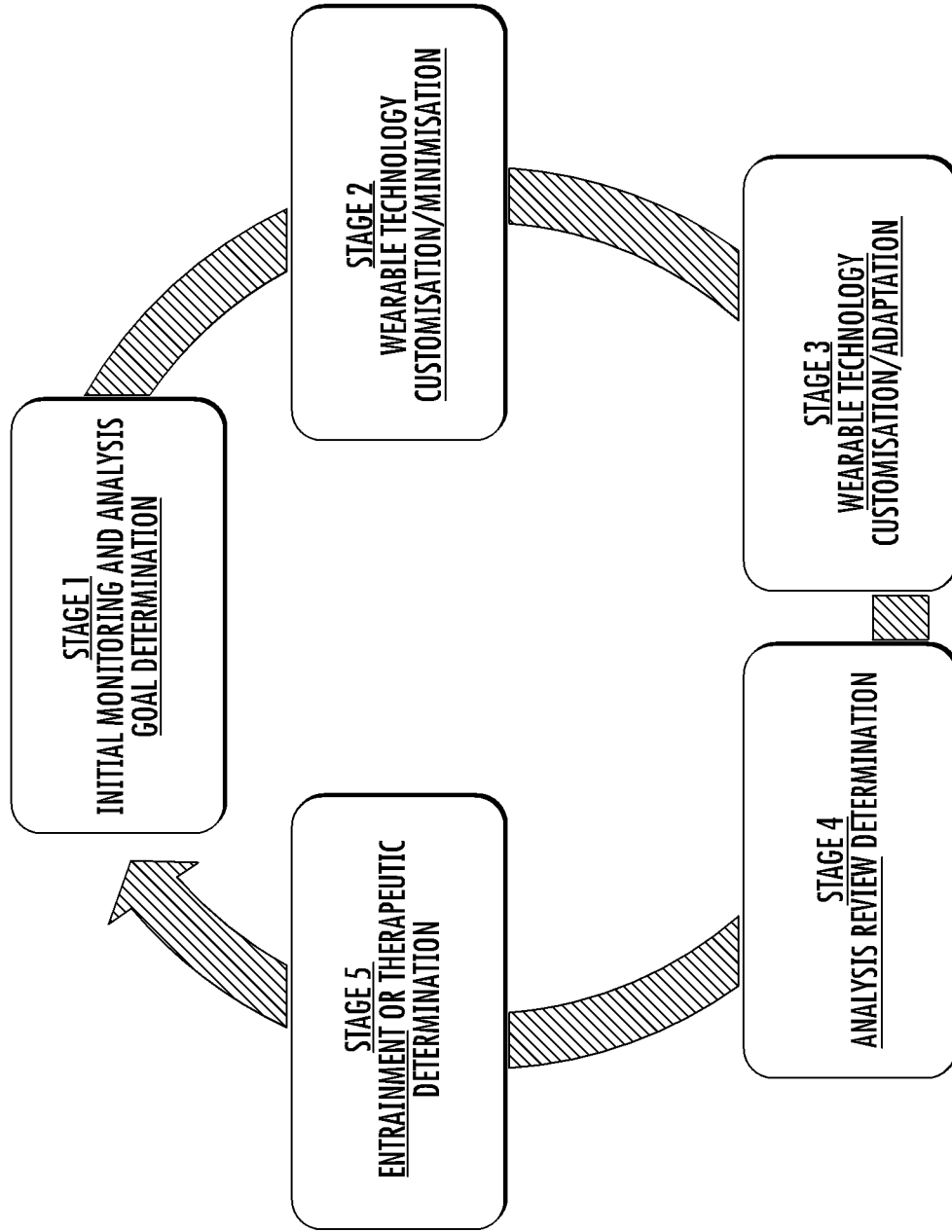


FIG. 97

VIGILANCE ALERT TRACKING FIGURES

