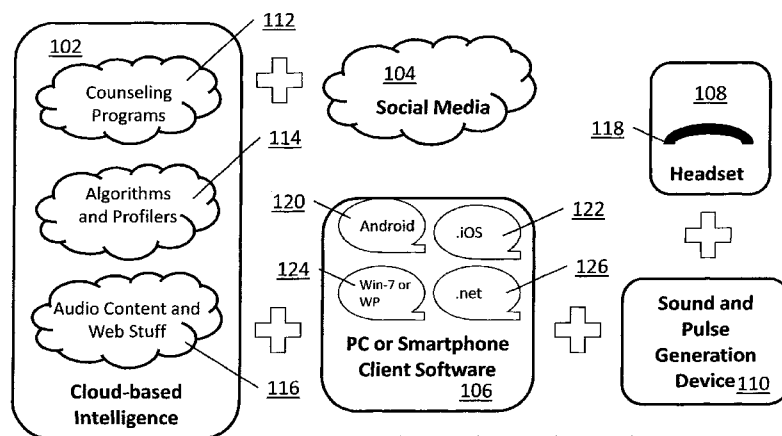




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(54) **Title:** METHOD AND SYSTEM FOR ADAPTIVE TREATMENT OF TINNITUS

Fig. 1



Illustrative terms: Architecture; Physical Product; Virtual Product; Embedded Intelligence

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(57) **Abstract:** Systems, methods and computer program products for adaptive treatment of tinnitus, including an end-to-end architecture for adaptive treatment of tinnitus. The end-to-end architecture can be configured to employ a user customized combination of acoustic therapy and vagal nerve stimulation according to an individual tinnitus profile of the user. The end-to-end architecture can be configured to employ audio and vagal nerve algorithm profilers that are verified by magnetoencephalography.

METHOD AND SYSTEM FOR ADAPTIVE TREATMENT OF TINNITUS

CROSS REFERENCE TO RELATED DOCUMENTS

[0001] The present invention is related and claims priority to U.S. Provisional Patent Application Serial No. 61/637,964 of Ylikoski et. al., entitled “METHOD AND SYSTEM FOR ADAPTIVE TREATMENT OF TINNITUS,” filed on April 25, 2012, and U.S. Provisional Patent Application Serial No. 61/495,521 of Ylikoski et. al., entitled “METHOD AND SYSTEM FOR ADAPTIVE TREATMENT OF TINNITUS,” filed on June 10, 2011, the entire disclosures of all of which are hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present disclosure generally relates to treatment of tinnitus and stress reduction related thereto, and more particularly to a method and system for adaptive treatment of tinnitus by a novel consumer-led process and end-to-end architecture with several sub-components.

Discussion of the Background

[0003] Traditionally, there has not been a well-defined, proven method and system for the treatment of tinnitus, which is one of the most common clinical conditions. The existing treatments have been by nature bulk-solutions and not customized according to the individual tinnitus profile of a user.

[0004] Tinnitus is defined as a “mystery sound” heard with no external source. Tinnitus is an individual experience that manifests itself as a phantom noise experience in the auditory cortex and is one of the most common clinical conditions. Tinnitus is a major driver for mental stress resulting in huge problems in today’s society.

[0005] Therefore, there is a need for methods and systems for the adaptive treatment of tinnitus that address the above and other problems with tinnitus and mental stress and lack of quality of life as driven by tinnitus.

SUMMARY OF THE INVENTION

[0006] The above and other needs are addressed by embodiments of the present disclosure, which provides systems and methods for adaptive treatment of tinnitus, including an end-to-end architecture. The systems and methods for the adaptive treatment of tinnitus include a novel process and end-to-end architecture for the adaptive treatment of tinnitus. The treatment according to the systems and methods can be extended to other more generic issues, such stress management, and the like, but focus in tinnitus as the illustrative problem solved. For the treatment of tinnitus, the systems and methods include an adaptive process of acoustic therapy combined with adaptive vagal nerve stimulation via tragus. The methods and systems allow the patient (e.g., the customer, user, etc.) on their own to master customization of the systems and methods, as enabled by the end-to-end architecture. For this purpose, the systems and methods include a web-enabled, intelligent, end-to-end architecture employed for the combined, adaptive acoustic and vagal nerve stimulation. The present disclosure describes the background for the adaptive treatment of tinnitus, the core components of the architecture, as well as their interaction model.

[0007] Accordingly, in illustrative aspects, there are provided systems, methods and computer program products for adaptive treatment of tinnitus, including an end-to-end architecture for adaptive treatment of tinnitus. The end-to-end architecture can be configured to employ a user customized combination of acoustic therapy and vagal nerve stimulation according to an individual tinnitus profile of the user. The end-to-end architecture can be configured to employ audio and vagal nerve algorithm profilers that are verified by magnetoencephalography, and the like.

[0008] The end-to-end architecture can include a physical product, a virtual product, and embedded intelligence. The physical product, the virtual product, and the embedded intelligence can be integrated via a cloud-based, intelligent web site, and the like.

[0009] The physical product can include a dedicated sound and pulse generating device, and a dedicated ear electrode that can be configured to be attached transcutaneously in a tragus of an ear.

[0010] The dedicated ear electrode can be configured as a V, O, or J shaped body, and the like, and having a built-in feedback loop.

[0011] The embedded intelligence can be configured to allow customization of tinnitus treatment by employing a plurality of parameters and algorithms including parameters and algorithms for audio customization of the dedicated sound and pulse generating device, and parameters and algorithms for managing customization of a current and flow of electricity to the dedicated ear electrode.

[0012] The end-to-end architecture can be further configured to employ the user customized combination of the acoustic therapy and the vagal nerve stimulation according to the individual tinnitus profile of the user and/or according to biofeedback about the user.

[0013] Still other aspects, features, and advantages of the present invention are readily apparent from the following detailed description, simply by illustrating a number of illustrative embodiments and implementations, including the best mode contemplated for carrying out the present invention. The present invention is also capable of other and different embodiments, and its several details can be modified in various respects, all without departing from the spirit and scope of the present invention. Accordingly, the drawings and descriptions are to be regarded as illustrative in nature, and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The embodiments of the present invention are illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings and in which like reference numerals refer to similar elements and in which:

[0015] FIG. 1 shows illustrative components adaptive systems and methods for treatment of tinnitus deployed according an end-to-end architecture;

[0016] FIG. 2 illustrates a position of a tragus in a human ear;

[0017] FIG.3 shows illustrative directions from which to attach electrodes to a tragus of a human ear;

- [0018] FIG. 4 shows illustrative ear electrode configurations for attachment to a tragus of a human ear;
- [0019] FIG. 5 shows illustrative system level components of customized treatment of tinnitus;
- [0020] FIG. 6 shows illustrative sub-elements for the customized treatment of tinnitus;
- [0021] FIG. 7 shows illustrative left-ear electrode with vagal nerve stimulation (VNS) signal input integration options;
- [0022] FIG. 8 shows illustrative audio and vagal nerve stimulation management and delivery device;
- [0023] FIG. 9 shows illustrative system set-up process;
- [0024] FIG. 10 shows illustrative system set-up screen;
- [0025] FIG. 11 shows illustrative log-in screen;
- [0026] FIG. 12 shows illustrative treatment management screen;
- [0027] FIG. 13 shows illustrative adjust treatment details, play and gather feedback process;
- [0028] FIG. 14 shows illustrative adjust treatment details and play screen;
- [0029] FIG. 15 shows illustrative gather feedback screen;
- [0030] FIG. 16 shows illustrative current data-flow for audio from sound generator;
- [0031] FIG. 17 shows illustrative data-flow for audio on the application;
- [0032] FIG. 18 shows illustrative tinnitus profile process;
- [0033] FIG. 19 shows illustrative tinnitus profile screen with embedded process steps;
- [0034] FIG. 20 shows illustrative tinnitus index screen;
- [0035] FIG. 21 shows illustrative account management screen;
- [0036] FIG. 22 shows illustrative pathway for vagal-auditory modulation;

[0037] FIG. 23 shows illustrative amplitude of the auditory N1m elicited by tones with tinnitus-matched pitch for individual patients;

[0038] FIG. 24 shows illustrative combined sound and pulse generator integrated in headset;

[0039] FIG. 25 shows illustrative current data-flow for audio and VNS;

[0040] FIG. 26 shows illustrative ideal data-flow for audio and VNS; and

[0041] FIG. 27 shows illustrative ideal data-flow for integrated combined sound and pulse generator integrated in headset.

DETAILED DESCRIPTION

[0042] Systems and methods for adaptive treatment of tinnitus, including an end-to-end architecture, are described. In the following description, for purposes of explanation, numerous specific details are set forth in order to provide thorough understanding of the present invention. It is apparent to one skilled in the art, however, that the present invention may be practiced without these specific details or with equivalent arrangement. In some instances, well-known structures and devices are shown in figures and diagrams in order to avoid unnecessarily obscuring the present invention.

[0043] Referring now to the drawings, wherein like reference numerals designate identical or corresponding parts throughout the several views, and more particularly to FIG. 1 thereof, there is illustrated the adaptive treatment of tinnitus, according to an illustrative embodiment. In FIG. 1, the adaptive treatment of tinnitus system claims that the key to the reduction and treatment of tinnitus is to customize the acoustic and vagal stimulation according to the individual tinnitus profile of the customer patient. Furthermore, this task can be given to the consumer when supported by an extensive end-to-end process and architecture designed for the treatment of tinnitus. This requires the adaptive treatment of tinnitus which has been extensively verified by magnetoencephalography. Finally, this assumes that in the most of the cases using both acoustic and vagal stimulation are employed, but a temporary focus in either of them may be employed in selected customization profiles for the best

outcome. As the key assumption, it can be concluded that both of them must be customized – normally and in the best case by the consumer himself, but in some circumstances as assisted by a doctor or tinnitus expert.

[0044] As shown in FIG. 1, the architecture includes illustrative components which can be integrated by using a cloud-based, intelligent set-up over the world-wide-web. The illustrative components can include the physical product including headset 108, ear electrode 118, and sound and pulse generator device 110; the virtual product including client software 106 which can be based on various software platforms (e.g., Android 120, iOS 122, Windows7, Windows Phone 124, .net 126, etc.) and cloud-based intelligence 102 as well as social media 104; and the embedded intelligence within the virtual product including counseling programs 112, algorithms and profilers 114 and audio content and web related stuff 116. Together, they form the baseline for the novel process for the treatment of tinnitus. Some of them – like the physical product - can be used individually, temporarily detached from the architecture, but for managing and enabling the adaptive experience they are bonded and integral parts of the system.

[0045] As shown in FIG. 1, the physical product includes a sound and pulse generator device 110, dedicated ear electrode 118 attached to the tragus of the customers, and a third party audio headset 108 which has been calibrated to meet the requirements of the end-to-end architecture. The physical product suggests that the ear electrode can be integrated to a dedicated audio headset

[0046] As derived from FIG. 1, FIG. 5 introduces the system level components of customized treatment of tinnitus. Cloud-based intelligence 102 can include software, intelligence, algorithms, databanks, and the like, residing in the cloud (e.g., a cloud based Internet system for the treatment of tinnitus). The illustrative elements of the cloud-based intelligence 102 are back-end database 502, back-end intelligence 504, and an Internet based user interface 506. Client software 106 can include software, applications, algorithms, and the like, residing in a client (e.g., a PC, smartphone, tablet or similar device, etc.). The illustrative elements of client software 106 include local database 508, user interface in the local client or application 510, and local internet browser 512 (e.g., such as Google Chrome,

Microsoft Internet Explorer, Firefox, etc.). Physical product 516 includes the physical device, devices or product parts with or without embedded software employed for the treatment of tinnitus. The illustrative elements of the physical product 516 are ear electrode 118, headset 108, sound and pulse generator 110, sound generator 112, and/or combined sound and pulse generator integrated in devices 514.

[0047] As shown in FIG. 1, the virtual product includes software driven components of the end-to-end architecture. The goal of the virtual product is to enable the user experience and convert the embedded intelligence for the treatment of tinnitus via the physical product. The virtual product includes the client software running on a personal computer, smart phone or a similar device, and the like, controlling the use of the sound and pulse generator device. The virtual product also includes a cloud-based, and the like, visual service component of the end-to-end architecture, for example, running on a web site, and the like. Furthermore, the virtual product manages the division of work between the client component and the cloud component for enabling a seamless user experience for the customer or user. The virtual product also can be upgraded based new software releases, and the like, to expand the capability of the physical device. Finally, the virtual product can include any suitable interfaces, and the like, as well as content targeted for social media applications, such as Facebook or Twitter, and the like, to build a community among tinnitus patients, to cultivate learning, to drive innovation, and the like.

[0048] As shown in FIG. 1, the embedded intelligence can reside in the cloud component, but it further illustrative embodiments also can reside in the client component software of personal computers, smartphones or similar devices, and the like. The embedded intelligence can be leveraged by the customers or other potential users by browsing a suitable web site with web browsing applications, and the like. The embedded intelligence can also be delivered to the patient, consumer or user, for example, as an automated process, via the user experience governed by the virtual product. The embedded intelligence can include any suitable databases, algorithms, profiling technologies, and the like, to enable customization of acoustic and vagal stimulation for the user.

[0049] In FIG. 6, sub-elements of the illustrative elements for the customized treatment of tinnitus are further illustrated. Accordingly, each element can be defined in detail as a set of sub-elements. The elements and sub-elements illustrate a tool, process or program, a piece of software, application, algorithm or intelligence, or a dedicated device or hardware to be deployed in order to perform a certain process steps or actions for the treatment of tinnitus. Each sub-element has its ideal location under one of the system-level components, but it may be currently located in a secondary location due to technology constraints. A sub-element may work alone, but may employ synchronization with other elements on regular basis. If a sub-element is designed to perform alone, it is shown as a vertical sub-element. Most of the sub-elements work in a combination of two or more sub-elements. These sub-elements are shown as horizontal sub-elements. In an adaptive process for the customized treatment of tinnitus, the horizontal sub-elements command the on-going treatment process. The illustrative sub-elements can include audio quality management 602, current quality management 604, treatment intelligence 606, tinnitus index 608, tinnitus status 610, account management 612, system set-up 614, treatment management 616, adjust treatment details and play and gather feedback 618, tinnitus profile 620, and biofeedback sensor 622.

[0050] Audio quality management 602 illustrates the quality control of the audio signal. Audio quality management 602 is used to control the digital raw audio signal stream including two directional management data stream and a sound scape stream. This can include continuous monitoring and maintenance of the sound pressure level as well as the progress of the treatment. Audio quality management process 602 is driven by back-end intelligence 504 with the help of user interfaces 506 or 510 or internet browser 512, and can be used for converting the signal to sound and pulse generator 110, sound generator 112 or combined sound and pulse generator integrated in devices 514 and finally to audio headset 108.

