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(54) IMPLANTABLE DEVICE FOR ACQUISITION AND MONITORING OF BRAIN BIOELECTRIC SIGNALS AND FOR INTRACRANIAL STIMULATION

IMPLANTIERBARE VORRICHTUNG ZUR ERFASSUNG UND ÜBERWACHUNG VON BIOELEKTRISCHEN SIGNALEN DES GEHIRNS UND ZUR INTRAKRANIALEN STIMULATION

DISPOSITIF IMPLANTABLE DESTINÉ À L'ACQUISITION ET À LA SURVEILLANCE DES SIGNAUX BIOÉLECTRIQUES DU CERVEAU ET À LA STIMULATION INTRACRÂNIENNE

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Description

[0001] The present invention relates to an implantable device for acquisition and monitoring of bioelectric signals from the brain of a patient, in particular electroencephalographic and electrocorticographic signals, as well as for intracranial stimulation. The invention also relates to a system for acquisition and processing of brain bioelectric signals comprising such an implantable device.

[0002] Within the framework of clinical neurosciences there has been a significant increase in the application of techniques for monitoring areas of the brain for diagnostic and therapeutic purposes, in particular in the treatment of drug-resistant epilepsy, Parkinson's disease, movement disorders and other psychiatric disorders such as, for example, the obsessive-compulsive disorder and chronic pain.

[0003] It is known that for the diagnosis and treatment of diseases afflicting the brain of a patient, such as epilepsy, is of fundamental importance to locate the areas, or "foci", in which these diseases originate and to make a precise mapping thereof. In the case of epilepsy, for example, those areas are called "epileptogenic zones", i.e. the set of cortical regions involved in the onset of the electrical discharge produced by neurons.

[0004] Known techniques of a non-invasive type for locating and monitoring the foci of brain diseases are, for example, electroencephalography (EEG) and magnetic resonance imaging mapping (MRI), which are based on the acquisition of bioelectrical signals through a plurality of electrodes applied on the scalp of a patient. Through these techniques it is also possible to monitor the seizures causing the typical symptoms of specific brain diseases.

[0005] Locating and monitoring techniques of an invasive type are also known, involving the use of implantable devices comprising a plurality of intracranial or intraparenchymal electrodes intended to be placed on the cortical surface or in the deep regions of the brain of a patient. These electrodes allow the acquisition of electrocorticographic signals (EcoG), providing the possibility of localizing the foci of brain diseases more accurately and of carrying out a mapping which is more detailed than the mapping that can be made by using conventional EEG signals. Thanks to the direct contact with the cortical surface or the deep regions of the brain in fact, the EcoG bioelectric signals are devoid of the typical disturbances of EEG signals, which are caused by the impedances resulting from the presence of the several layers separating the brain from the electrodes in contact with the scalp.

[0006] Locating the foci of brain diseases and defining their boundaries allow to carry out selective surgery on a patient within the limits imposed by the functional anatomy of the brain.

[0007] Recent studies in the field of epilepsy enabled to understand that the neural mechanism causing the onset of a epileptic seizure is a process of synchronizing epileptic neurons that begin to "discharge" simultaneously. Therefore, the use of implantable devices provided with electrodes has been considered not only for locating and mapping the foci of brain diseases and for monitoring the seizures, but also as a means of electrical stimulation of the brain, for example in order to prevent the neural recruitment at basis of an epileptic seizure. It is known that electrical stimulation produces an effect of desynchronization of the neurons that may prevent a seizure at the onset.

[0008] Some locating and monitoring techniques of an invasive type require the use of subcutaneous connection cables connected at one end to the electrodes of the devices implanted in the brain and at the opposite end to a data acquisition and processing system.

[0009] The presence of connecting cables coming out from the skull of a patient and connected to the processing apparatus requires hospitalization and constant monitoring of the patient, which is anyway exposed to high risks of infection. The patient is also exposed to risks of injury, for example due to the possible stripping of the connecting cables in the event of a seizure. These risks strongly limit the duration of intensive monitoring, which makes it difficult and sometimes impossible to correctly localize the foci of a brain disease.

[0010] There are also known invasive monitoring techniques based on a wireless connection between the implanted devices and the related data acquisition and processing system. The wireless connection allows to eliminate the risk of infection and injury for a patient, as subcutaneous connection cables are completely eliminated. Thanks to these features is also possible to perform monitoring of a patient for longer periods without the need for hospitalization, which allows observation of the patient under normal life conditions, when the manifestation of a seizure related to a brain disease is most likely.

[0011] An example of this kind of monitoring techniques is provided by the patent publication US 2008/0234598 A1, which discloses devices and methods for monitoring the neurological condition of patients with epilepsy. The monitoring methods are based on the analysis of physiological signals from the brain, detected by a plurality of implantable devices comprising a plurality of electrodes. The implantable devices are connected in a wireless mode to an external monitoring device, which allows storage and processing of data related to the bioelectric signals acquired. The electrodes of the implantable devices may be arranged in grid patterns comprising one or more "active" electrodes, i.e. that can acquire bioelectric signals, which are respectively connected via suitable paths to one or more "passive" electrodes, suitable to form a closed circuit with the active electrodes.

[0012] Notwithstanding the availability of acquisition and monitoring systems of bioelectric signals based on wireless implantable devices, there still exists the need to provide implantable devices and methods for locating, monitoring and mapping brain bioelectric signals, which allow to improve the locating and mapping process of the foci of a brain disease and the process of evaluating their extension, which is an object of the present invention.