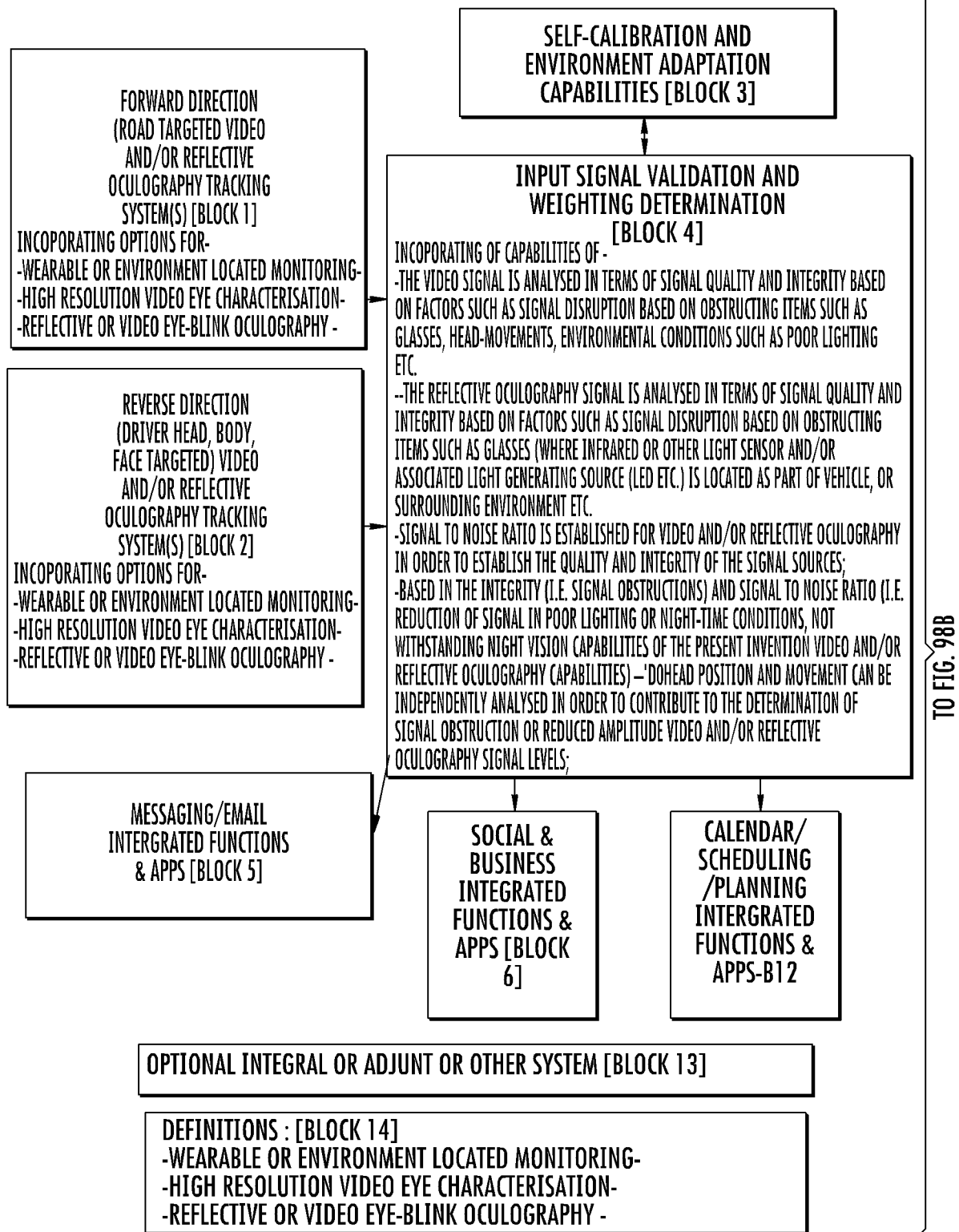


FIG. 98A

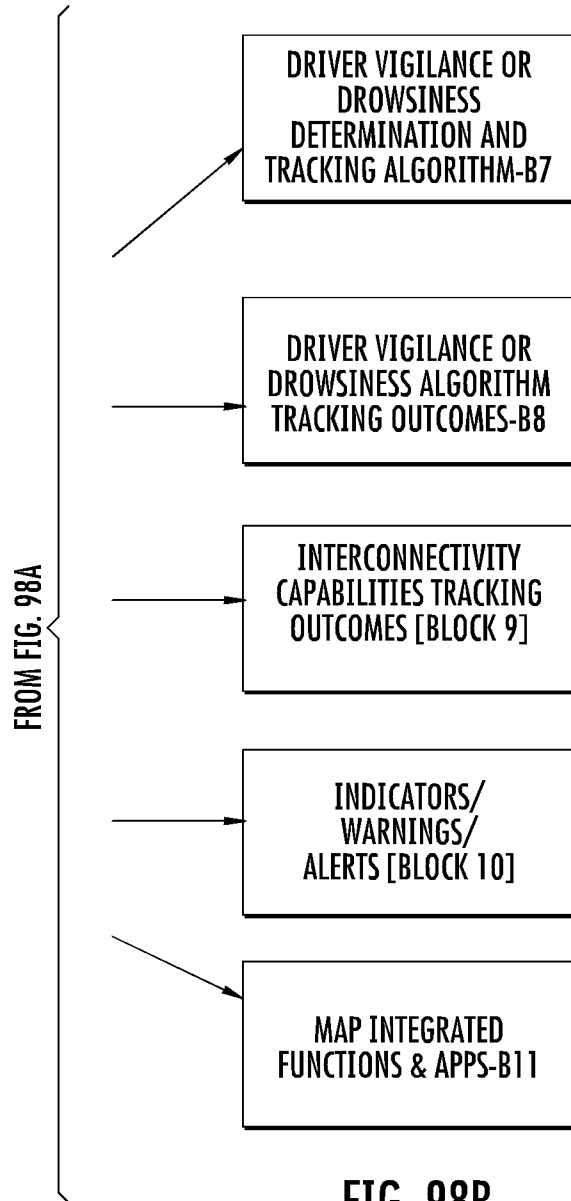


FIG. 98B