[0051] Current quality management 604 illustrates the quality control of the electric current enabling the (e.g., transcutaneous) vagal nerve stimulation (VNS). To start the process, back-end intelligence 504 either guides user interfaces 506 or 510 to instruct sound generator 112, or instructs directly combined sound and pulse generator

integrated in devices 514 to deliver VNS current signal through electrode 118 to the tragus of the ear. For quality control, current quality management 604 can establish a continuous, two directional management data stream between back-end intelligence 504, combined sound and pulse generator integrated in devices 514 and electrode 118, or user interface 510, sound generator 112 and electrode 118. Overall, the current quality management process 604 facilitates a continuous, two directional management data stream provided for and derived from the dynamic VNS current through various illustrative parameters that can be changed during the process and can include: (a) frequency (e.g., 1Hz - 1000Hz), (b) mode (e.g., mono or bi-phase), (c) pulse-width (e.g., 20us - 5000us), (d) stimulation voltage (e.g., 10V - 70V); (e) constant current (e.g., 0.1mA - 5mA), (f) burst (e.g., 3 count - 1000 count); and (g) pause between pulses (e.g., 0.1s - 20s). The dynamic VNS current can be defined within and in combination of these parameters.

[0052] Treatment intelligence 606 is an illustrative function of back-end intelligence 504 and can include an embedded, process and intelligence used to manage and customize the tinnitus treatment, and can have the overall lead in the adaptive treatment of tinnitus. Accordingly, in principle, treatment intelligence 606 can be used governs other system level components, elements, and sub-elements.

[0053] Tinnitus index 608 can be used for user queries and for analyzing processes of back-end intelligence 504 and the outcome of such processes. Tinnitus index 608 merges and summarizes various data points collected in back-end database 502 through partnering activities and as received from tinnitus status 610, account management 612, and tinnitus profile 620. As a result, tinnitus index 108 presents a visual graphical projection illustrating how much the tinnitus is currently present on the scale from “0” to “10,” where a result of “10” reflects a best possible situation where the tinnitus is not present, nor creating any trouble or stress, and a result of “0” illustrates the worst possible situation in terms of the tinnitus severity. The index can be used to present a snap shot about the current status or any time in history as well as to project a trend line over the time. FIG. 20 shows an illustrative tinnitus index screen.

[0054] Tinnitus status 610 provides a question-based process to analyze the severity of the tinnitus and its implications to the customer. Tinnitus status process 6q0 is driven by treatment intelligence 606 with the gathered data saved in back-end database 502.

[0055] Account management 612 provides a process to manage the account information of the customer. This is driven by treatment intelligence 606 with the gathered data saved in back-end database 502. FIG. 21 shows an illustrative account management screen.

[0056] System set-up 614 (e.g., as shown in FIG. 9) provides a process to prepare for a tinnitus analysis or customized treatment session. System set-up 614 can be started by clicking an icon illustrating the start of the program (step 902). Thereafter, system set-up 614 reviews and confirms the end-to-end readiness of the architecture (step 904). This is done in several steps including checking the quality of the Internet connectivity (step 906) with an option to flag any issues and move to local database (step 918), checking the status of the local content (step 908) with an option to synchronize with the back-end (step 920) or in the case of issues to synchronize to a guide (step 930) and initiate a forced exit (step 934), validating log-in credentials of the user (step 910) with an option to re-confirm (step 922) and in the case of multiple error messages to a guide (step 932) and initiate a forced exit (step 934), checking the connectivity with the physical devices 110, 112 or 514 (step 912) with an option to flag issues (step 924), checking the validity of tinnitus check (step 914) with an option to force to complete – if on-line (step 926), and finally verifying the validity of tinnitus profile with options force to complete (step 928), continue, guide (step 936) and force to exit (step 934) depending on the customer profile and system end-to-end readiness. During the process, the progress is monitored by end-to-end status messages (step 938), resulting in allowing access to treatment management (step 940) in case of successful system set-up. Accordingly, access to treatment management is provided in case of successful completion of the end-to-end readiness test. Alternatively, a forced exit can be initiated. FIG. 10 illustrates a system set-up screen corresponding to step 938. FIG. 11 illustrates a log-in screen corresponding to step 910.

[0057] Treatment management screen 616 corresponds to step 940 as a part of system set-up 614. Treatment management screen 616 is a hub and control screen for the regular treatment management of tinnitus. As shown in FIG. 12, there are provided illustrative sections, including information area 1202 that shows the illustrative treatment options, for example, as “acute”, “chronic”, “sleep”, and “relax.” They can be related to the specifically tailored treatment programs as guided by treatment intelligence 606. Information area 1204 displays a tinnitus index (e.g., as derived from tinnitus status 610). Information area 1206 summarizes the treatment log information. Finally, information area 1208 displays a web-feed derived from back-end intelligence 504, and highlights user information provided from account management 612.

[0058] Adjust treatment details, and play and gather feedback 618 provides a process to start and fine-tune a treatment session according to the headset 108 in use. In FIG. 13, the process includes selecting the headphone in use (step 1302), which is calibrated and aligned with the back-end intelligence 504 (step 1304). Next the track illustrating the type of sound scape environment preferred is selected (step 1306) and aligned with back-end intelligence 504 (step 1308). Thereafter the treatment starts (step 1310). During the treatment the user can monitor its progress (step 1312) or interrupt same (step 1314). Finally, the instant feedback about the treatment is gathered (step 1316) and synchronized with the back-end intelligence 504 (step 1318) before returning to treatment management (step 1320). In FIG. 14, drop down menu 1402 corresponds to step 1302, drop down menu 1404 to step 1306, and indicator 1408 to step 1312. Finally, message area 1406 illustrates a potential error message derived from system set-up 616, for example, if something goes wrong during the treatment session

[0059] Tinnitus profile 620 illustrates a process to define an individual tinnitus profile of a customer in detail. The deployment of the process is driven by treatment intelligence 606. The process can take place at various times (e.g., once a month). As shown in FIG. 18, in the first step of the process (step 1802) the user defines the position and/or direction of a tinnitus tone. This is done in a 360 degree open space around a figure illustrating the head of the user, so that when the user looks at the

screen, the user can practice looking at the back of their head. Thereafter, the severity level of the experienced tinnitus tone is defined (step 1804) in terms of the annoyance and loudness of the tone. Next, the characteristics of the sound type of the tinnitus tone are categorized (step 1806) within several options ranging from a sinusoidal tone to buzz tone, to a hum or even a custom made sound type as guided from back-end intelligence 504. After verifying and saving the tinnitus tone (step 1810), the user can either add more tinnitus tones, clear the tones established so far or exit (step 1812). If the user decides to add more tone, steps 1802, 1804, 1806 and 1808 can be performed in a repetitive loop as many times as wanted, unless automatically limited by back-end intelligence 504. When the user selects to exit, an encrypted data file is transmitted (step 1818) to back-end intelligence 504 to be further manipulated by treatment intelligence 606 for the next steps of the treatment process. The process is closed by returning to treatment management (step 1816). FIG. 19 shows an illustrative tinnitus profile screen with embedded process steps, where area 1902 corresponds to step 1802, area 1904 to step 1804, and area 1906 to step 1806.

[0060] As shown in FIGs. 1 and 5, dedicated devices can be employed in order to master the audio parameters for the acoustic stimulation as well as the composition of the electric current used for the vagal stimulation. Typically, this cannot be achieved by normal personal computers, laptops, hand held computers or smartphones for reason related to safety and quality of the treatment.

[0061] Sound generator 112 illustrates an element of physical product 516, as a device for converting a native digital source stream, for example, with greater than 48000 Hz and greater than 24 bit resolution audio support, as driven by audio quality management 602, into a dynamic acoustic audio signal delivered to headset 108.

[0062] Sound and pulse generator 110 illustrates as an element of physical product 516, and can convert a native digital source stream, for example, with greater than 48000 Hz and greater than 24 bit resolution audio support, as driven by audio quality management 602, into a dynamic acoustic audio signal delivered to headset 108, and electric input power received through USB port and managed by current quality management 604, into dynamic VN signal delivered to ear electrode 118.

[0063] FIG. 8 illustrates sound and pulse generator 110. In FIG. 8, via USB interface 806, sound and pulse generator 110 receives the input power 802, and digital audio signal 804. USB interface 806 also serves as a two directional link for quality management streams 602 and 604. Next the streams are delivered to isolator 806, which provides the electric stream into illustrative components, including audio controller 818 for managing audio stream, battery 816 to restore power for offline usage, and VNS controller 814 to manage vagal nerve stimulation. From audio controller 818, the audio signal can be saved in internal memory or it can be sent to audio decoder 820 for converting the signal from digital into analog format, if employed. Audio controller 818 also is linked to user interface controller 824, which is used to divert the audio signal through an A-connector 826 as A-audio signal 834 to headset 108. In similar manner, VNS controller 814 controls the vagal nerve stimulation combined with memory 812 and link to user interface controller 824. User interface controller 824 is managed from visual display 822. Visual display 822 can take a form of a key pad, a touch display, and the like, with one or more keys 828. User interface controller 824 controls the delivery of the treatment on sound and pulse generator 110. User interface controller 824 can be guided either from visual display 822, directly from user interface 510 or back-end intelligence 504. User interface controller 824 also can be voice activated. User interface controller 824 includes a relay to B-connector 832 enabling the embedding of biodata signal 836 received from biofeedback sensor 622 into the on-line management of the treatment procedure. Finally, sound and pulse generator 110 delivers the vagal nerve stimulation through V-connector 830 and VN-signal 702 to ear electrode 118.

[0064] Biofeedback sensor 622 adds real-time biofeedback to an adaptive process for the customized treatment of tinnitus. Biofeedback sensor 622 embeds heart rate data and heart rate variance data as well as oxygen saturation data. Biofeedback sensor 622 can be connected to directly to sound generator 112 or devices 514 or alternatively to user interface 510. The data received through biofeedback sensor 622 is managed by treatment intelligence 606.

[0065] FIG. 24 illustrates a combined sound and pulse generator integrated in a headset. In FIG. 24, the combined sound and pulse generator integrates sound and

pulse generator 110 with stand-alone wireless connectivity module 2402 (e.g., such as cellular access or W-LAN, etc.) and intelligence to communicate directly with back-end intelligence 504 in a headset format 2404. Accordingly, streams 602 and 604 are used in two directional format to guide devices 514, while audio signal 804, biodata signal 836 and input power 802 provide inbound data stream and electricity support. In outbound mode, signal 702 is used for delivering vagal nerve stimulation and signal 834 for delivering the A-audio signal.

[0066] In FIG. 2, tragus 202 is introduced as the attachment point for a method and apparatus for transcutaneous electrical stimulation of the vagus nerve (e.g., Xth cranial nerve) in a human. The vagus nerve is stimulated through its peripheral afferent branch, the Arnold's nerve (e.g., Ramus auricularis nervi vagi), which is innervating in the external auditory meatus region the medial aspect of the tragus and the cavum conchae. By stimulation, the electrical impulses are transported into the brain areas associated with higher order relay nuclei of vagal afferent pathways, including the nucleus of the solitary tract and the reticular formation.

[0067] FIG. 3 shows how the ear electrode is positioned transcutaneously in the tragus 202 of the left or right human ear with one stimulation electrode on the other side and the reference electrode on the other side of the tragus 202. The ear electrode is attached with the majority of the body on the outer side of the tragus and with wires going towards the cheek as in 302 or 304.

[0068] The stimulation is non-invasive, though the skin surface (e.g., transcutaneous) using a clip-like attachment systems, as shown in FIG. 4. In FIG. 4, the ear electrode has one stimulation electrode on one side of the tragus and a reference electrode on the other side of the tragus. The shape of the ear electrode can be configured in V-type, O-type or J-type, and the like, and can include a clip or peg like body, for example, made of a conductive, flexible material, and the like, to allow attachment to tragus. The ear electrode can be similar to a clothes peg inserted in the tragus, so that the stimulating electrode is in direct contact with the medial surface of the tragus skin. The aim of such electrical stimulation is to stimulate the vagus nerve so as to activate the parasympathetic nervous system activity.

[0069] Ear electrode 118 is a novel piece of electronics to provide VNS current to the tragus of the customer. FIG. 7 illustrates a working prototype of the ear electrode 118 with VNS signal 702 carrying the modified electric current from sound and pulse generator 110 or devices 514 to ear electrode 118. As shown in 704, the first location option to wire the VNS current into electrode 118 is demonstrated, while 706 shows a second option for the wiring. In addition, 708 illustrates the stimulation electrode and 710 the reference electrode.

[0070] Data stream flows as shown in FIGs. 16, 17, 25, 26, and 27 illustrate how the architectural structure for an adaptive system for the treatment of tinnitus is enabled. They novel data streams used for communicating between the elements include back-end data stream 1602, back-end user experience stream 1604, user interface link 1608, virtual link 1608 between back-end intelligence 504 of cloud-based intelligence 102 and user interface in the local client or application 510 of client software 106, local data stream 1610, local user experience stream 1612, physical link 1614 between client software 106 and sound generator 112; direct virtual link 2602 between back-end intelligence 504 of cloud-based intelligence 102 and sound and pulse generator 110; and direct virtual super link 2702 between back-end intelligence 504 of cloud-based intelligence 102, and combined sound and pulse generator integrated in headset 514.

[0071] FIG. 16 illustrates the current data-flow in case of delivering audio from sound generator 112. Accordingly, in FIG. 16, streams involve communication between back-end database 502 and back-end intelligence 504 as stream 1602, back-end intelligence 504 and user interface 506 as stream 1604, back-end intelligence 504 and client or application 510 as stream 1608, user interface 506 and internet browser 512 as stream 1606, client or application 510 and local database 508 as stream 1610, client or application 510 and internet browser 512 as stream 1612, and client or application 510 and headset 108 as stream 834.

[0072] FIG. 17 illustrates flow of data when audio is delivered directly from client or application 510 to headset 108. Accordingly, in FIG. 17, streams involve communication between back-end database 502 and back-end intelligence 504 as stream 1602, back-end intelligence 504 and user interface 506 as stream 1604, back-

end intelligence 504 and client or application 510 as stream 1608, user interface 506 and internet browser 512 as stream 1606, client or application 510 and local database 508 as stream 1610, client or application 510 and internet browser 512 as stream 1612, and client or application 510 and headset 108 stream 834.

[0073] FIG. 25 illustrates the current flow for audio and vagal nerve stimulation. Accordingly, in FIG. 25, streams involve communication between back-end database 502 and back-end intelligence 504 as stream 1602, back-end intelligence 504 and user interface 506 as stream 1604, back-end intelligence 504 and client or application 510 as stream 1608, user interface 506 and internet browser 512 as stream 1606, client or application 510 and local database 508 as stream 1610, client or application 510 and internet browser 512 as stream 1612, and client or application 510 and sound and pulse generator 110 as stream 1614, sound and pulse generator 110 and electrode 118 as stream 702, and sound and pulse generator 110 and 108 as stream 834.

[0074] FIG. 26 illustrates ideal data flow for audio and vagal nerve stimulation. Accordingly, in FIG. 26, streams involve communication between back-end database 502 and back-end intelligence 504 as stream 1602, back-end intelligence 504 and client or application 510 as stream 1608, back-end intelligence 504 and sound and pulse generator 110 as stream 2602, sound and pulse generator 110 and electrode 118 as stream 702, and sound and pulse generator 110 and headset 108 as stream 834.