[0013] It is also an object of the present invention to provide a wireless implantable device that allows to extend the monitoring period of a patient as much as possible.

[0014] Finally, it is an object of the present invention to provide an implantable device that may also be used for intracranial stimulation.

[0015] An idea of solution underlying the present invention is to provide an implantable device comprising a plurality of subdural or intraparenchymal active electrodes, i.e. electrodes suitable for detecting bioelectric signals, and at least one passive or reference electrode, wherein the electrodes are connected to an electronic module comprising a control microprocessor connected to a memory unit. The active electrodes are arranged on a grid connected to the electronic module and are individually connected to at least one analog input unit of the electronic module through suitable connections. The at least one analog input unit comprises an analog-to-digital converter for each active electrode, whereby it is possible to acquire in parallel the bioelectric signals detected by each active electrode.

[0016] In other words, the acquisition of the signals from the active electrodes is simultaneous in all the points of the grid of the implantable device, everyone of which has a precise spatial location and therefore corresponds to a uniquely defined point of the cortical surface. This allows to locate and map a focus of a brain disease very precisely, e.g. an epileptic focus, because at each instant of the acquisition period data are available of bioelectric signals detected in the whole area of the brain on which the implantable device is applied.

[0017] The grid of the active electrodes of the implantable device is preferably formed on a flexible printed circuit, while the electronic module comprises a rigid printed circuit board on which the flexible printed circuit is fixed and electrically connected. This configuration allows to house the electronic components required for the operation of the implantable device within a small size electronic module, while maximizing the contact area of the active electrodes arranged on the grid and facilitating their contact with the brain thanks to the deformability of the flexible printed circuit.

[0018] The flexible printed circuit is preferably made of polyimide and may advantageously be provided with a coating of biocompatible and non-stick material, which allows to minimize the problems of adhesion to cerebral tissues during the monitoring period of the patient, after which the device is removed. The monitoring period can thus be advantageously longer than what is currently permitted by known monitoring and acquisition devices of brain bioelectrical signals, thus paving the way for the study of brain diseases.

[0019] According to an embodiment of the invention, the active electrodes are provided with a coating having a rough surface, e.g. obtained by depositing through sublimation a layer of platinum according to the pulsed laser technology. This advantageously allows to increase the contact surface of the individual active electrodes, thereby minimizing the problems related to contact impedances and thus improving the quality of the bioelectrical signals acquired from the implantable device.

[0020] The implantable device is advantageously of a wireless type and to this aim it comprises an antenna connected to the electronic module and suitable for wireless transmission of the data related to bioelectric signals acquired by the active electrodes, which allows remote connection of the implantable device to a data acquisition and processing system comprising a base station adapted to receive data transmitted from the electronic module of the implantable device and connectable to an computer, for example a personal computer.

[0021] The data acquisition and processing system may also comprise a portable radio device adapted to receive data transmitted from the electronic module of the implantable device in order to transfer them to a computer. This configuration of the data acquisition and processing system is particularly advantageous, because it enables monitoring of the brain activity of a patient without requiring the patient to remain in the vicinity of a radio base station.

[0022] According to a further aspect of the invention, the monitoring and acquisition device may also be used for brain stimulation by way of electrical pulses, which is particularly advantageous in the preventive treatment of the seizures typical of brain diseases in combination with the long monitoring periods provided by the structural features of the device. Brain stimulation is preferably localized, performed by identifying a focus through a warning signal and by activating only the electrodes located in this region of the brain.

[0023] To this aim, the control microprocessor of the implantable device may be programmed to generate electrical pulses and comprises a digital-to-analog converter connected to one or more of the active and/or passive electrodes through an amplifier and at least one switch.

[0024] The possibility of using the device for brain stimulation in a localized manner and to leave the device *in situ* for extended periods of time provides the additional advantage of allowing the development of brain-computer interfaces, for example for rehabilitation purposes following ischemic episodes or for the treatment of chronic neuropsychiatric diseases such as e.g. drug abuse, anorexia, bulimia and depression.

[0025] Moreover, the development of brain-computer interfaces may allow patients with severe lesions of the neurological system to control robotic devices such as, for example, exoskeletons, artificial limbs and the like, as well as transport devices such as wheelchairs for disabled people, and more generally automated devices such as doors, gates and elevators.

[0026] Further advantages and features of the implantable device for the acquisition and monitoring of brain bioelectric signals according to the present invention will become clear to those skilled in the art from the following detailed and non-limiting description of embodiments thereof with reference to the accompanying drawings in which:

- Figure 1 shows a block diagram of a system for acquiring and processing data comprising an implantable device for the acquisition and monitoring of brain bioelectric signals according to the invention;
- Figure 2 shows a schematic perspective view of the implantable device of the system of Figure 1 implanted in the skull of a patient;
- Figures 3a and 3b respectively show a schematic plan view from below and a schematic view in longitudinal section of the implantable device according to the invention;
- Figure 4 shows a circuit diagram of the implantable device according to the invention;
- Figure 5 shows a partial cross-sectional view of the skull of a patient in which the implantable device of the invention is implanted;
- Figure 6 shows a block diagram of a radio base station of the system of Figure 1;
- Figure 7 shows a partial cross-sectional view similar to that of Figure 5, wherein the implantable device is coupled to a charging device;
- Figure 8 shows a perspective view of a portable device of the system of Figure 1, and
- Figure 9 shows a schematic perspective view of a radio base station of the system of Figure 1 connected to a computer.