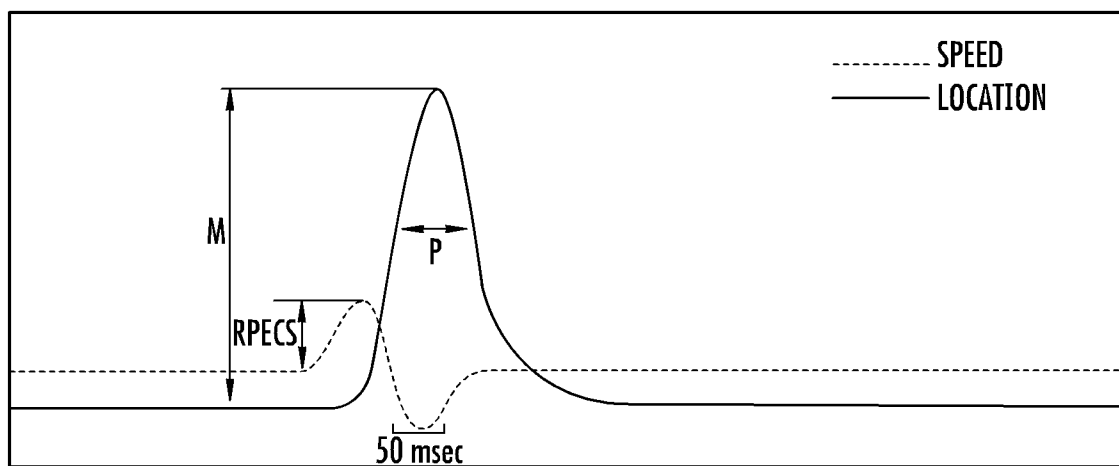


FIG. 99

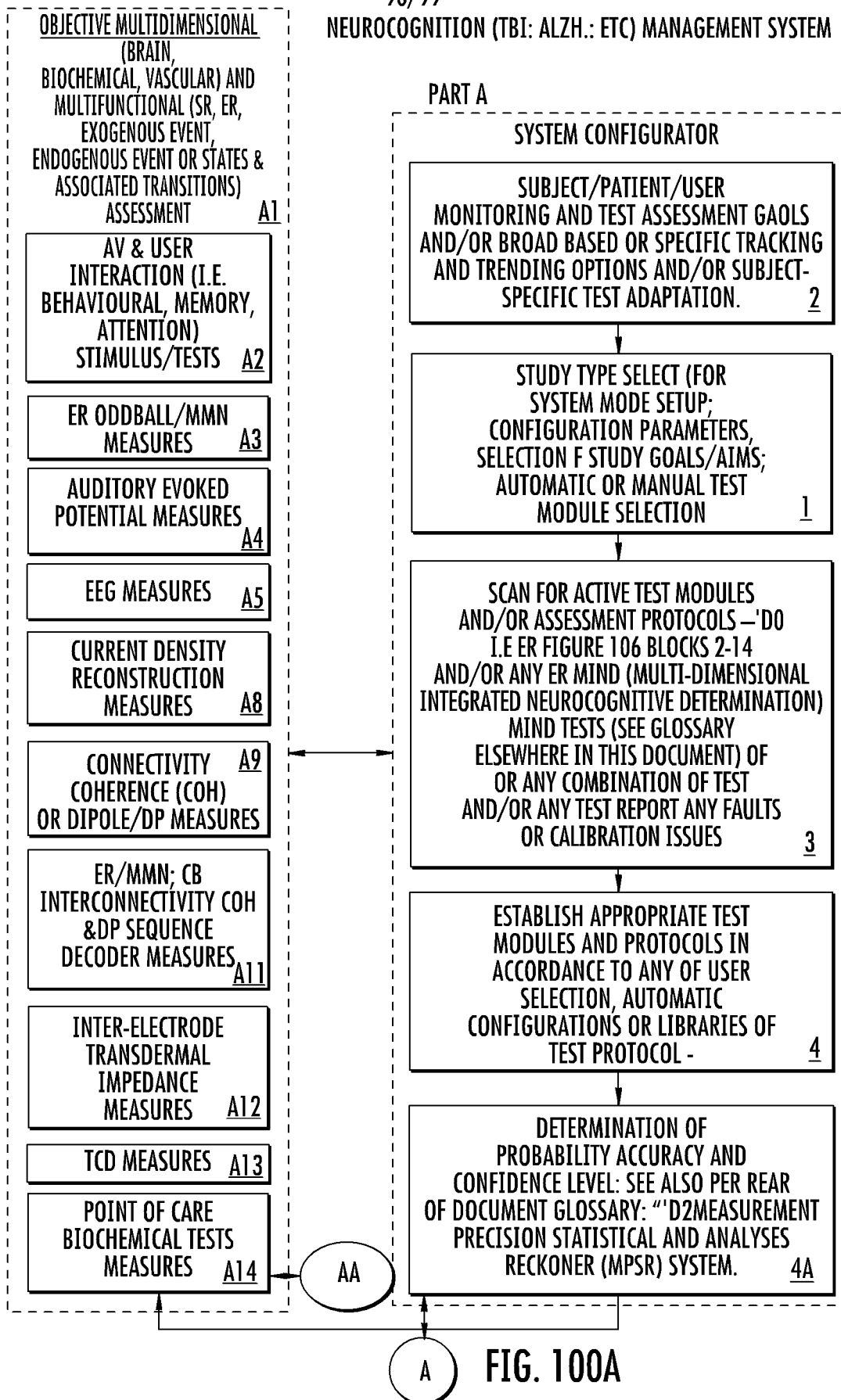


FIG. 100A