[0075] FIG. 27 illustrates ideal data-flow for integrated combined sound and pulse generator integrated in headset. Accordingly, in FIG. 27, streams involve communication between back-end database 502 and back-end intelligence 504 as stream 1602, back-end intelligence 504 and client or application 510 as stream 1608, back-end intelligence 504 and devices 514 as stream 2702, devices 514 and electrode 118 as stream 702, and devices 514 and headset 108 as stream 834.

[0076] FIG. 22 illustrates the pathway for the vagal-auditory modulation from tragus 202 in the ear via vagus nerve 2004 to the limbic systems 2006. Accordingly, (e.g., transcutaneous) vagus nerve stimulation (VNS) deactivates limbic system which, in turn, attenuates auditory cortical hyperactivity in tinnitus patients. FIG. 23 shows graphs for illustrating how transcutaneous vagus nerve stimulation (tVNS)

attenuates auditory cortical responsiveness as driven system for adaptive treatment of tinnitus. The effects of VNS being on or off shown in legend 2306 on the cortical activity of tinnitus patients are proven with magnetoencephalography (MEG), where the N1m amplitude is prevalently reduced by applying VNS at left shown in 2302 and right shown in 2304 hemispheres.

[0077] The above-described devices and subsystems of the illustrative embodiments can include, for example, any suitable servers, workstations, PCs, laptop computers, PDAs, Internet appliances, handheld devices, cellular telephones, wireless devices, other devices, and the like, capable of performing the processes of the illustrative embodiments. The devices and subsystems of the illustrative embodiments can communicate with each other using any suitable protocol and can be implemented using one or more programmed computer systems or devices.

[0078] One or more interface mechanisms can be used with the illustrative embodiments, including, for example, Internet access, telecommunications in any suitable form (e.g., voice, modem, and the like), wireless communications media, and the like. For example, employed communications networks or links can include one or more wireless communications networks, cellular communications networks, G3 communications networks, Public Switched Telephone Network (PSTNs), Packet Data Networks (PDNs), the Internet, intranets, cloud computing networks, a combination thereof, and the like.

[0079] It is to be understood that the described devices and subsystems are for illustrative purposes, as many variations of the specific hardware used to implement the illustrative embodiments are possible, as will be appreciated by those skilled in the relevant art(s). For example, the functionality of one or more of the devices and subsystems of the illustrative embodiments can be implemented via one or more programmed computer systems or devices.

[0080] To implement such variations as well as other variations, a single computer system can be programmed to perform the special purpose functions of one or more of the devices and subsystems of the illustrative embodiments. On the other hand, two or more programmed computer systems or devices can be substituted for any one of the devices and subsystems of the illustrative embodiments. Accordingly,

principles and advantages of distributed processing, such as redundancy, replication, and the like, also can be implemented, as desired, to increase the robustness and performance of the devices and subsystems of the illustrative embodiments.

[0081] The devices and subsystems of the illustrative embodiments can store information relating to various processes described herein. This information can be stored in one or more memories, such as a hard disk, optical disk, magneto-optical disk, RAM, and the like, of the devices and subsystems of the illustrative embodiments. One or more databases of the devices and subsystems of the illustrative embodiments can store the information used to implement the illustrative embodiments of the present inventions. The databases can be organized using data structures (e.g., records, tables, arrays, fields, graphs, pigeons, trees, lists, and the like) included in one or more memories or storage devices listed herein. The processes described with respect to the illustrative embodiments can include appropriate data structures for storing data collected and/or generated by the processes of the devices and subsystems of the illustrative embodiments in one or more databases thereof.

[0082] All or a portion of the devices and subsystems of the illustrative embodiments can be conveniently implemented using one or more general purpose computer systems, microprocessors, digital signal processors, micro-controllers, and the like, programmed according to the teachings of the illustrative embodiments of the present inventions, as will be appreciated by those skilled in the computer and software arts. Appropriate software can be readily prepared by programmers of ordinary skill based on the teachings of the illustrative embodiments, as will be appreciated by those skilled in the software art. Further, the devices and subsystems of the illustrative embodiments can be implemented on the World Wide Web. In addition, the devices and subsystems of the illustrative embodiments can be implemented by the preparation of application-specific integrated circuits or by interconnecting an appropriate network of conventional component circuits, as will be appreciated by those skilled in the electrical art(s). Thus, the illustrative embodiments are not limited to any specific combination of hardware circuitry and/or software.

[0083] Stored on any one or on a combination of computer readable media, the illustrative embodiments of the present inventions can include software for

controlling the devices and subsystems of the illustrative embodiments, for driving the devices and subsystems of the illustrative embodiments, for enabling the devices and subsystems of the illustrative embodiments to interact with a human user, and the like. Such software can include, but is not limited to, device drivers, firmware, operating systems, development tools, applications software, and the like. Such computer readable media further can include the computer program product of an embodiment of the present inventions for performing all or a portion (if processing is distributed) of the processing performed in implementing the inventions. Computer code devices of the illustrative embodiments of the present inventions can include any suitable interpretable or executable code mechanism, including but not limited to scripts, interpretable programs, dynamic link libraries (DLLs), Java classes and applets, complete executable programs, Common Object Request Broker Architecture (CORBA) objects, and the like. Moreover, parts of the processing of the illustrative embodiments of the present inventions can be distributed for better performance, reliability, cost, and the like.

[0084] As stated above, the devices and subsystems of the illustrative embodiments can include computer readable medium or memories for holding instructions programmed according to the teachings of the present inventions and for holding data structures, tables, records, and/or other data described herein. Computer readable medium can include any suitable medium that participates in providing instructions to a processor for execution. Such a medium can take many forms, including but not limited to, non-volatile media, volatile media, transmission media, and the like. Non-volatile media can include, for example, optical or magnetic disks, magneto-optical disks, and the like. Volatile media can include dynamic memories, and the like. Transmission media can include coaxial cables, copper wire, fiber optics, and the like. Transmission media also can take the form of acoustic, optical, electromagnetic waves, and the like, such as those generated during radio frequency (RF) communications, infrared (IR) data communications, and the like. Common forms of computer-readable media can include, for example, a floppy disk, a flexible disk, hard disk, magnetic tape, any other suitable magnetic medium, a CD-ROM, CDRW, DVD, any other suitable optical medium, punch cards, paper tape, optical mark sheets, any other suitable physical medium with patterns of holes or other

optically recognizable indicia, a RAM, a PROM, an EPROM, a FLASH-EPROM, any other suitable memory chip or cartridge, a carrier wave or any other suitable medium from which a computer can read.

[0085] Although the illustrative embodiments are described in terms of the adaptive treatment of tinnitus, the present invention is applicable more general treatment of mental stress and human well-being, as will be appreciated by those skilled in the relevant art(s).

[0086] While the present inventions have been described in connection with a number of illustrative embodiments, and implementations, the present inventions are not so limited, but rather cover various modifications, and equivalent arrangements, which fall within the purview of the appended claims.

WHAT IS CLAIMED IS:

1. A system for adaptive treatment of tinnitus, comprising:
an end-to-end architecture for adaptive treatment of tinnitus;
the end-to-end architecture is configured to employ a user customized combination of acoustic therapy and vagal nerve stimulation according to an individual tinnitus profile of the user; and
the end-to-end architecture is configured to employ audio and vagal nerve algorithm profilers that are verified by magnetoencephalography.
2. The system of claim 1, wherein the end-to-end architecture includes a physical product, a virtual product, and embedded intelligence, and
the physical product, the virtual product, and the embedded intelligence are integrated via a cloud-based, intelligent web site.
3. The system of claim 2, wherein the physical product includes:
a dedicated sound and pulse generating device; and
a dedicated ear electrode configured to be attached transcutaneously in a tragus of an ear.
4. The system of claim 3, wherein the dedicated ear electrode is configured as a V, O, or J shaped body with a built-in feedback loop.
5. The system of claim 2, wherein the embedded intelligence is configured to allow customization of tinnitus treatment by employing a plurality of parameters and algorithms including parameters and algorithms for audio customization of the dedicated sound and pulse generating device, and parameters and algorithms for managing customization of a current and flow of electricity to the dedicated ear electrode.
6. The system of claim 2, wherein the end-to-end architecture is further configured to employ the user customized combination of the acoustic therapy and the

vagal nerve stimulation according to the individual tinnitus profile of the user and/or according to biofeedback about the user.

7. A method for adaptive treatment of tinnitus corresponding to the system of claims 1-6.

8. A computer program product including computer readable instructions for adaptive treatment of tinnitus corresponding to the system of claims 1-6.

Fig. 1

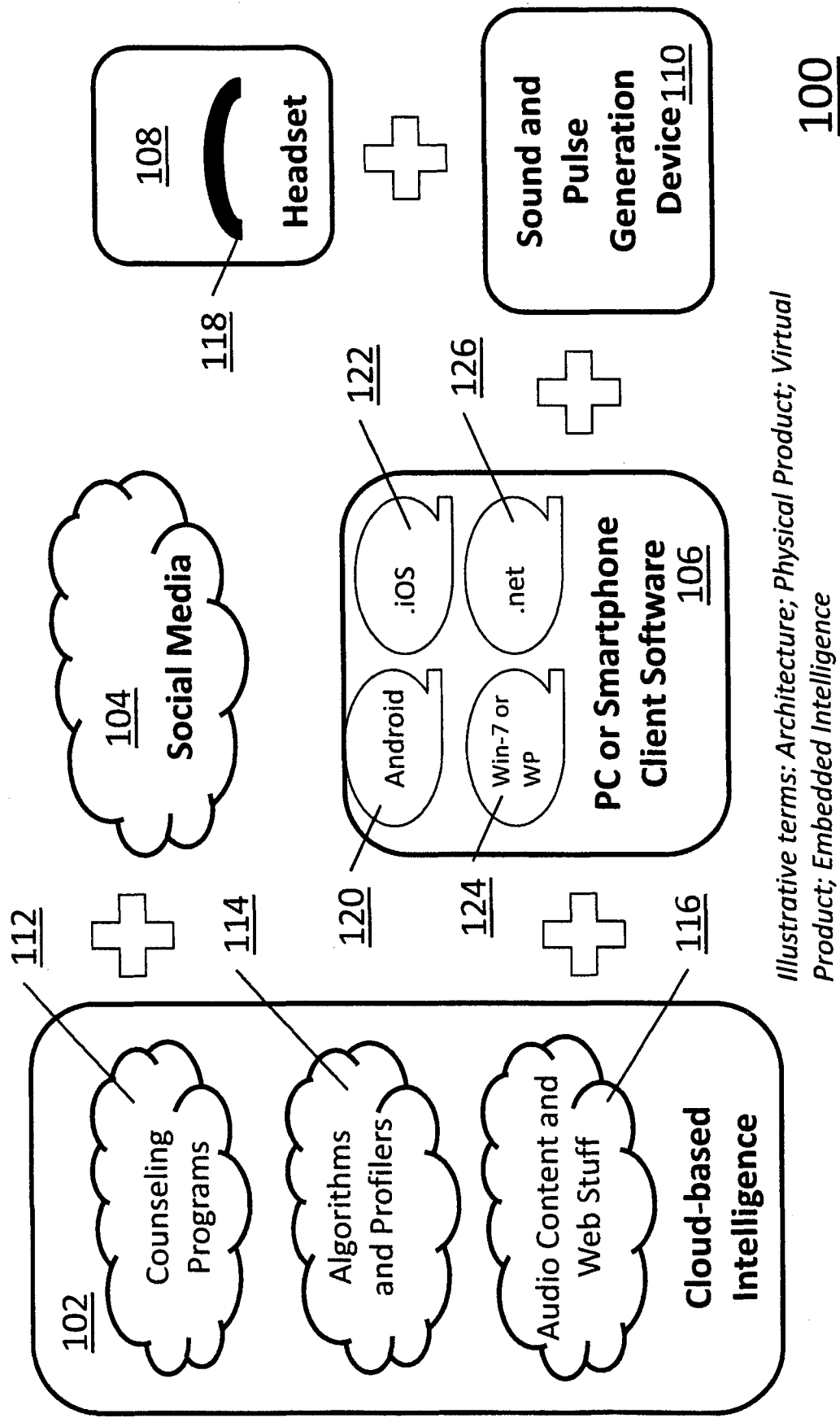
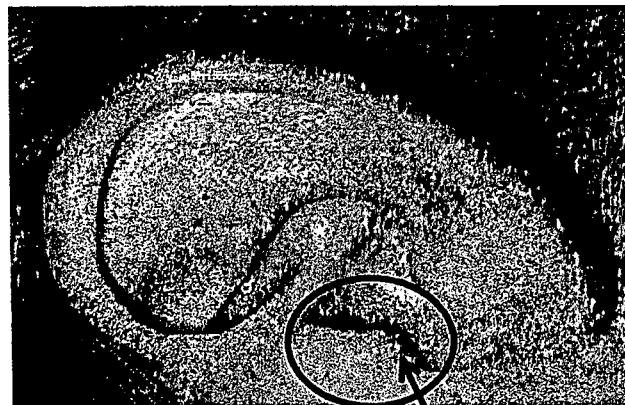