[0027] Figure 1 shows a system for acquiring and processing data comprising an implantable device, indicated with reference number 150. As shown in Figure 2, the implantable device 150 is intended to be implanted in the skull of a patient in contact with a portion of the cortical surface.

[0028] The implantable device 150 according to the invention comprises a grid 1000 on which a plurality of active electrodes suitable for detecting brain bioelectric signals are arranged, in particular EcoG signals. The grid 1000 is connected to an electronic module 200 of the implantable device 150.

[0029] The implantable device 150 is preferably of a wireless type and to this aim it is provided with an antenna 216 connected to the electronic module 200 and suitable to allow wireless transmission of data related to bioelectric signals acquired by the active electrodes to a data acquisition and processing system. The antenna 216 is preferably of microstrip planar type.

[0030] The implantable device 150 is also provided with an energy storage system, such as a battery, preferably of a rechargeable type, housed in the electronic module 200. In order to allow charging of the battery, the implantable device 150 also comprises a winding suitable to convert picked up electromagnetic waves into an electric voltage. In the illustrated embodiment this winding is for example a magnetic transducer 225 connected to the electronic module 200.

[0031] The data acquisition and processing system suitable to receive the bioelectric signals acquired by the active electrodes of the implantable device 150 comprises a radio base station 600 connected to a computer 800, for example a personal computer, and is provided with an antenna 610 suitable to receive in a wireless mode the data relating to the brain bioelectric signals transmitted from the antenna 216 of the implantable device 150.

[0032] The radio base station 600 allows to control the operation of the implantable device 150 and to store the data acquired through the active electrodes for their further processing, and also comprises a winding configured to generate electromagnetic waves suitable to recharge the rechargeable battery of the implantable device 150 through the magnetic transducer 225. In the illustrated embodiment this winding is in particular an inductive coupler 690. The radio base station 600 can also be used for transmission of data to the implantable device 150, in particular for its electronic programming through a dedicated software.

[0033] The data acquisition and processing system may also comprise a portable device 400 provided with an antenna 410 suitable for wireless reception of the data transmitted from the antenna 216 of the implantable device 150. Similarly to the base station, the portable device 400 allows to control the operation of the implantable device 150 and to store the data relating to the acquired bioelectric signals, for example on a removable memory card suitable to allow transfer of data to a processing unit. The provision of a portable apparatus is advantageous in particular for medium/long term monitoring, as it makes the patient independent from the base station while maintaining the connection with the implantable device 150.

[0034] The radio base station 600 may be advantageously configured to communicate with the portable device 400, both to download the data stored in the memory card of the latter and to update its software.

[0035] The portable device 400, the radio base station 600 and its connections to a computer are schematically illustrated in Figures 8 and 9.

[0036] The wireless transmission of data related to the bioelectric signals acquired by the active electrodes is preferably carried out according to the MICS standard (Medical Implant Communications Service), in the frequency band from 402 MHz to 405MHz. The frequencies and the radiated power define a good propagation through the tissues of the human body and cover distances, typically a few meters, which are useful to these types of application without creating risks to the health of the patient in which the implantable device 150 is implanted.

[0037] Depending on the desired monitoring period, the type of brain disease and the health condition of the patient, data transmission from the implantable device 150 may be accomplished according to a continuous or real time mode, or to a discontinuous mode, in which data are transmitted at predetermined time intervals or in response to an event typical of the patient's disease, for example an epileptic seizure.

[0038] The electronic module 200 comprises a container made of a biocompatible material within which the electronic components necessary for the operation of the implantable device 150 are housed.

[0039] Referring now to Figures 3a, 3b and 4, the implantable device 150 comprises a plurality of active electrodes 1100 arranged on the grid 1000 according to a predefined pattern. In the illustrated embodiment the grid 1000 has a substantially Latin cross shape at the base of which the electronic module 200 is arranged. It will be understood that the Latin cross shape of the grid 1000 is not binding in the invention and that other shapes are possible, for example designed to be adapted to particular areas of the cortical surface.

[0040] The grid 1000 is preferably made on a flexible printed circuit 900, which is elastically deformable by a force of a limited extent, allowing ease of adaptation of the implantable device 150 to the shape, in particular the curvature, of the portion of the cortical surface onto which it is applied.

[0041] As shown in Figures 3a and 3b, the electronic module 200 instead comprises a rigid printed circuit board 901, i.e. not elastically deformable, on which all the electronic components necessary for the operation of the implantable device 150 are mounted.

[0042] With reference to Figure 5, while the flexible printed circuit 900 is intended to come into contact with the cortical surface, the electronic module 200 is intended to be housed in a seat formed in the skull of the patient.

[0043] Figure 3b schematically shows an example of coupling between the rigid printed circuit board 901 and the flexible printed circuit 900. The rigid printed circuit board 901 includes in particular two portions respectively arranged on opposite faces of the flexible printed circuit 900. Reference numbers 950 and 960 schematically indicate the electronic components mounted on the rigid printed circuit board 901, while reference number 219 indicates the rechargeable battery of the implantable device 150, for example a lithium battery, suitable to supply the electronic components 950 and 960.