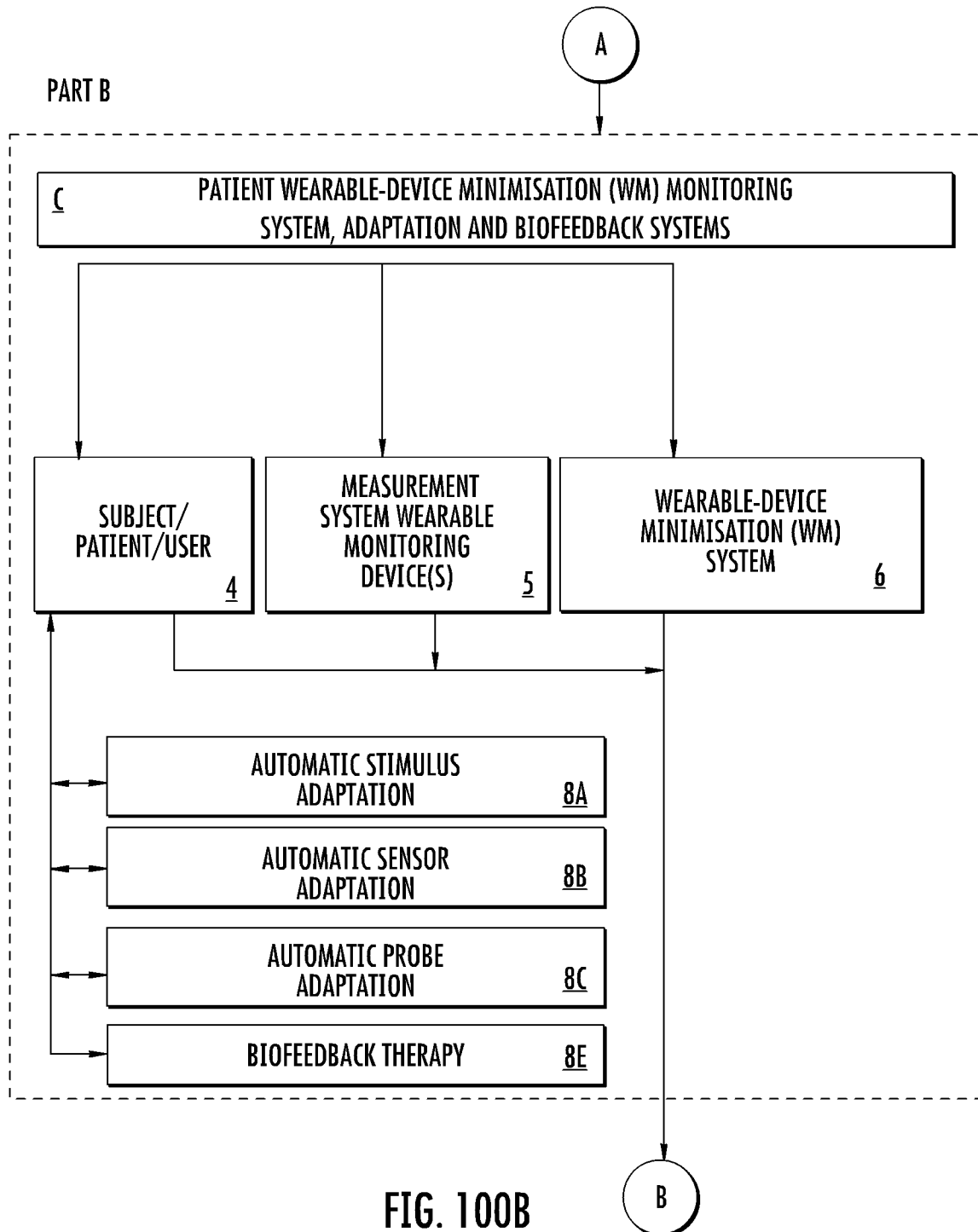
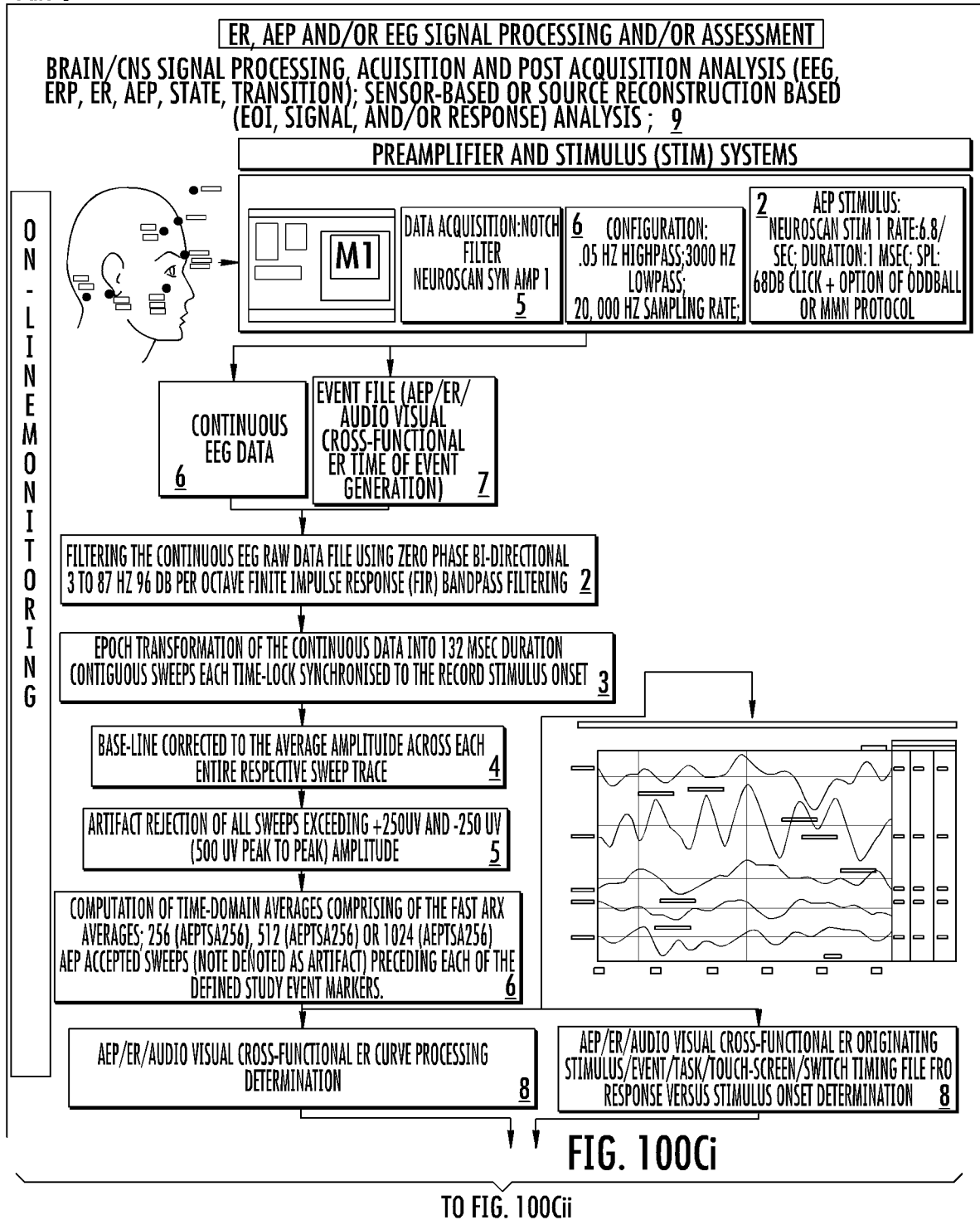
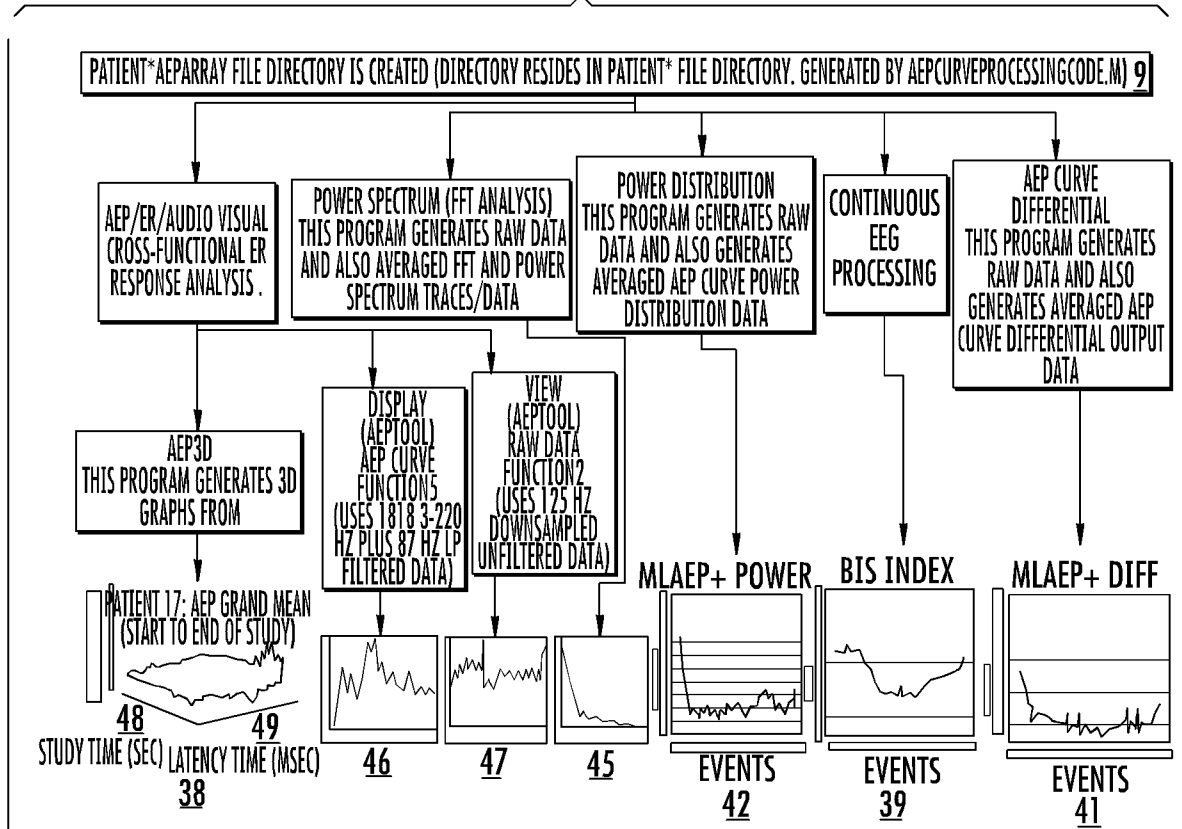