Fig. 2



200

202

tragus

Fig. 3

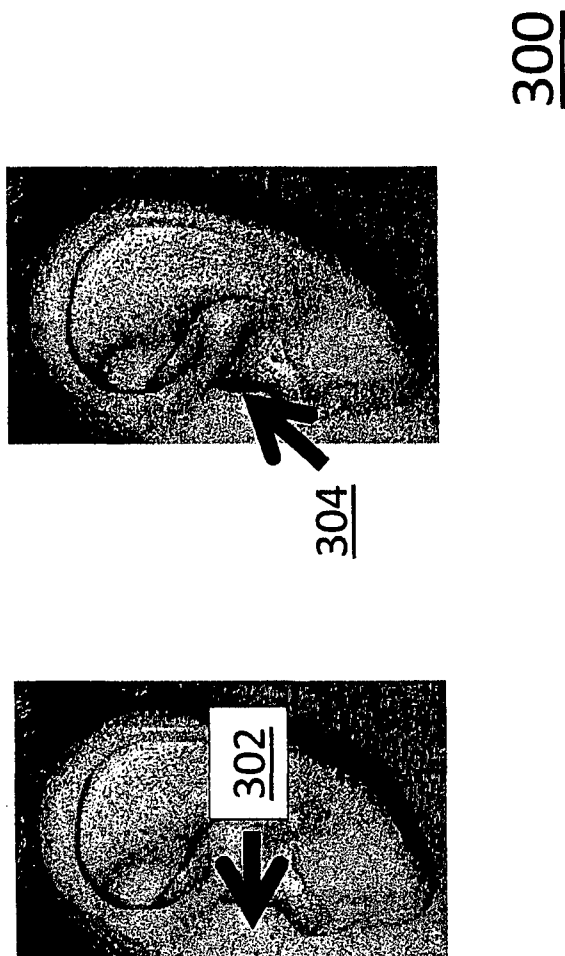


FIG. 4

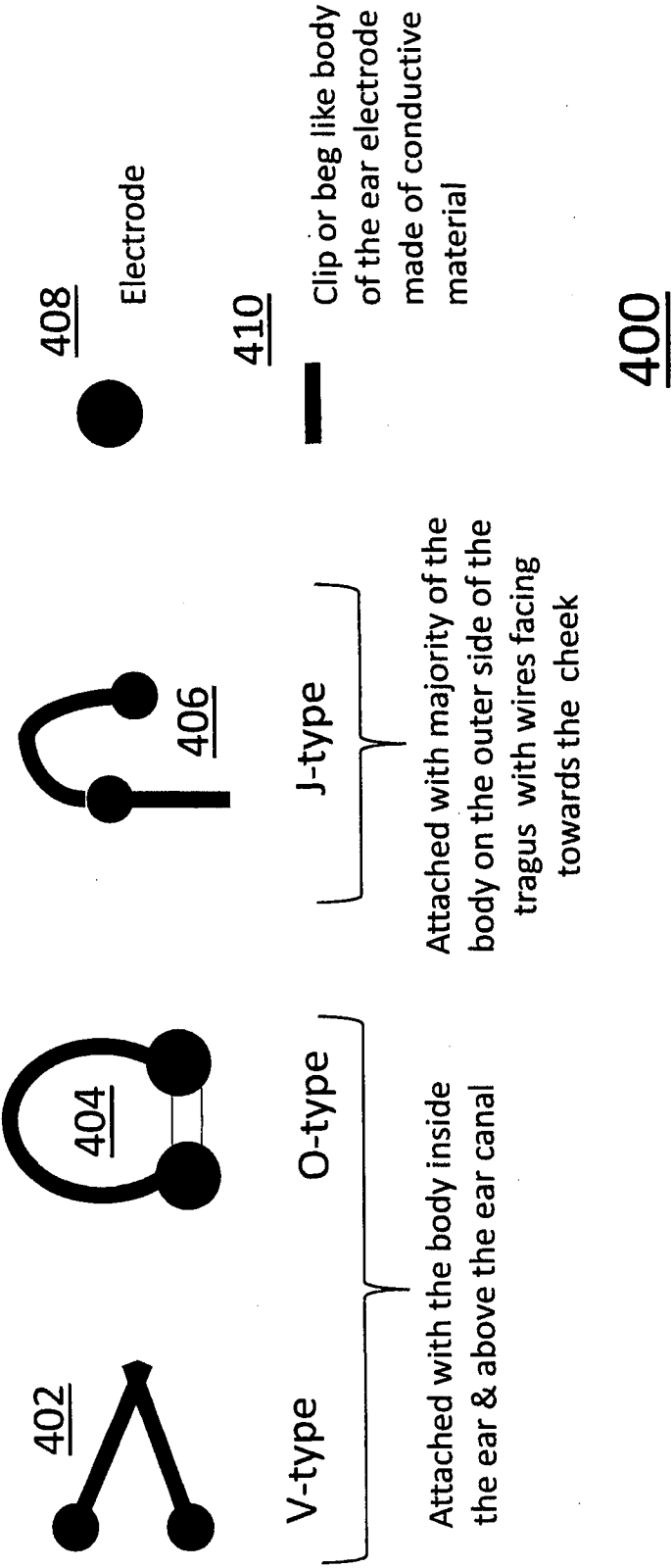
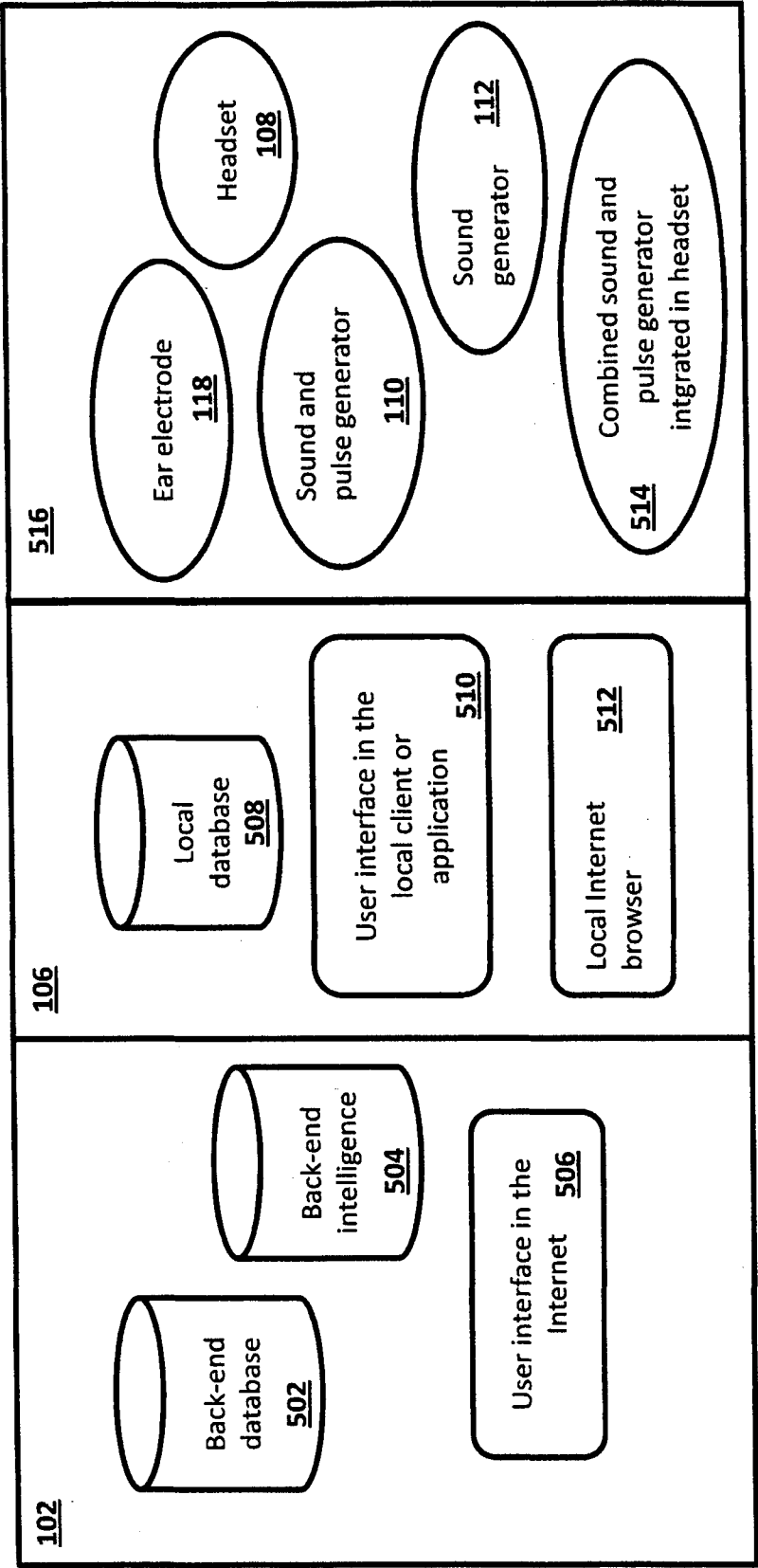