[0044] The magnetic transducer 225 necessary for charging the rechargeable battery 219 and the radio antenna 216 are respectively connected to the electronic module 200, for example on opposite sides thereof. These components are preferably mounted on flexible printed circuits, for example on portions of the same flexible printed circuit board 900 on which the active electrodes 1100 are arranged.

[0045] The flexible printed circuit 900 is preferably made of polyimide and is provided with a coating of biocompatible and non-stick material, which allows to minimize the adhesion problems between the implantable device 150 and brain tissues during the monitoring period of the patient, after which the implantable device 150 is generally removed. The coating of non-stick material is not applied on the active electrodes 1100, which must instead contact the brain tissue.

[0046] Among the suitable non-stick coatings, particularly effective is the use of polymers of the family of poly(para-xylylene) applied through processes of chemical vapor deposition. These polymers are already known for the coating of implantable biomedical devices, but it has been experimentally verified that they also allow to minimize the interference problems in the wireless transmission of the data related to the bioelectrical signals. Among these polymers, particularly effective is the use of the commercial product Parylene C, already known for the insulating coating of electronic circuits.

[0047] The monitoring period can thus be advantageously longer than the monitoring periods achievable with known monitoring and acquisition devices of brain bioelectrical signals, thus paving the way for the study of brain diseases and allowing to foresee the possibility of a permanent implant.

[0048] The electrodes 1100 are preferably made of a titanium-tungsten alloy and may be advantageously provided with a rough contact surface, which allows to increase the contact surface area at the interface between the active electrodes and the cortical surface, thus minimizing disturbances deriving from contact impedances. The electrodes 1100 preferably comprise a coating of a noble metal, e.g. platinum, applied by using the pulsed laser deposition technology, also known under the acronym USPLD (Ultra Short Pulsed Laser Deposition), which makes the surface porous by sublimation.

[0049] The number of active electrodes 1100 on the grid 1000 may vary depending on the size of the surface area of the cortical surface to be monitored, as well as on the desired mapping resolution, and may for example be equal to one hundred twenty eight, two hundred fifty six, one thousand twenty four and two thousand forty eight. In the illustrated embodiment one hundred twenty eight active electrodes 1100 are shown.

[0050] According to the present invention, the active electrodes 1100 are individually connected to the electronic module 200 so as to allow the acquisition of bioelectrical signals in parallel in the whole area of the portion of the cortical surface on which the active electrodes 1100 of the implantable device 150 are arranged.

[0051] The connection of the active electrodes 1100 is carried out by means of respective paths 115 formed on the grid 1000 and connected to at least one analog input unit arranged in the electronic module 200. The analog input unit is in turn connected to a microprocessor 213 of the electronic module 200 through a data bus 214, for example of serial type.

[0052] The analog input unit is also connected to at least one passive electrode and comprises an analog-to-digital converter for each active electrode 1100, which allows to acquire in parallel and simultaneously all the bioelectric signals detected by the active electrodes 1100. Each analog-to-digital converter is configured to generate digital replicas of the analog signals received from the active electrodes 1100 and the microprocessor 213 is adapted to simultaneously read the outputs of the analog-to-digital converters.

[0053] The simultaneous acquisition of bioelectrical signals from all the active electrodes 1100, everyone of which has a precise spatial location on the grid 1000 and thus corresponds to a uniquely defined point of the cortical surface, allows to obtain a remarkable accuracy in the localization of a focus of a brain disease and in its mapping, because at each detection instant data of the bioelectrical signals detected in the whole area of the cortical surface on which the implantable device 150 is applied are available.

[0054] According to an embodiment of the invention, shown in Figure 4, the active electrodes 1100 may advantageously be divided into groups, for example eight groups of sixteen electrodes 1100, everyone of which is connected to a respective analog input unit, hereinafter referred to as AFE (Analog Front End).

[0055] In the illustrated embodiment the one hundred and twenty eight active electrodes 1100 are indicated with reference numbers 1 to 16, 17 to 32, 33 to 48, 49 to 64, 65 to 80, 81 to 96, 97 to 112 and 113 to 128, while the eight AFE are indicated with reference numbers 201 to 208. A passive electrode is associated to each group of sixteen active electrodes 1100, the passive electrodes being indicated by REF1 to REF8 and being connected to each one of the eight AFE, respectively.

[0056] As explained above, each AFE comprises an analog-to-digital converter, e.g. a 24-bit analog-to-digital converter, for each active electrode connected thereto. Each AFE further comprises for each active electrode a protective circuit on the analog input port, an amplification stage, a low-pass filter and its control logic for interfacing with the microprocessor 213 of the electronic module 200 through the data bus 214.

[0057] The data related to the bioelectric signals acquired are transmitted to the microprocessor 213, which analyzes and compresses them before transferring them to a transceiver 215 connected to the antenna 216. In order to do this, the microprocessor 213 is provided with a RAM memory 230.

[0058] With particular reference to Figures 4, 6 and 7, the implantable device 150 may also advantageously comprise a detection system suitable to allow locating the magnetic transducer 225 for charging the rechargeable battery 219.

[0059] In the illustrated embodiment, the locating system includes an LED 221 associated with the magnetic transducer 225 of the electronic module 200. The LED 221 is preferably arranged at the center of the magnetic transducer 225, which allows to facilitate the placement of an inductive coupler coil.

[0060] The LED 221 is preferably of an infrared type, which is known to allow a good visibility through the skin.