FIG. 100B



FROM FIG. 100Ci



C

FIG. 100Cii

PART D

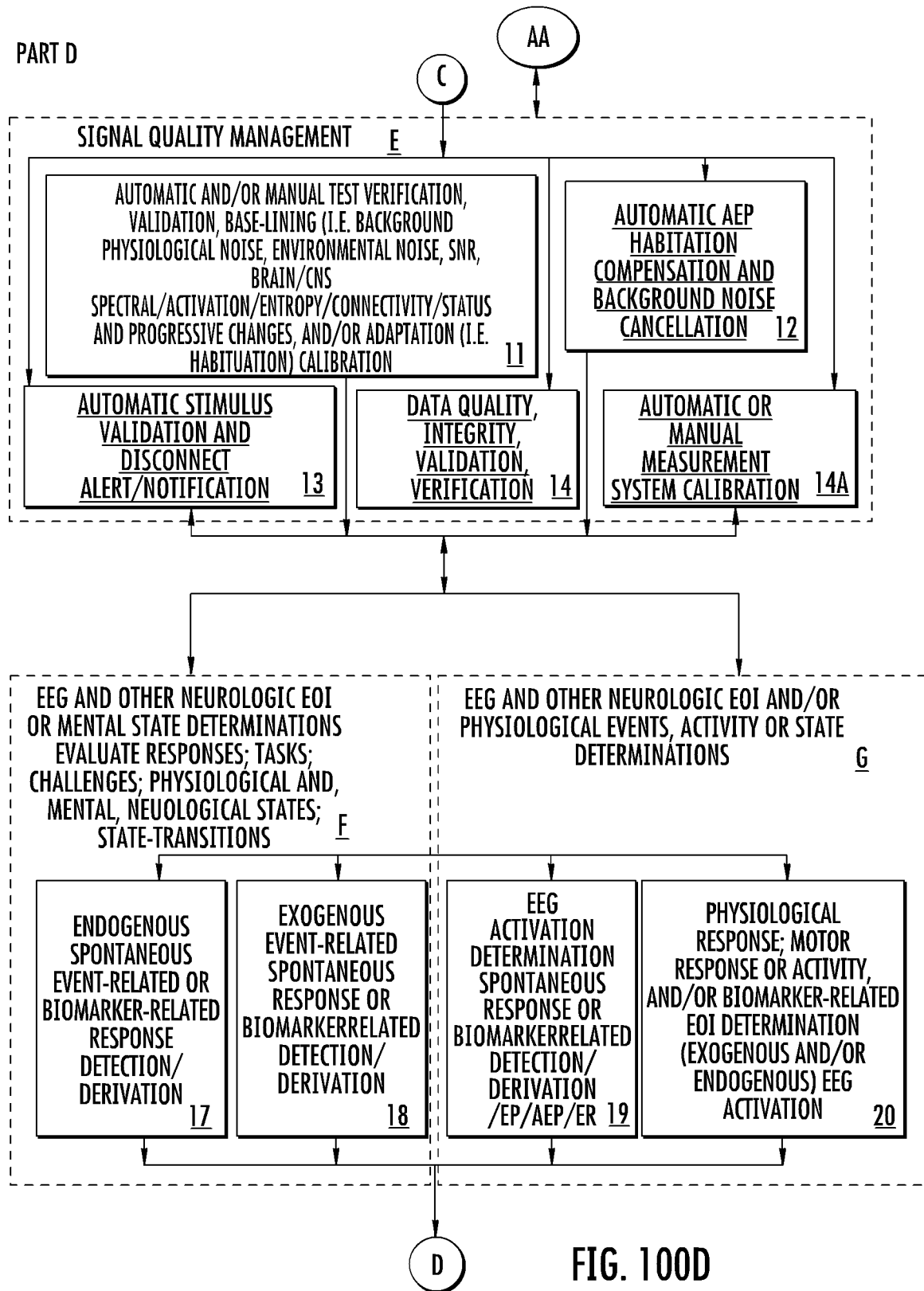


FIG. 100D

PART E

D

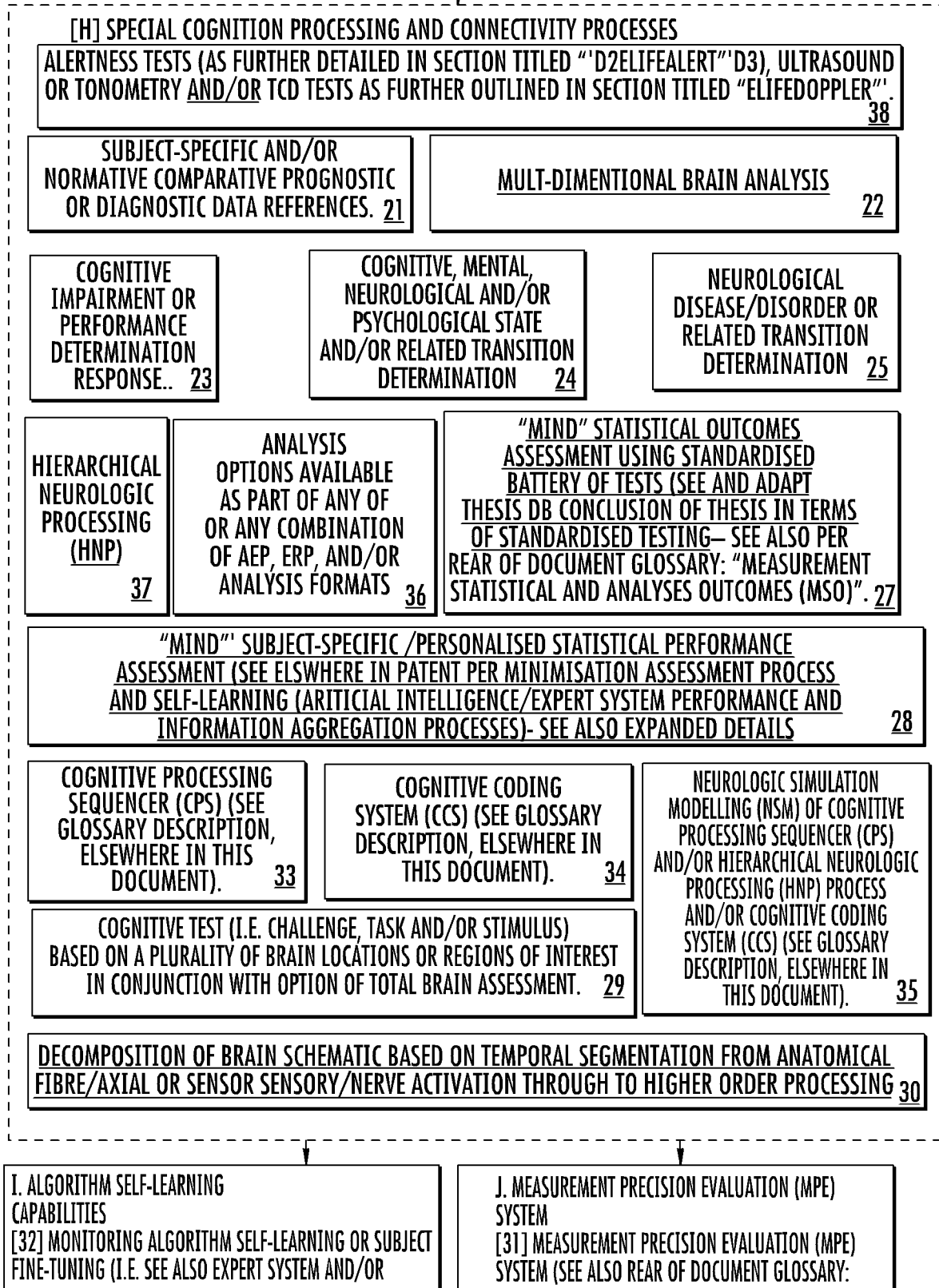


FIG. 100E

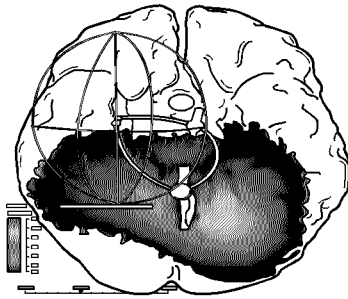


FIG. 101A

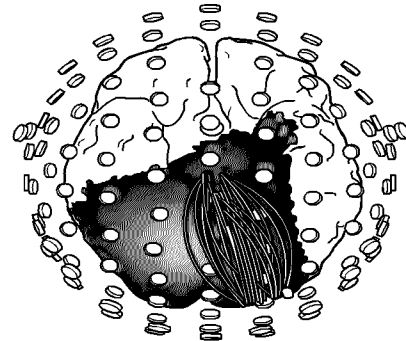


FIG. 101B

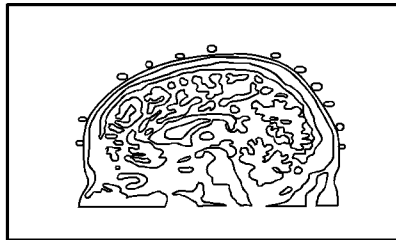


FIG. 101C

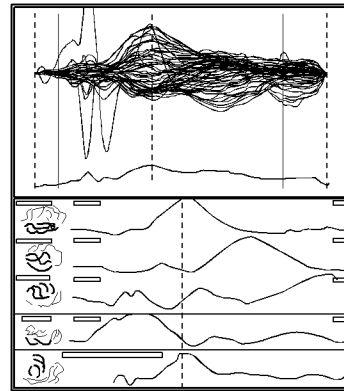


FIG. 101D

SOURCE COHERENCE (FIXED) FOR DIPOLES (3 FIXED MUSIC) (ALL AREAS): 2 ARCS, LAGS FROM 7.5...120.0ms, MIN. DISTANCE 5.0mm, CLIPPED AT 0.5					
SOURCE COHERENCE (FIXED) FOR DIPOLES (3 FIXED MUSIC) ANALYSIS: NO. OF ARCX (LAGS FROM 7.4..120.0mm, MIN. DISTANCE 5.0mm, CLIPPED AT 0.5					
BRAIN AREA	TOTAL	ANTERIOR	POSTERIOR	ANTERIOR-POSTERIOR	SUPERIOR-INFERIOR
BOTH HEMISPHERES	3	1	0	2	2
LEFT HEMISPHERE	0	0	0	0	0
RIGHT HEMISPHERE	1	0	0	1	1
MIDLINE	1	0	0	1	1
INTRA-HEMISPHERE	1	0	0	1	1
INTER-HEMISPHERE	2	1	0	1	1
SOURCE COHERENCE (FIXED) FOR DIPOLES (3 FIXED MUSIC) (ALL AREAS): 3 ARCS, LAGS FROM 7.4...120.0ms, MIN. DISTANCE 5.0mm, CLIPPED AT 0.5					