Fig. 5,



500

Fig. 6,

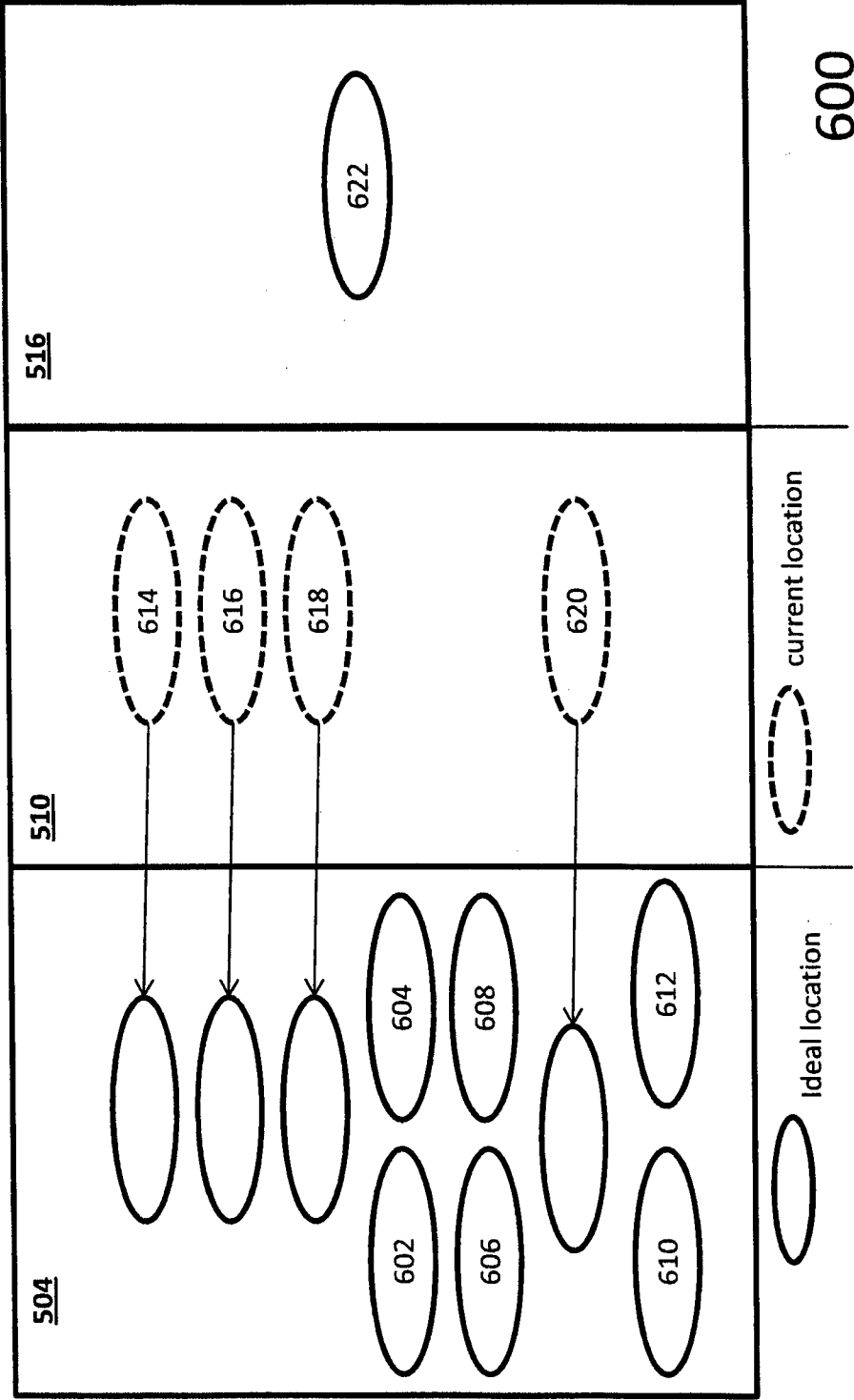


Fig. 7,

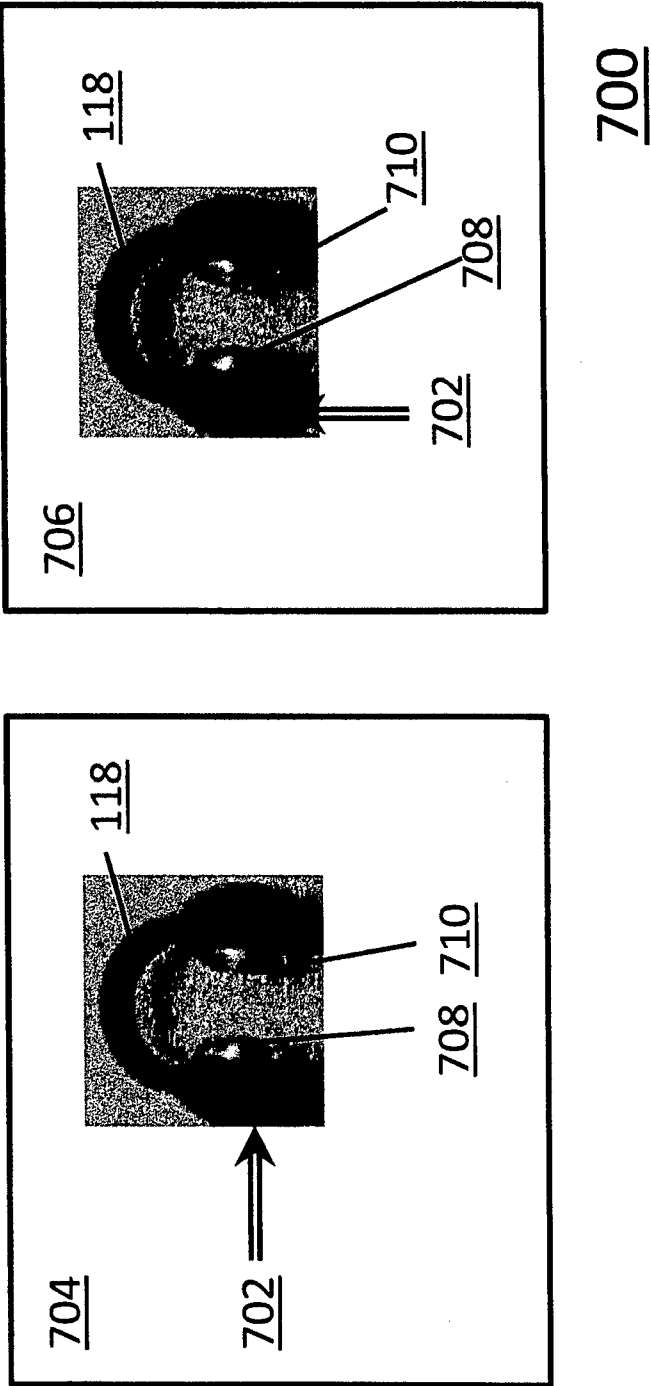


Fig. 8,

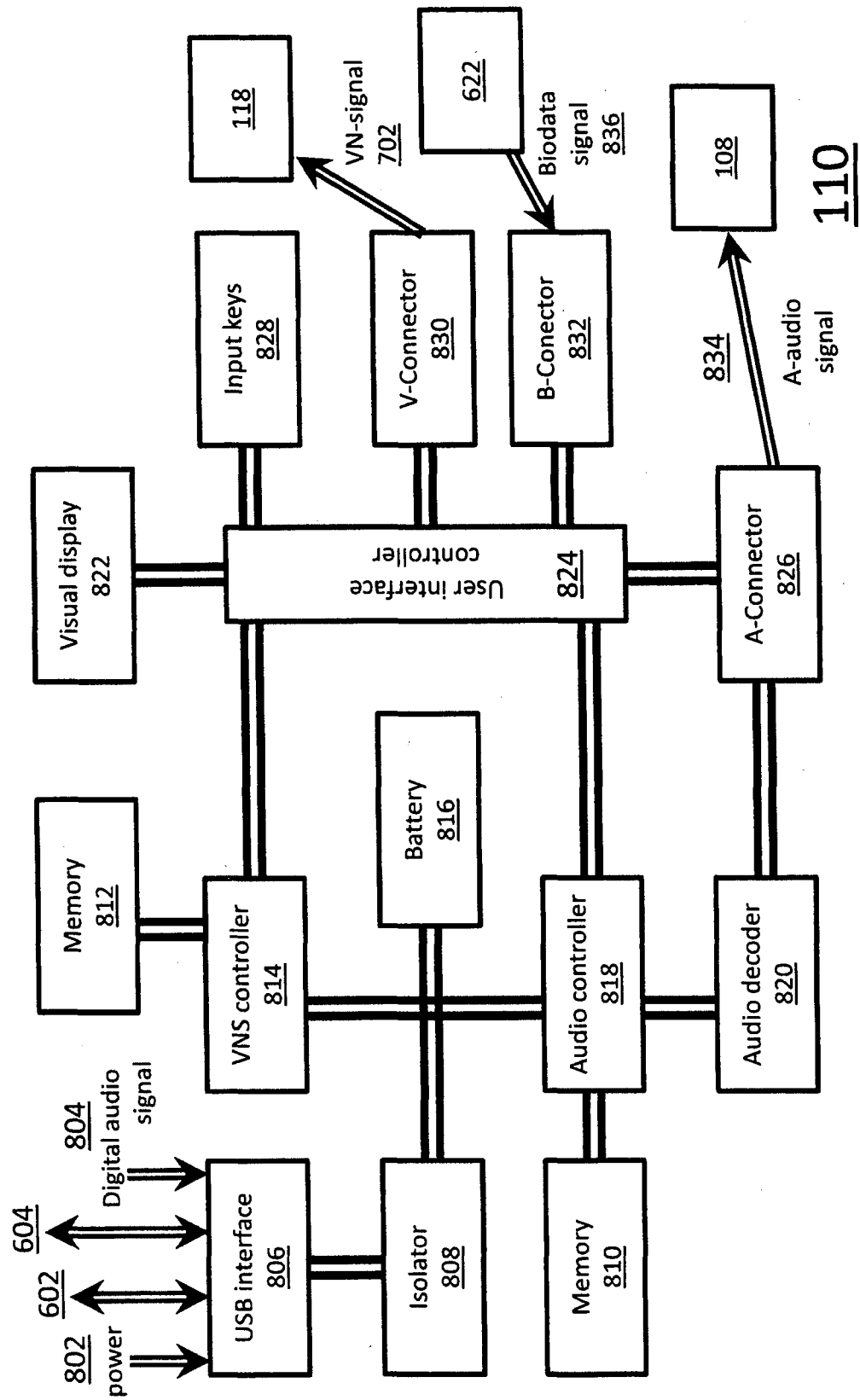


Fig. 9,

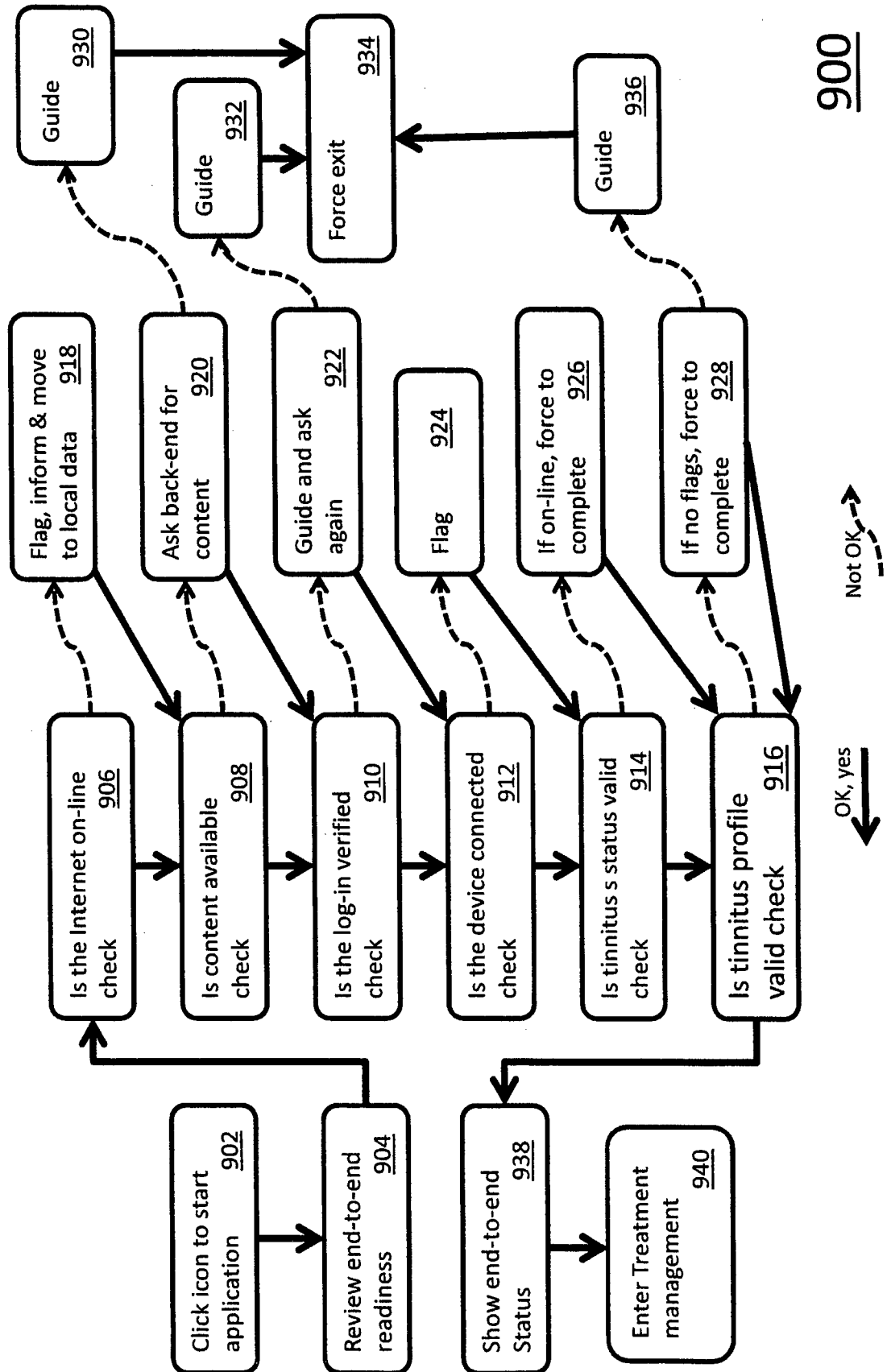
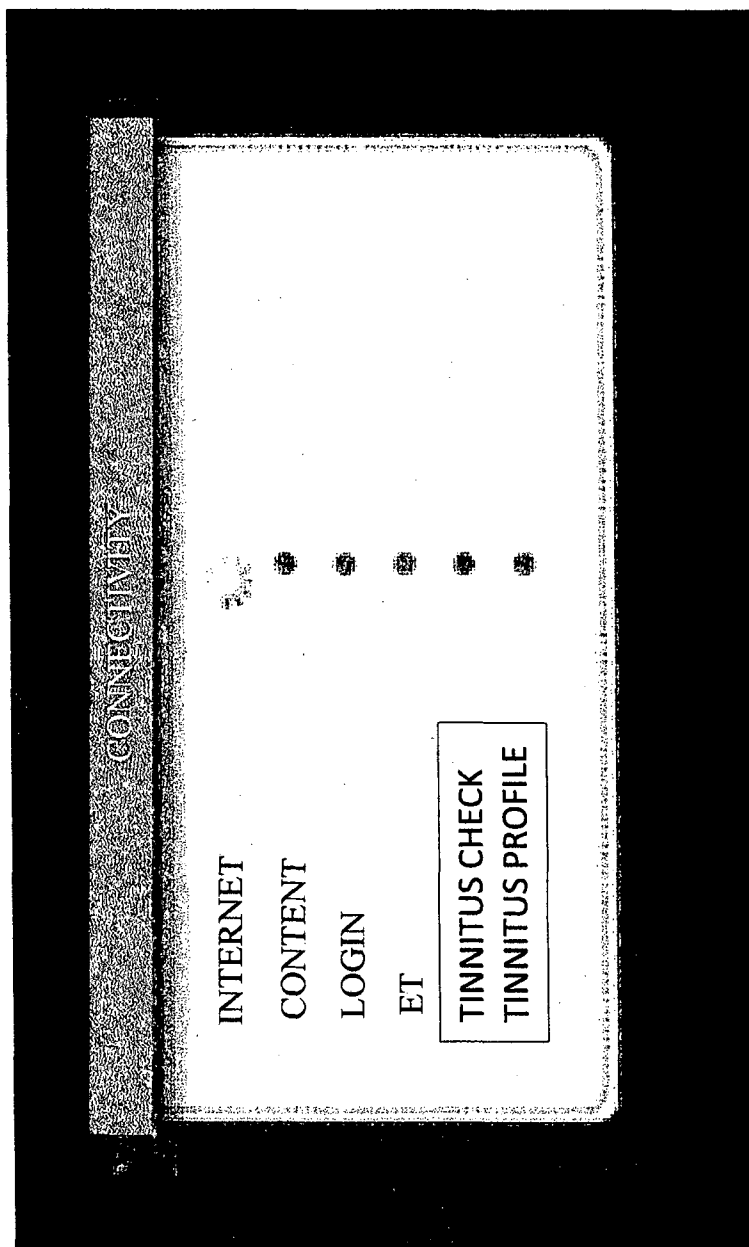