[0061] Being able to locate the position of the magnetic transducer 225 from the outside, it is possible to align an outer inductive coupler coil for charging the battery 219. In the illustrated embodiment, the inductive coupler 690 of the radio base station 600 comprises to this aim a coil 630.

[0062] The process of alignment between the magnetic transducer 225 and the coil 630 may advantageously be automated, thus allowing to increase the alignment accuracy for the benefit of the charging process. In the illustrated embodiment, the inductive coupler 690 is for example equipped with a photo transistor 625, operating in the same frequency band of the LED 221 and preferably arranged at the center of the coil 630. The correct alignment between the inductive coupler 690 and the magnetic transducer 225 allows to obtain the best magnetic coupling and thus the largest possible transfer of energy, that can induce on the coil of the magnetic transducer 225 a voltage higher than 5V for charging the rechargeable battery 219.

[0063] According to a further aspect of the invention, the implantable device 150 may be used not only for the acquisition of bioelectrical signals from the cortical surface, but also for its electrical stimulation, for example to prevent the epileptic seizures at their onset.

[0064] Still with reference to Figure 4, the implantable device 150 comprises to this aim at least one digital-to-analog converter arranged inside the microprocessor 213 and programmable in order to generate electric pulses having a predefined waveform and voltage on one or more pairs of active electrodes 1100 or on one or more pairs formed of one active electrode 1100 and one passive electrode.

[0065] The electric pulses generated by the digital-to-analog converter are amplified by an amplifier 224 connected to the microprocessor 213 and arranged in the electronic module 200, and sent to at least one switch connected to a plurality of pairs of active and/or passive electrodes.

[0066] In the embodiment shown in Figure 4, four switches are shown indicated by reference numerals 209 to 212, everyone of which comprises two sixteen paths switches that allow to send electric pulses to all the one hundred twenty eight active electrodes. The choice of the pair or pairs of active and/or passive electrodes to which the electric pulses must be sent is directly managed by the microprocessor 213 through a data bus 232, e.g. a parallel type data bus.

[0067] The embodiments of the invention herein disclosed and illustrated are only examples susceptible of numerous variants. For example, the implantable device 150 may comprise an accelerometer, e.g. an accelerometer of the MEMS type, connected to the microprocessor 213 and suitable to allow automatic detection of the movement of the patient. This further feature may be useful when the implantable device 150 is used with epileptic patients, because it allows to detect the onset conditions

of an epileptic seizure, in particular convulsions, in a different way with respect to the direct acquisition of EcoG signals.
The invention is defined by the attached claims 1-12.

Claims

1. An implantable device (150) for the acquisition and monitoring of brain bioelectric signals, said implantable device (150) comprising a plurality of active electrodes (1100) suitable to be placed in contact with a patient's brain in order to detect brain bioelectric signals, said active electrodes (1100) being arranged on a grid (1000) connected to an electronic module (200) of the implantable device (150), wherein the active electrodes (1100) are connected to a microprocessor (213) of said electronic module (200) through respective paths (115) different from each other, formed on said grid (1000) and connected to analog input units (201, 202, 203, 204, 205, 206, 207, 208) arranged in the electronic module (200), wherein each analog input unit is in turn connected to a respective passive reference electrode (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8) suitable for being placed in contact with a patient's brain and to said microprocessor (213) through a data bus (214), each analog input unit (201, 202, 203, 204, 205, 206, 207, 208) is coupled in parallel to a respective set made up of a plurality of said active electrodes (1100) and comprises an analog-to-digital converter for each active electrode (1100) of said plurality connected thereto, said analog-to-digital converter being configured to generate digital replicas of the analog signals received from the active electrodes (1100) referred to the electric potential of the respective reference electrode (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8) of the set to which the active electrode belongs to and wherein said microprocessor (213) is configured to read the outputs of the analog-to-digital converters simultaneously and in parallel, the implantable device (150) further comprising at least one digital-to-analog converter arranged within the microprocessor (213) and configured to generate electrical pulses having predetermined waveform and voltage on one or more pairs of electrodes comprising active electrodes (1100) and/or passive electrodes (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8), the microprocessor being configured to perform brain stimulation, said reference electrodes being electrically coupled among them only through the respective analog input units.

2. An implantable device according to claim 1, wherein the grid (1000) is made of a flexible printed circuit (900) and wherein the electronic module (200) comprises a rigid printed circuit board (901), said flexible printed circuit (900) being fixed and electrically connected to said rigid printed circuit board (901).

3. An implantable device (150) according to claim 1 or 2, wherein the flexible printed circuit (900) is made of polyimide and is provided with a coating of biocompatible and non-stick material, said biocompatible and non-stick material being a polymer of the family of poly(para-xylylene).

4. An implantable device (150) according to any one of claims 1 to 3, wherein the active electrodes (1100) are provided with a rough contact surface.

5. An implantable device (150) according to any one of claims 1 to 4, further comprising a transceiver (215) and an antenna (216) that are associated with the electronic module (200) and suitable to allow wireless transmission of data related to the bioelectric signals acquired by the active electrodes (1100), said antenna (216) being connected to said transceiver (215) which is in turn connected to the microprocessor (213).

6. An implantable device (150) according to any one of claims 1 to 5, further comprising a rechargeable battery (219) suitable for supplying the electronic module (200), as well as a winding (225) suitable for converting picked up electromagnetic waves into an electric voltage, said winding (225) being configured to allow the charging of said rechargeable battery (219).