FIG. 101E

SECONDARY AEP TRANSFORMS	PRIMARY AEP TRANSFORMS		
	AEP_A	AEP_{DA}	AEP_{iA}
SUM OF ABSOLUTE AEPA VALUES (AS)	AEP_{iAS}	AEP_{iDAS}	AEP_{iIAS}
SUM OF SQUARE ROOT OF AEPA VALUES (ASQ)	AEP_{iASQ}	AEP_{iDASQ}	AEP_{iIASQ}
SUM OF POWER OF 2 OF AEPA VALUES (ASP)	AEP_{iASP}	AEP_{iDASP}	AEP_{iIASP}
ENTROPY1 AEP VALUES	$ENTROPY1AEP_{iA}$	$ENTROPY1AEP_{iDA}$	$ENTROPY1AEP_{iIA}$
ENTROPY2 AEP VALUES	$ENTROPY2AEP_{iA}$	$ENTROPY2AEP_{iDA}$	$ENTROPY2AEP_{iIA}$

FIG. 102A

AEP ANALYSIS ACRONYM	ANALYSIS
1. AEP_{iDAS}	DIFFERENTIAL
2. AEP_{iDASQ}	DIFFERENTIAL
3. AEP_{iDASP}	DIFFERENTIAL
4. $ENTROPY1AEP_{iDA}$	ENTROPY
5. $ENTROPY2AEP_{iDA}$	ENTROPY
6. AEP_{iIAS}	INTEGRATION
7. AEP_{iIASQ}	INTEGRATION
8. AEP_{iIASP}	INTEGRATION
9. $ENTROPY1AEP_{iIA}$	ENTROPY
10. $ENTROPY2AEP_{iIA}$	ENTROPY
11. AEP_{iAS}	AMPLITUDE
12. AEP_{iASQ}	AMPLITUDE
13. AEP_{iASP}	AMPLITUDE
14. $ENTROPY1AEP_{iA}$	ENTROPY
15. $ENTROPY2AEP_{iA}$	ENTROPY
16.BIS	BIS