Fig. 10,



1000

Fig. 11,

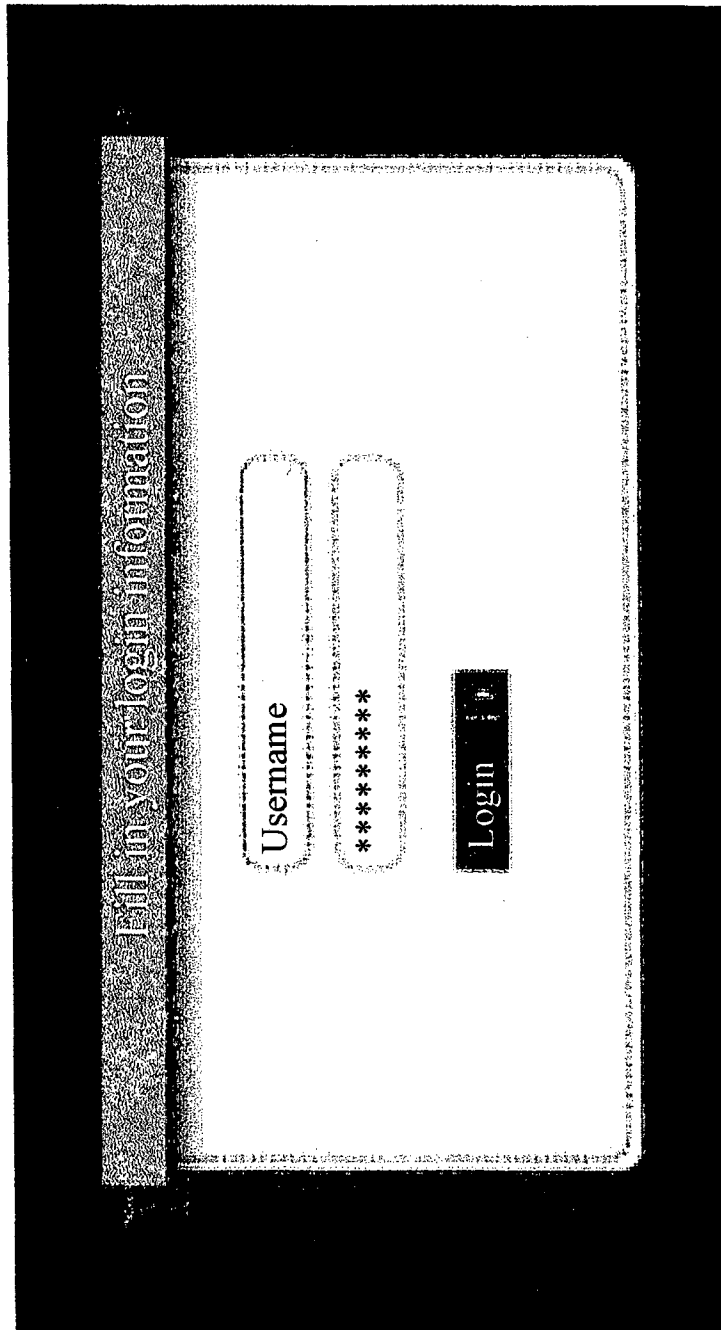
1100

Fig. 12,

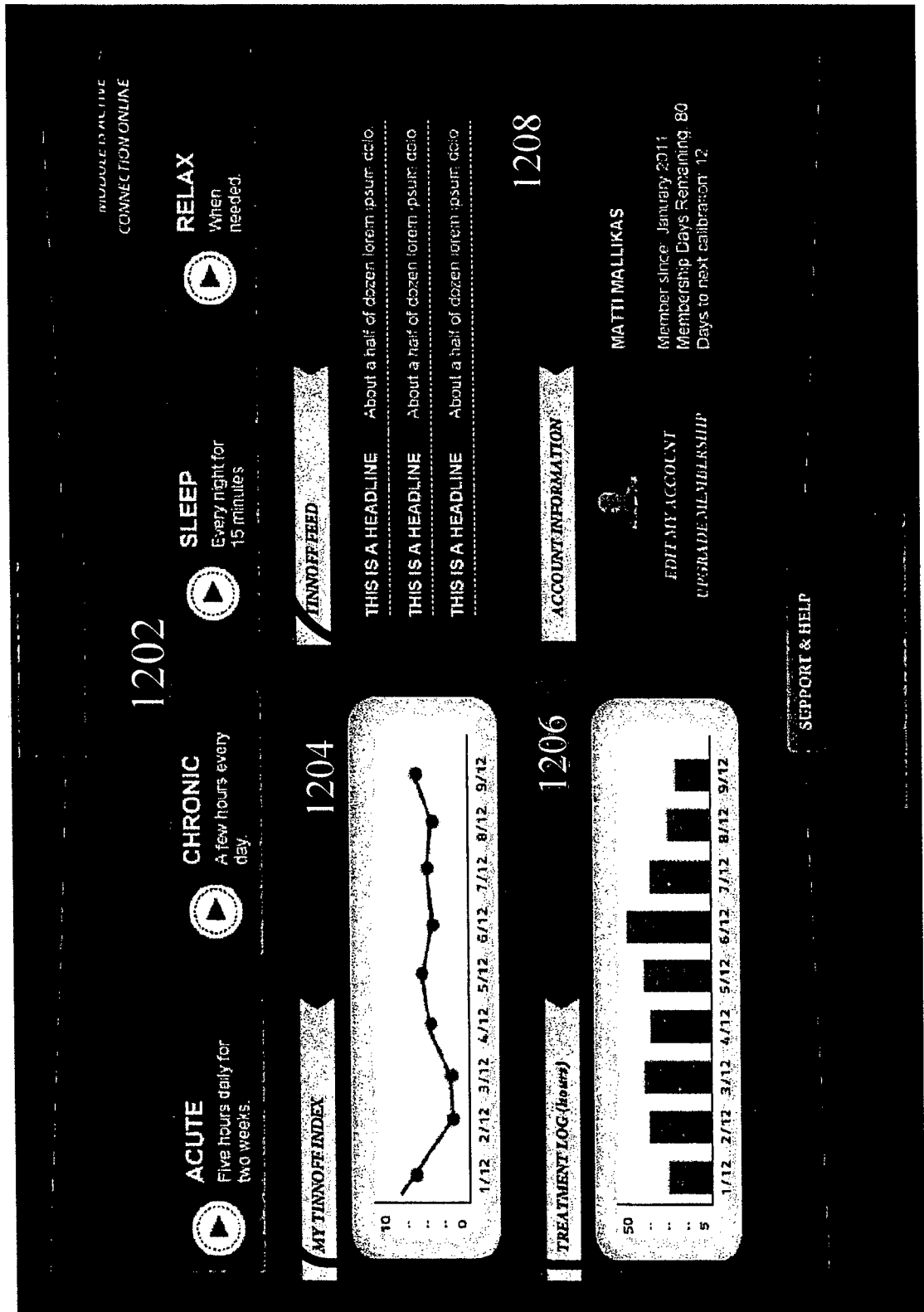


Fig. 13,

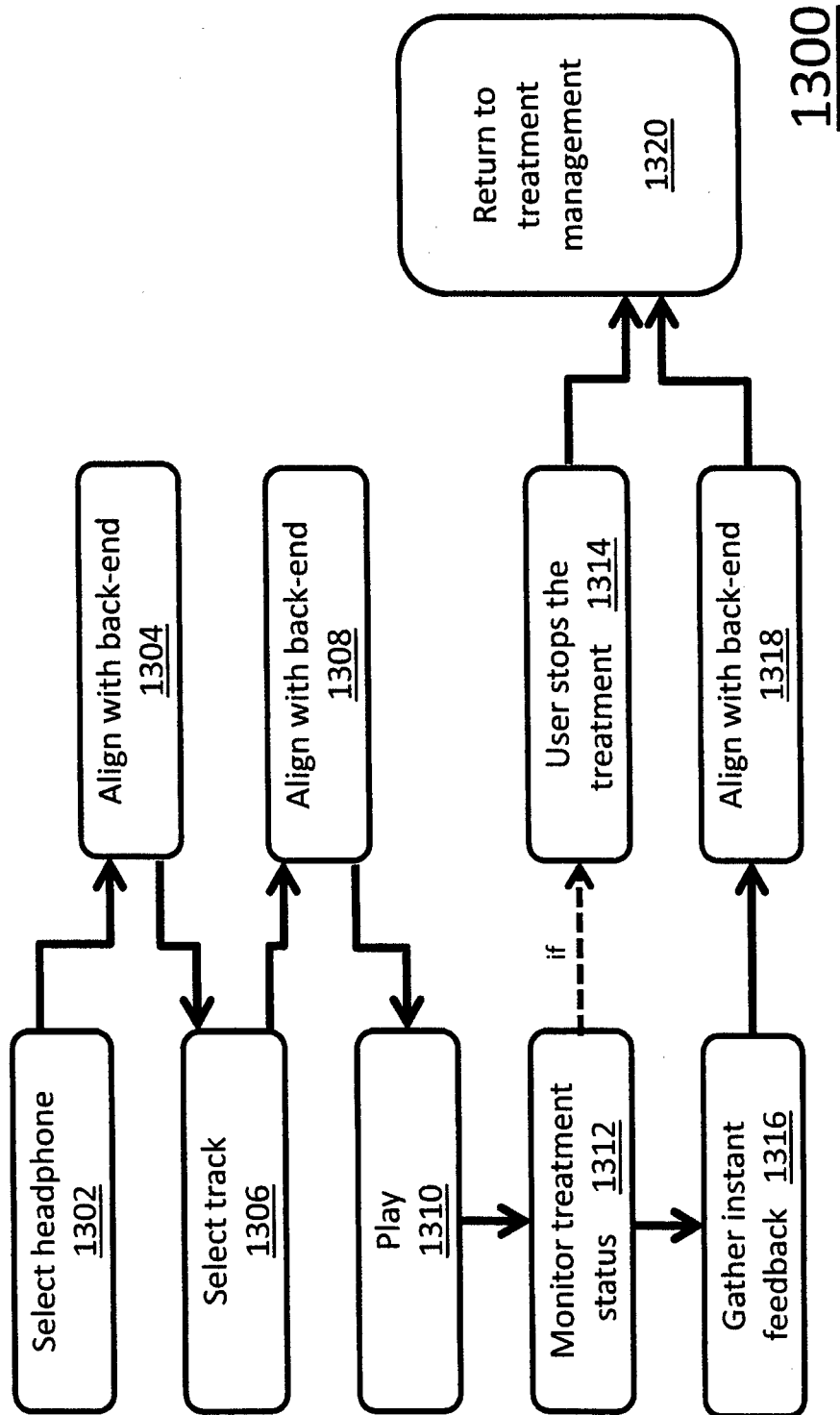


Fig. 14,

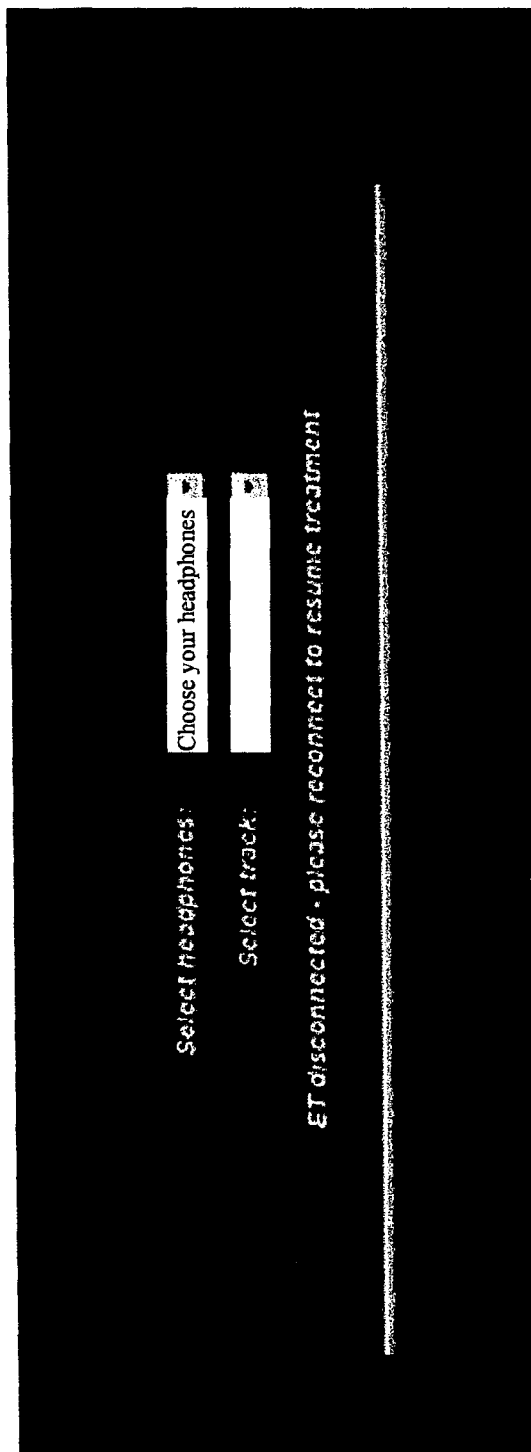
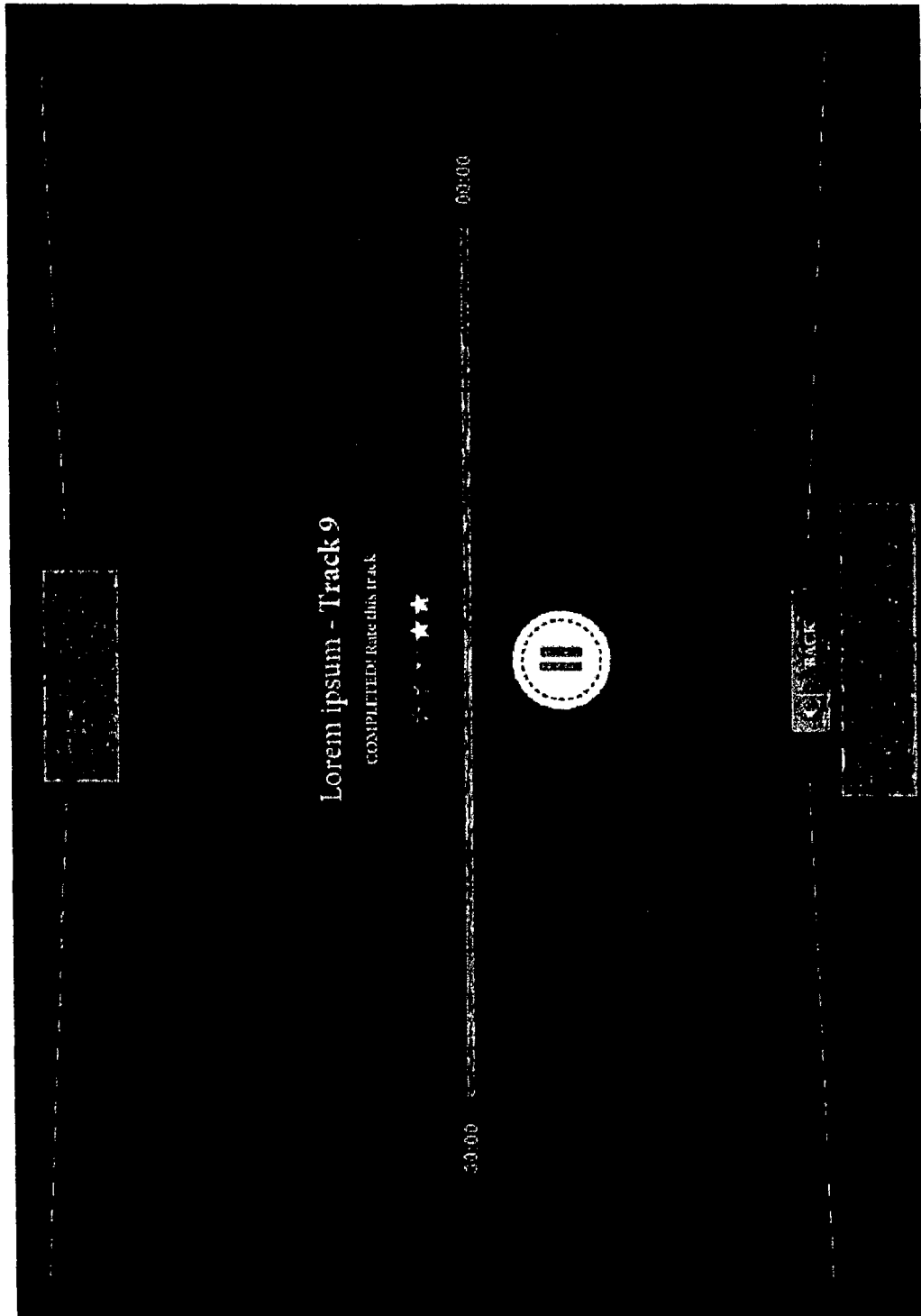
1400