7. An implantable device (150) according to claim 6, further comprising a locating system suited to allow detection of the magnetic transducer (225) in an operative condition of the implantable device (150), said locating system comprising an LED (221) associated to the magnetic transducer (225).

8. An implantable device (150) according to claim 7, wherein said LED (221) is arranged at the center of the magnetic transducer (225) and is an infrared-type LED.

9. An implantable device (150) according to claim 1, further comprising an amplifier (224) connected to the microprocessor (213) and arranged in the electronic module (200), said amplifier (224) being configured to amplify the electrical pulses generated by said at least one digital-to-analog converter, and at least one switch (209, 210, 211, 212) connected to a plurality of pairs of active electrodes (1100) and/or passive electrodes (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8).

10. An implantable device (150) according to claim 9, further comprising a data bus (232) suitable to con-

nect the microprocessor (213) to the at least one switch (209, 210, 211, 212) for the selection of the pair or pairs of active electrodes (1100) and/or passive electrodes (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8) to which the electrical pulses generated by the at least one digital-to-analog converter must be sent.

11. A data acquisition and processing system comprising a radio base station (600), said radio base station (600) being provided with an antenna (610) suitable for wireless reception of data relating to the brain bioelectric signals transmitted from an antenna (216) of an implantable device (150) for acquisition and monitoring of bioelectric signals, as well as a portable device (400), said portable device (400) being provided with an antenna (410) suitable for wireless reception and storage of data transmitted by the antenna (216) of said implantable device (150), **characterized in that** the implantable device (150) is a device according to any one of claims 1 to 10.

12. A data acquisition and processing system according to claim 11, wherein the radio base station (600) further comprises a winding (219) configured to generate electromagnetic waves suitable to allow recharging of the rechargeable battery (219) of the implantable device (150).

Patentansprüche

1. Eine implantierbare Vorrichtung (150) zur Erfassung und Überwachung von bioelektrischen Signalen des Gehirns, wobei die besagte, implantierbare Vorrichtung (150) eine Mehrzahl von aktiven Elektroden (1100) umfasst, geeignet, in Kontakt mit dem Gehirn eines Patienten platziert zu werden, um bioelektrische Signale des Gehirns zu detektieren, wobei die besagten aktiven Elektroden (1100) an einem Gitternetz (1000) angeordnet sind, das an einem Elektronikmodul (200) der implantierbaren Vorrichtung (150) angeschlossen ist, wobei die aktiven Elektroden (1100) an einen Mikroprozessor (213) des besagten Elektronikmoduls (20) über zugeordnete, jeweils voneinander unabhängige Pfade (115) angeschlossen sind, die in dem besagten Gitternetz (1000) ausgeformt und an analogen Eingangseinheiten (201, 202, 203, 204, 205, 206, 207, 208) angeschlossen sind, welche in dem Elektronikmodul (200) angeordnet sind, wobei jede analoge Eingangseinheit ihrerseits an jeweils einer passiven Bezugselektrode (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8) angeschlossen ist, welche geeignet ist, in Kontakt mit dem Gehirn eines Patienten versetzt zu werden sowie mit dem besagten Mikroprozessor (213) über einen Datenbus (214), wobei jede analoge Eingangseinheit (201, 202, 203, 204, 205, 206, 207, 208) parallel an je einen Satz aus einer Mehrzahl der besagten, aktiven Elektroden (1100) gekoppelt ist und einen Analog-zu-Digital-Wandler für jede aktive Elektrode (1100) der besagten, angekoppelten Mehrzahl aufweist, wobei ein derartiger Analog-zu-Digital-Wandler konfiguriert ist, um digitale Nachbildungen der von den besagten, aktiven Elektroden (1100) empfangenen, analogen Signale zu erzeugen, welche sich auf das elektrische Potential der zugeordneten Referenzelektrode (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8) desjenigen Satzes beziehen, zu der die aktive Elektrode gehört, und wobei der besagte Mikroprozessor (213) dazu konfiguriert ist, die Ausgangssignale der Analog-zu-Digital-Wandler simultan und parallel zu lesen, wobei die implantierbare Vorrichtung (150) ferner wenigstens einen innerhalb des Mikroprozessors (213) angeordneten Digital-zu-Analog-Wandler umfasst, der dazu konfiguriert ist, elektrische Impulse mit vorgegebenem Kurvenverlauf und Spannung an einem oder mehreren Paaren von Elektroden, umfassend aktive Elektroden (1100) und/oder passive Elektroden (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8), hervorzurufen, wobei der Mikroprozessor konfiguriert ist, um eine Stimulation des Gehirns durchzuführen, wobei die besagten Referenzelektroden untereinander nur durch die zugeordneten, analogen Eingangseinheiten elektrisch gekoppelt sind.

2. Eine implantierbare Vorrichtung gemäß Anspruch 1, wobei das Gitternetz (1000) aus einem biegsamen, gedruckten Schaltkreis (900) hergestellt ist, und wobei das Elektronikmodul (200) einen festen, gedruckten Schaltkreis (901) umfasst, wobei der besagte, biegsame, gedruckte Schaltkreis (900) an dem besagten, festen, gedruckten Schaltkreis (901) befestigt und elektrisch angeschlossen ist.

3. Eine implantierbare Vorrichtung (150) gemäß Anspruch 1 oder 2, wobei der biegsame, gedruckte Schaltkreis (900) aus Polyimid besteht und mit einem Überzug aus einem biokompatiblen und haftfreien Material versehen ist, wobei das besagte, biokompatible und haftfreie Material ein Polymer aus der Familie von Poly(para-Xylylen) ist.