FIG. 102B

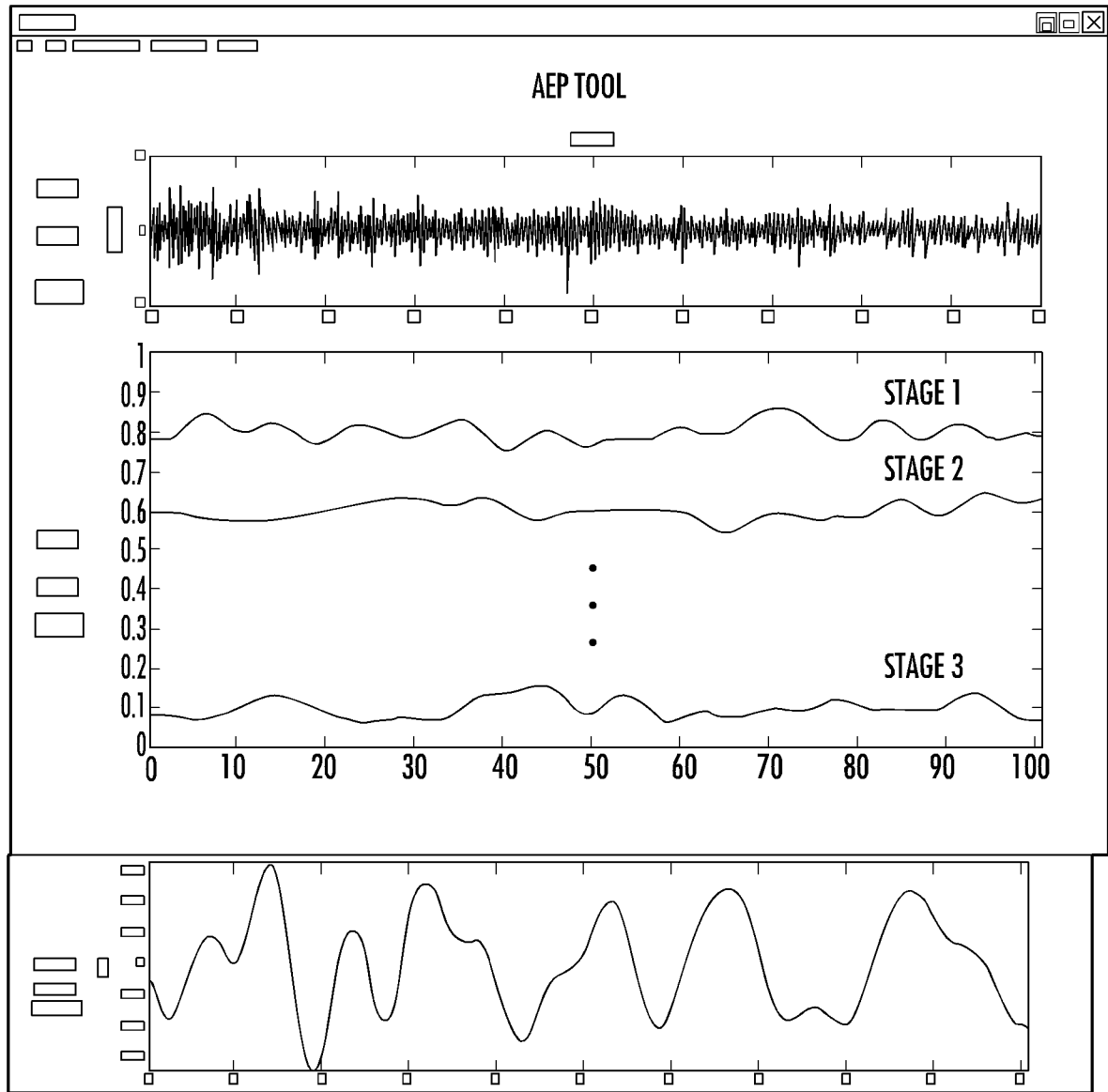


FIG. 102C

99/99