Fig. 15,



1500

Fig. 16,

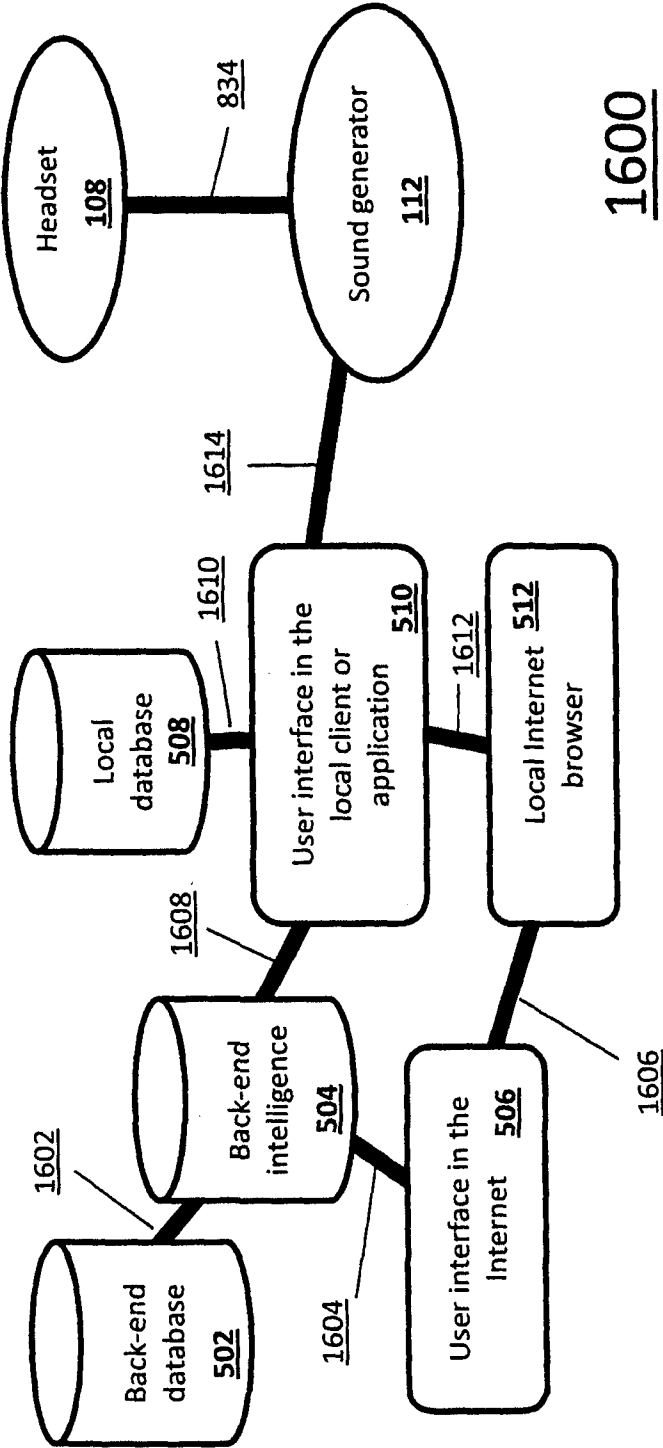


Fig. 17,

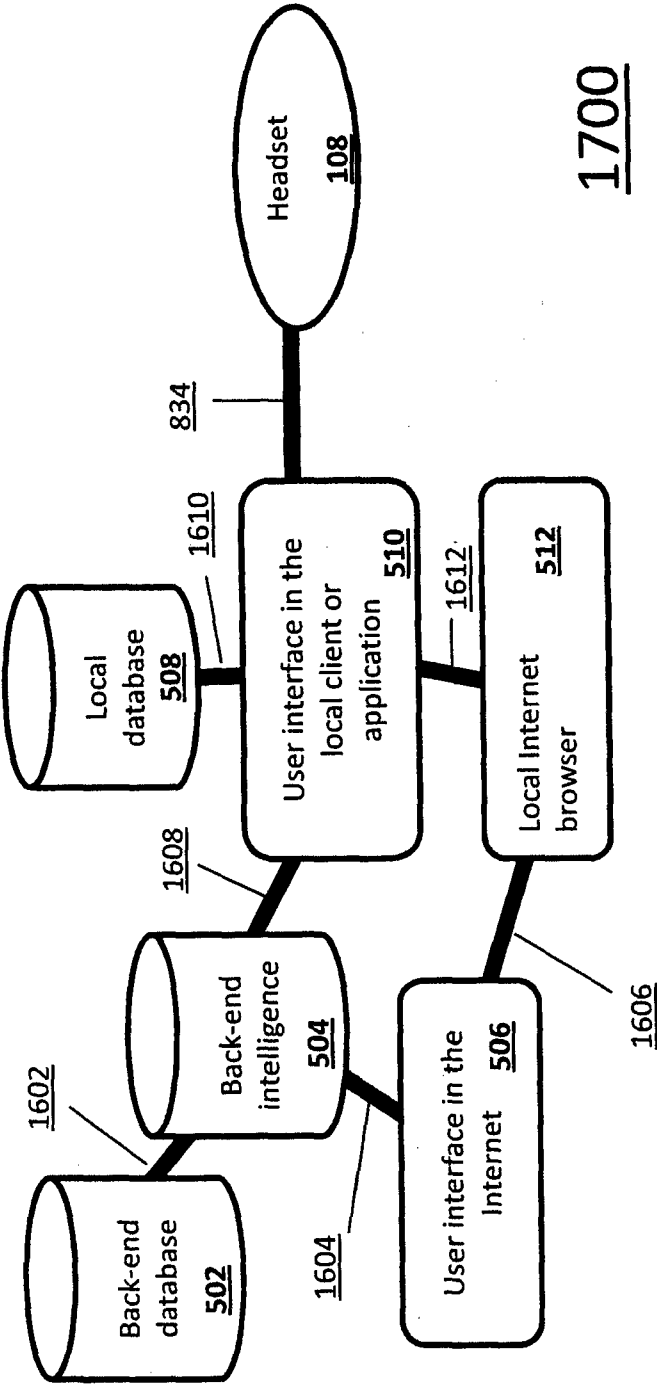
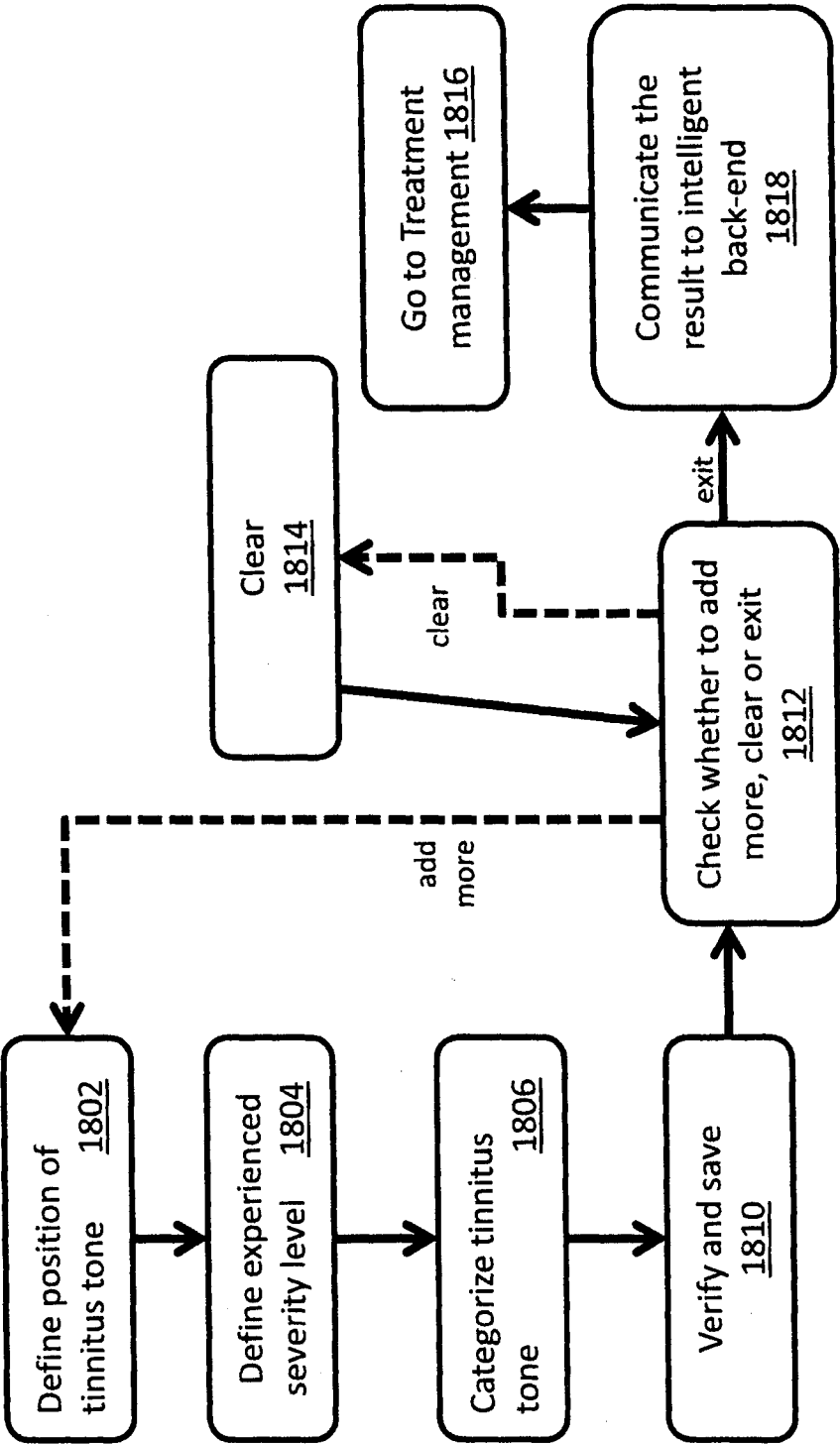
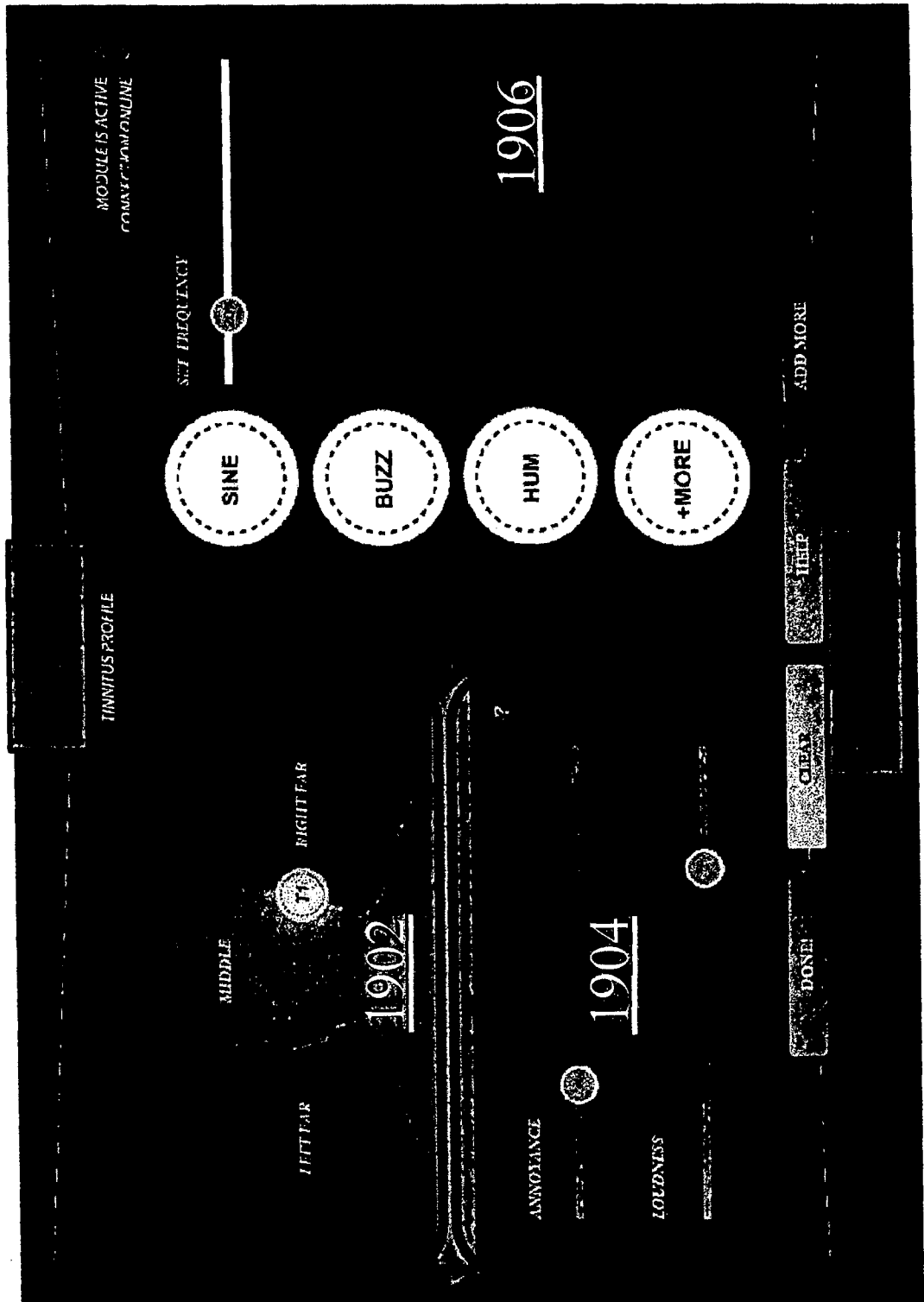


Fig. 18,



1800

Fig. 19,



1900

Fig. 20,

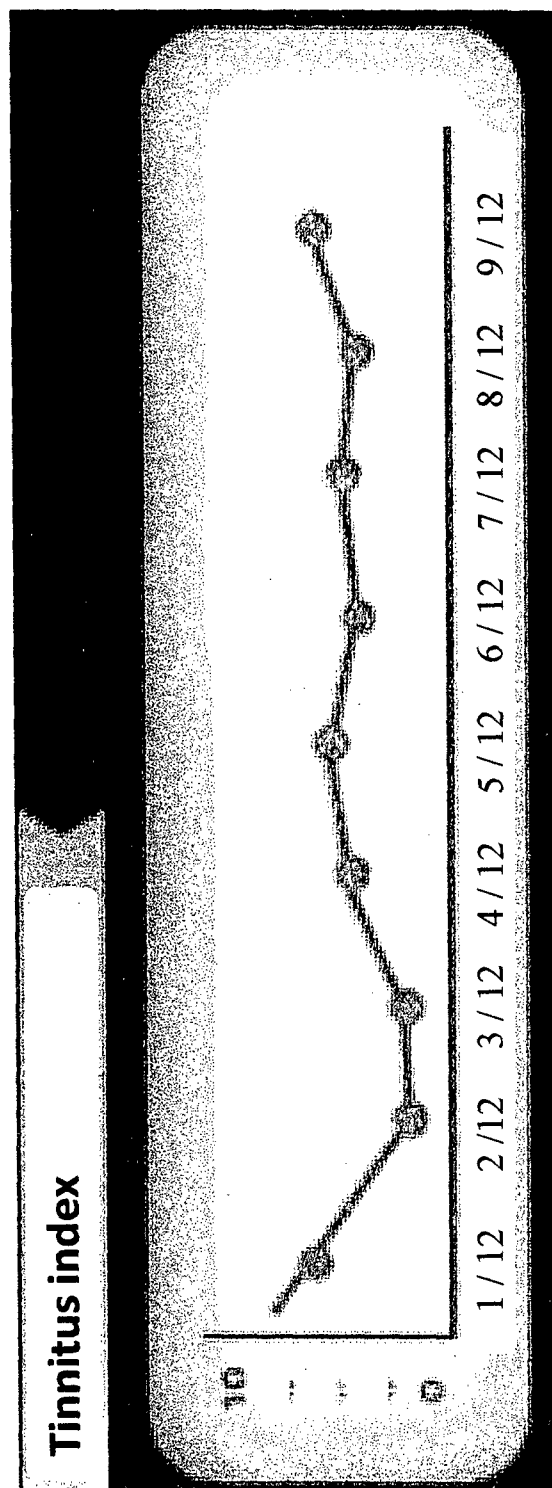
1204

Fig. 21,

KÄYTTÄJÄTILI

Käyttäjätili

finnish

*****@gmail.com

Yhteystietoni

*****@gmail.com

Koivula

senatorantti

Halsuandie 1

Naimisissa

1969

Testing, adding data from Galaxy

2100

SUBSTITUTE SHEET (RULE 26)