4. Eine implantierbare Vorrichtung (150) gemäß einem der Ansprüche 1 bis 3, wobei die aktiven Elektroden (1100) mit einer rauen Kontaktoberfläche versehen sind.

5. Eine implantierbare Vorrichtung (150) gemäß einem der Ansprüche 1 bis 4, ferner umfassend eine Sende-Empfangs-Einrichtung (215) und eine Antenne (216), welche mit dem Elektronikmodul (200) verbunden sind und geeignet sind, eine drahtlose Übertragung von Daten zu ermöglichen, welche mit den von den aktiven Elektroden (1100) erfassten bioelektrischen Signalen in Zusammenhang stehen, wobei die besagte Antenne (216) an die besagte Sende-Empfangs-Einrichtung (215) angeschlossen ist, welche ihrerseits an den Mikroprozessor (213) angeschlossen ist.

6. Eine implantierbare Vorrichtung (150) gemäß einem der Ansprüche 1 bis 5, ferner umfassend eine wiederaufladbare Batterie (219), geeignet zur Versorgung des Elektronikmoduls (200), sowie eine Wicklung (225), geeignet zur Umwandlung aufgefangener elektromagnetischer Wellen in eine elektrische Spannung, wobei die besagte Wicklung (225) dazu konfiguriert ist, das Aufladen der wiederaufladbaren Batterie (219) zu erlauben.

7. Eine implantierbare Vorrichtung (150) gemäß Anspruch 6, ferner umfassend ein Ortungssystem, geeignet, um die Erkennung des magnetischen Energiewandlers (225) in einem Betriebszustand der implantierbaren Vorrichtung (150) zu erlauben, wobei das besagte Ortungssystem eine LED (221) umfasst, die dem magnetischen Energiewandler (225) zugeordnet ist.

8. Eine implantierbare Vorrichtung (150) gemäß Anspruch 7, wobei die besagte LED (221) im Zentrum des magnetischen Energiewandlers (225) angeordnet und eine Infrarot-LED ist.

9. Eine implantierbare Vorrichtung (150) gemäß Anspruch 1, ferner umfassend einen an den Mikroprozessor (213) angeschlossenen und in dem Elektronikmodul (200) angeordneten Verstärker (224), wobei der besagte Verstärker (224) dazu konfiguriert ist, die von dem wenigstens einen Digital-zu-Analog-Wandler erzeugten Impulse zu verstärken, sowie wenigstens einen an eine Mehrzahl von Paaren von aktiven Elektroden (1100) und/oder passiven Elektroden (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8) angeschlossenen Schalter (209, 210, 211,212).

10. Eine implantierbare Vorrichtung (150) gemäß Anspruch 9, ferner umfassend einen Datenbus (232), geeignet, um den Mikroprozessor (213) mit dem wenigstens einem Schalter (209, 210, 211, 212) für die Auswahl desjenigen Paares oder derjenigen Paare von aktiven Elektroden (1100) und/oder passiven Elektroden (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8) zu verbinden, an welche(s) die von dem wenigstens einen Digital-zu-Analog-Wandler erzeugten, elektrischen Impulse gesandt werden sollen.

11. Ein System zur Erfassung und Verarbeitung von Daten, umfassend eine Funkbasisstation (600), wobei die besagte Funkbasisstation (600) mit einer Antenne (610) versehen ist zum drahtlosen Empfang von Daten, welche mit den bioelektrischen Signalen des Gehirns in Zusammenhang stehen, die von einer Antenne (216) einer implantierbaren Vorrichtung (150) zur Erfassung und Überwachung von bioelektrischen Signalen gesendet wurden, sowie ein tragbares Gerät (400), wobei das besagte, tragbare Gerät (400) mit einer Antenne (410) versehen ist zum drahtlosen Empfang und zur Speicherung von Daten, welche von der Antenne (216) der implantierbaren Vorrichtung (150) gesendet wurden, **dadurch gekennzeichnet, dass** die implantierbare Vorrichtung (150) eine Vorrichtung nach einem der Ansprüche 1 bis 10 ist.

12. Ein System zur Erfassung und Verarbeitung von Daten gemäß Anspruch 11, wobei die Funkbasisstation (600) ferner eine Wicklung (219) umfasst, welche dazu konfiguriert ist, um elektromagnetische Wellen zu erzeugen, die geeignet sind, um die Nachladung der wiederaufladbaren Batterie (219) der implantierbaren Vorrichtung (150) zu erlauben.