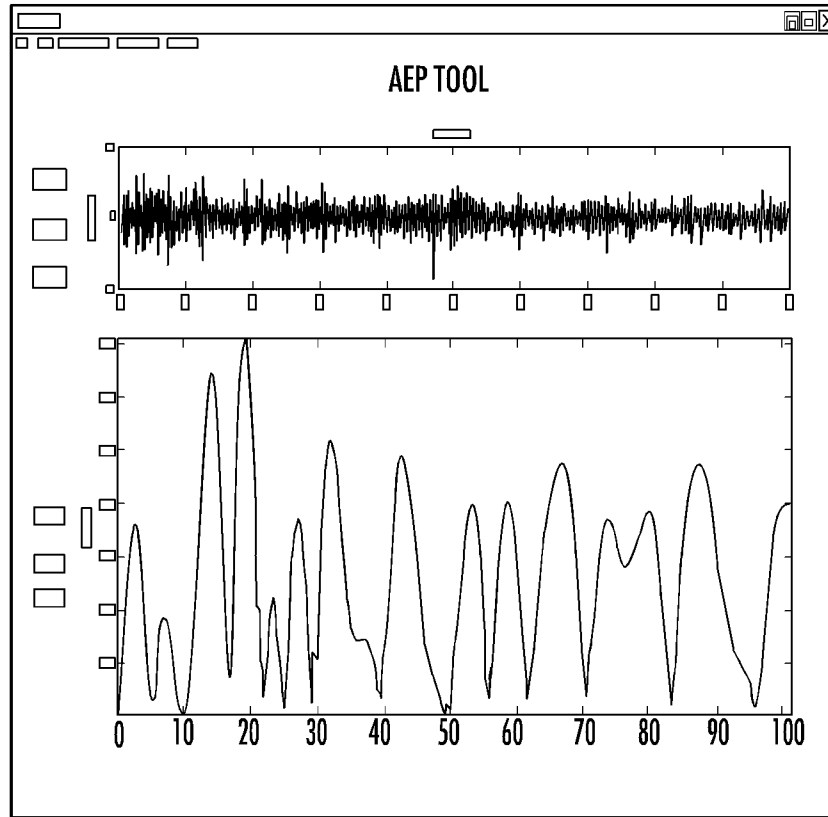


FIG. 102D

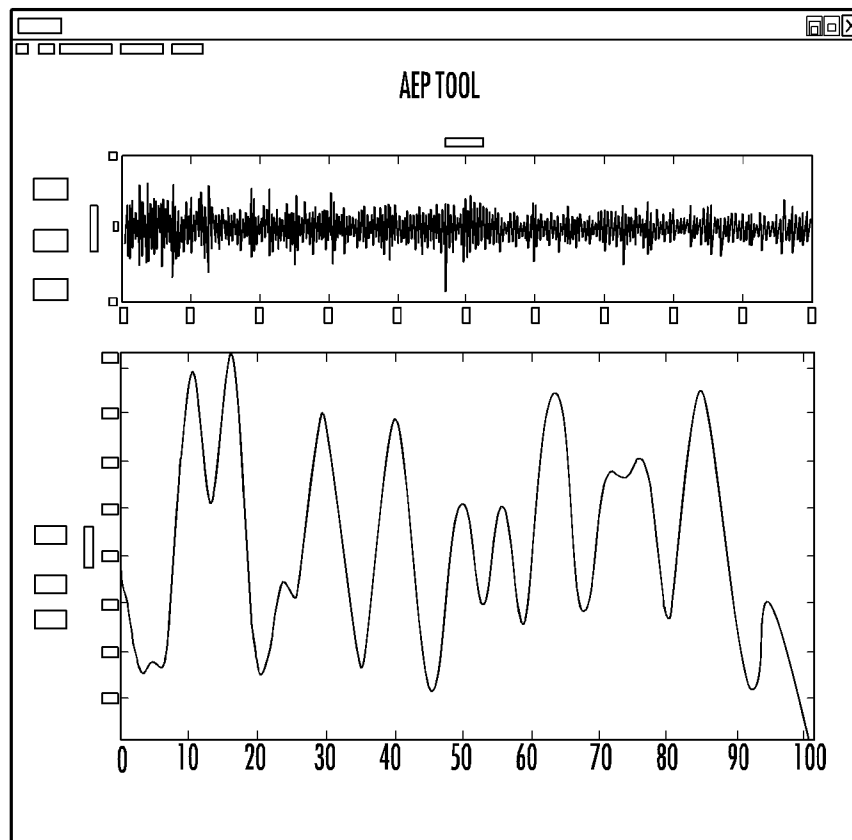


FIG. 102E