Fig. 22,

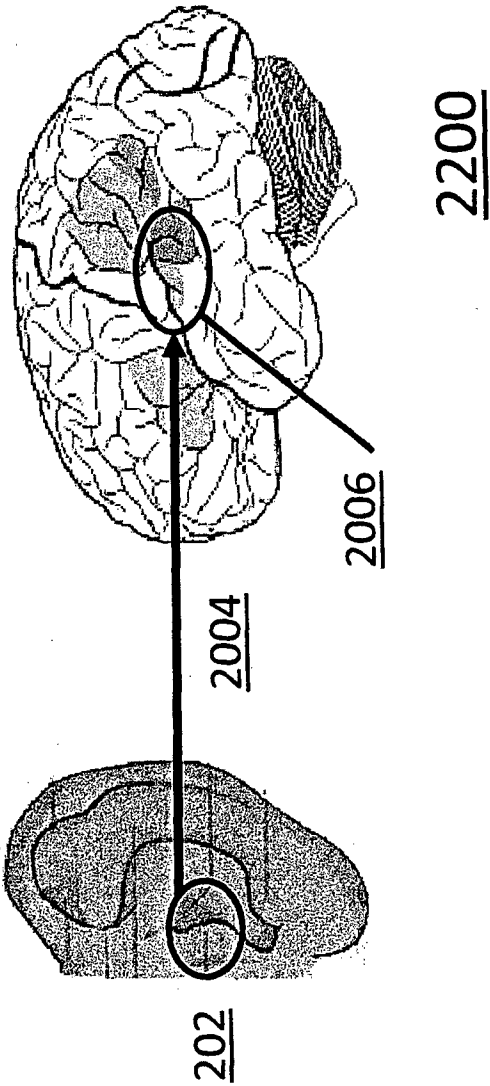


Fig. 23,

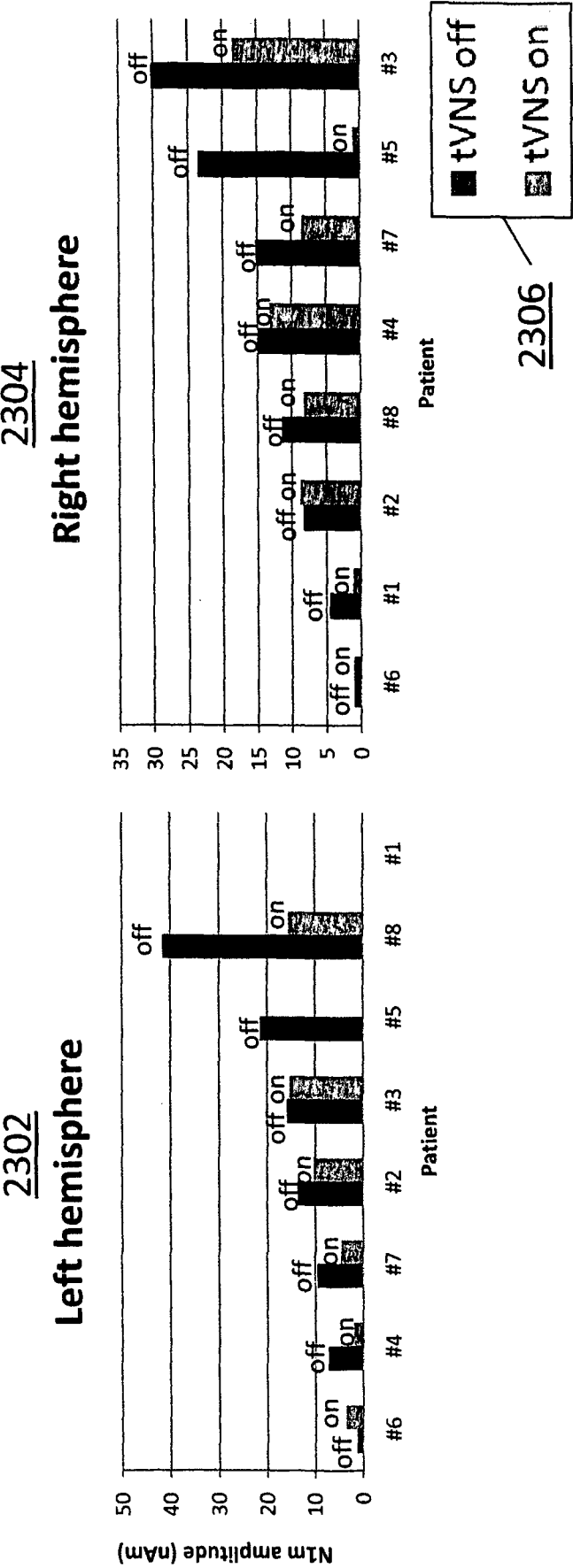
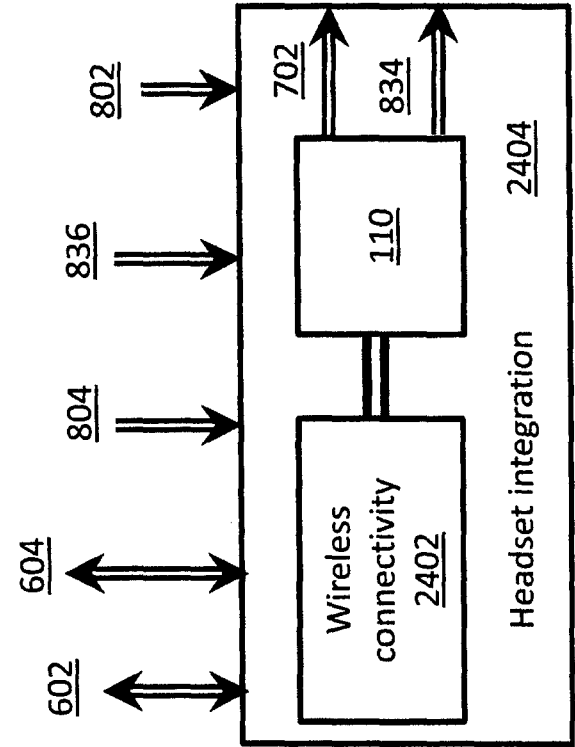


Fig. 24,



514

Fig. 25,

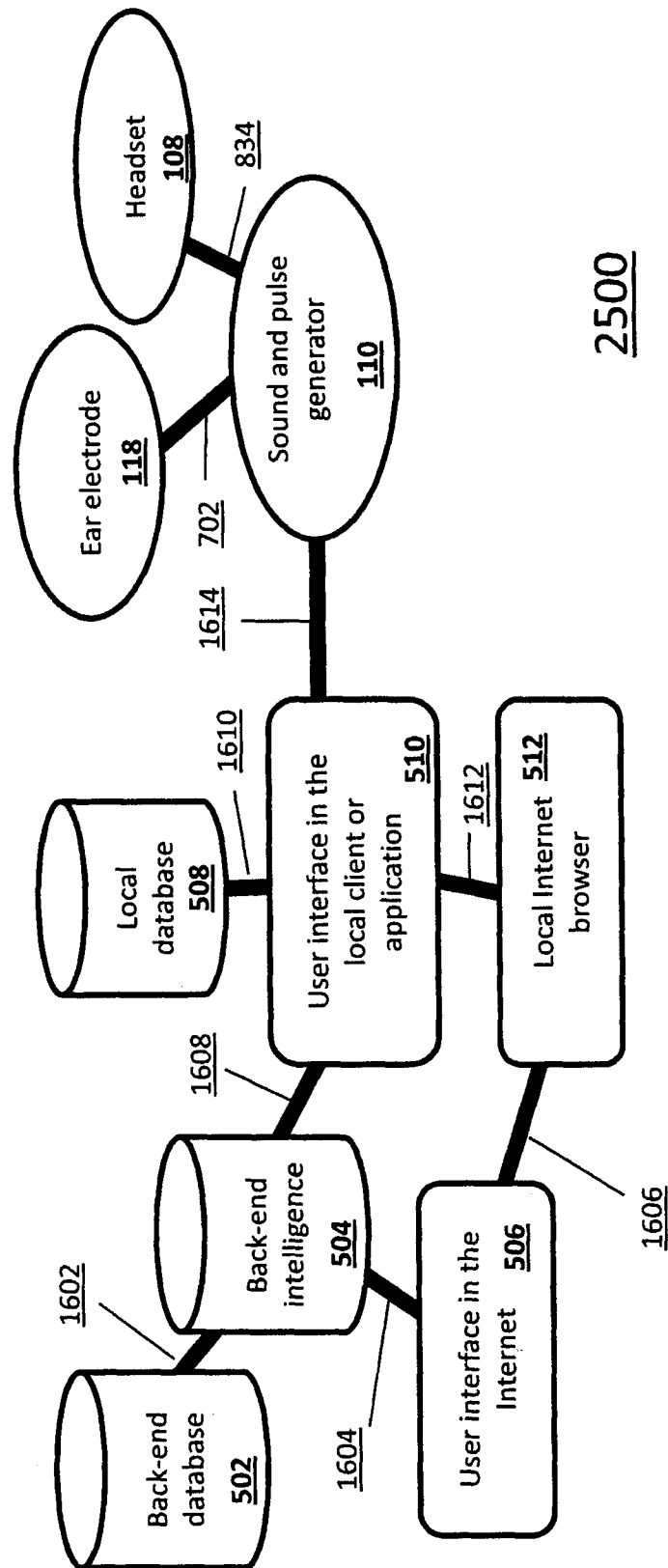
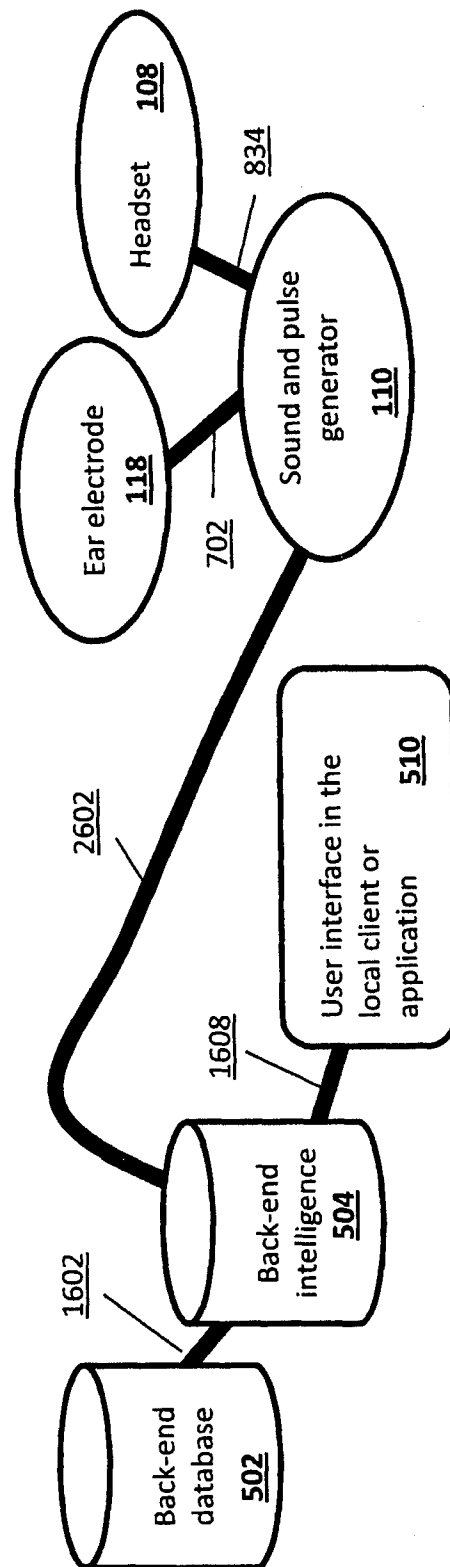
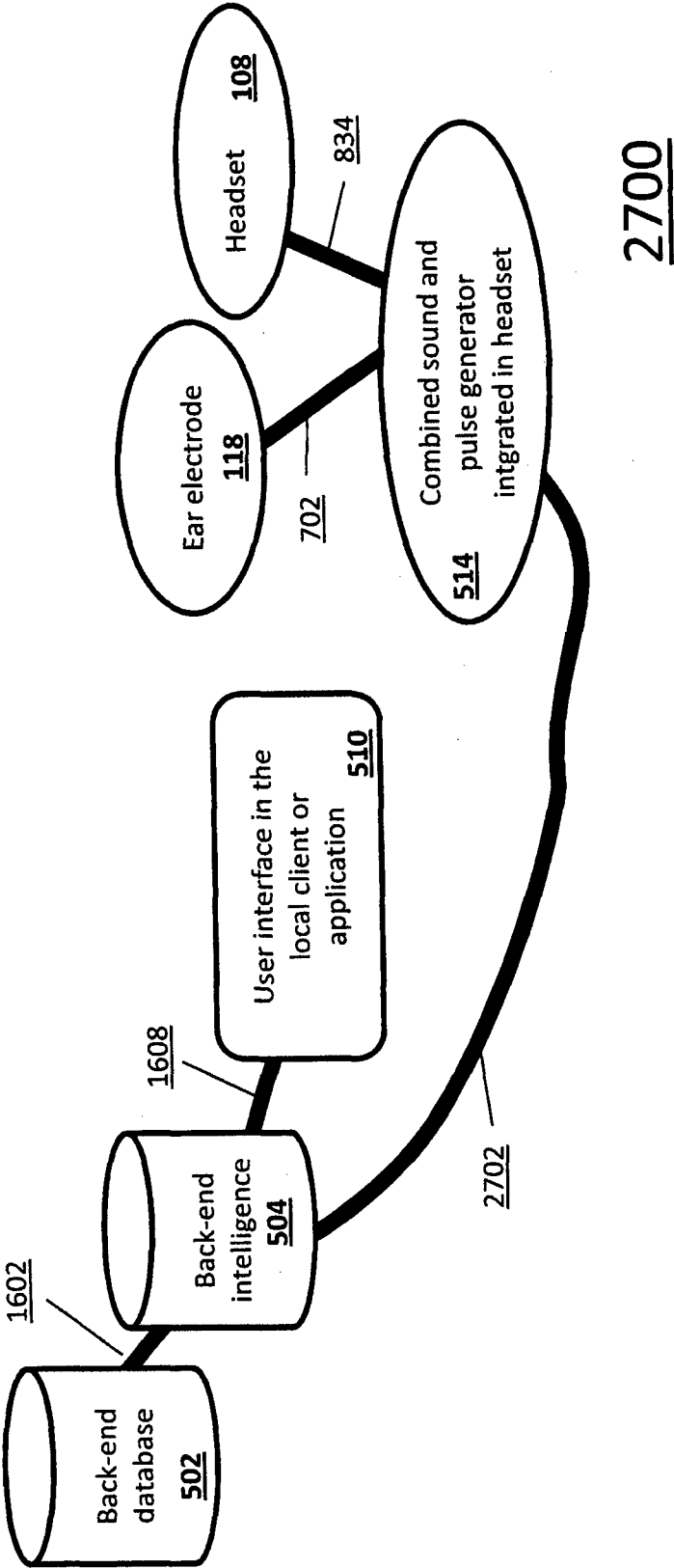


Fig. 26,



2600

Fig. 27,



INTERNATIONAL SEARCH REPORT

International application No
PCT/FI2012/050507

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/36 A61B5/12
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N A61B G06F H04R

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EP0-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2009/045449 A1 (TINNITUS OTOSOUND PRODUCTS LLC [US]; PINEDA JAIME A [US]; VIIRRE ERIK) 9 April 2009 (2009-04-09) figure 1 paragraph [0013] - paragraph [0055] paragraph [0087]	1-6,8
Y	WO 2007/134804 A1 (CERBOMED GMBH [DE]; DIETRICH STEFAN [DE]; FREITAG TIMO [DE]) 29 November 2007 (2007-11-29) figures 4, 9 page 12, line 14 - page 15, line 28	1-6,8
A	US 2006/093997 A1 (KEARBY GERALD W [US] ET AL) 4 May 2006 (2006-05-04) the whole document	1-6,8
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

31 July 2012

Date of mailing of the international search report

09/08/2012

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Ließmann, Frank

INTERNATIONAL SEARCH REPORT

International application No
PCT/FI2012/050507

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2008/083429 A1 (WINKLER PETER ANTHONY [AU]) 17 July 2008 (2008-07-17) the whole document	1-6,8
A	----- WO 2008/009363 A1 (CERBOMED GMBH [DE]; DIETRICH STEFAN [DE]) 24 January 2008 (2008-01-24) the whole document -----	1-6,8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI2012/050507

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 7
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/FI2012/050507

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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