Revendications

1. Dispositif implantable (150) destiné à l'acquisition et à la surveillance de signaux bioélectriques du cerveau, ledit dispositif implantable (150) comprenant une pluralité d'électrodes actives (1100) adaptées pour être placées en contact avec le cerveau d'un patient afin de détecter les signaux bioélectriques du cerveau, lesdites électrodes actives (1100) étant placées sur une grille (1000) reliée à un module électronique (200) du dispositif implantable (150), dans lequel les électrodes actives (1100) sont reliées à un microprocesseur (213) dudit module électronique (200) par le biais de trajets respectifs (115) différents les uns des autres, formés sur ladite grille (1000) et reliés à des unités d'entrée analogiques (201, 202, 203, 204, 205, 206, 207, 208) placées dans le module électronique (200), dans lequel chaque unité d'entrée analogique est à son tour reliée à une électrode de référence passive respective (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8) adaptée pour être placée en contact avec le cerveau d'un patient et ledit microprocesseur (213) par le biais d'un bus de données (214), chaque unité d'entrée analogique (201, 202, 203, 204, 205, 206, 207, 208) étant reliée en parallèle à un ensemble respectif composé d'une pluralité desdites électrodes actives (1100) et comprenant un convertisseur analogique-numérique pour chaque électrode active (1100) de ladite pluralité reliée à celle-ci, ledit convertisseur analogique-numérique étant configuré pour générer des répliques numériques des signaux analogiques reçus de la part des électrodes actives (1100), désignées potentiel électrique de l'électrode de référence respective (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8) de l'ensemble auquel l'électrode active appartient et dans lequel ledit microprocesseur (213) est configuré pour lire les sorties des convertisseurs analogique-numérique de manière simultanée et en parallèle, le dispositif implantable (150) comprenant en outre au moins un convertisseur analogique-numérique placé à l'intérieur du microprocesseur (213) et configuré pour générer des impulsions électriques ayant une forme d'onde et une tension prédéterminées sur une ou plusieurs paire(s) d'électrodes comprenant des électrodes actives (1100) et/ou des électrodes passives (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8), le microprocesseur étant configuré pour réaliser une stimulation cérébrale, lesdites électrodes de référence étant électriquement reliées entre elles et uniquement par le biais des unités d'entrée analogique respectives.

2. Dispositif implantable selon la revendication 1, dans lequel la grille (1000) est composée d'un circuit imprimé souple (900) et dans lequel le module électronique (200) comprend une carte de circuit imprimé rigide (901), ledit circuit imprimé souple (900) étant fixé et électriquement relié à ladite carte de circuit imprimé rigide (901).

3. Dispositif implantable (150) selon la revendication 1 ou 2, dans lequel le circuit imprimé souple (900) est composé de polyimide et est muni d'un revêtement en matériau non collant et biocompatible, ledit matériau non collant et biocompatible étant un polymère de la famille du poly(paraxylylène).

4. Dispositif implantable (150) selon l'une quelconque des revendications 1 à 3, dans lequel les électrodes actives (1100) sont munies d'une surface de contact rugueuse.

5. Dispositif implantable (150) selon l'une quelconque des revendications 1 à 4, comprenant en outre un émetteur-récepteur (215) et une antenne (216) qui sont associés au module électronique (200) et adaptés pour permettre la transmission sans fil de données relatives aux signaux bioélectriques reçus par les électrodes actives (1100), ladite antenne (216) étant reliée audit émetteur-récepteur (215) qui est à son tour relié au microprocesseur (213).

6. Dispositif implantable (150) selon l'une quelconque des revendications 1 à 5, comprenant en outre une batterie rechargeable (219) adaptée pour alimenter le module électronique (200), et une bobine (225) adaptée pour convertir des ondes électromagnétiques captées en une tension électrique, ladite bobine (225) étant configurée pour permettre le chargement de ladite batterie rechargeable (219).

7. Dispositif implantable (150) selon la revendication 6, comprenant en outre un système de localisation adapté pour permettre la détection du transducteur magnétique (225) dans un état de fonctionnement du dispositif implantable (150), ledit système de localisation comprend une LED (221) associée au transducteur électromagnétique (225).

8. Dispositif implantable (150) selon la revendication 7, dans lequel ladite LED (221) est placée au milieu du transducteur électromagnétique (225) et est une LED de type infrarouge.

9. Dispositif implantable (150) selon la revendication 1, comprenant en outre un amplificateur (224) relié au microprocesseur (213) et placé dans le module électronique (200), ledit amplificateur (224) étant configuré pour amplifier les impulsions électriques générées par ledit au moins un convertisseur analogique-numérique, et au moins un commutateur (209, 210, 211, 212) relié à la pluralité de paires d'électrodes actives (1100) et/ou d'électrodes passives (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8).

10. Dispositif implantable (150) selon la revendication 9, comprenant en outre un bus de données (232) adapté pour relier le microprocesseur (213) au au moins un commutateur (209, 210, 211, 212) pour la sélection de la paire ou des paires d'électrodes actives (1100) et/ou d'électrodes passives (REF1, REF2, REF3, REF4, REF5, REF6, REF7, REF8) auxquelles les impulsions électriques générées par le convertisseur analogique-numérique au moins doivent être envoyées.

11. Système d'acquisition et de traitement de données comprenant une station de base radio (600), ladite station de base radio (600) étant munie d'une antenne (610) adaptée pour la réception sans fil des données relatives aux signaux bioélectriques du cerveau transmis par une antenne (216) d'un dispositif implantable (150) pour l'acquisition et la surveillance de signaux bioélectriques, et un dispositif portable (400), ledit dispositif portable (400) étant muni d'une antenne (410) adaptée pour la réception sans fil et le stockage des données transmises par l'antenne (216) dudit dispositif implantable (150), **caractérisé en ce que** le dispositif implantable (150) est un dispositif selon l'une quelconque des revendications 1 à 10.

12. Système d'acquisition et de traitement de données selon la revendication 11, dans lequel ladite station de base radio (600) comprend en outre une bobine (219) configurée pour générer des ondes électromagnétiques adaptées pour permettre le rechargement de la batterie rechargeable (219) du dispositif implantable (150).

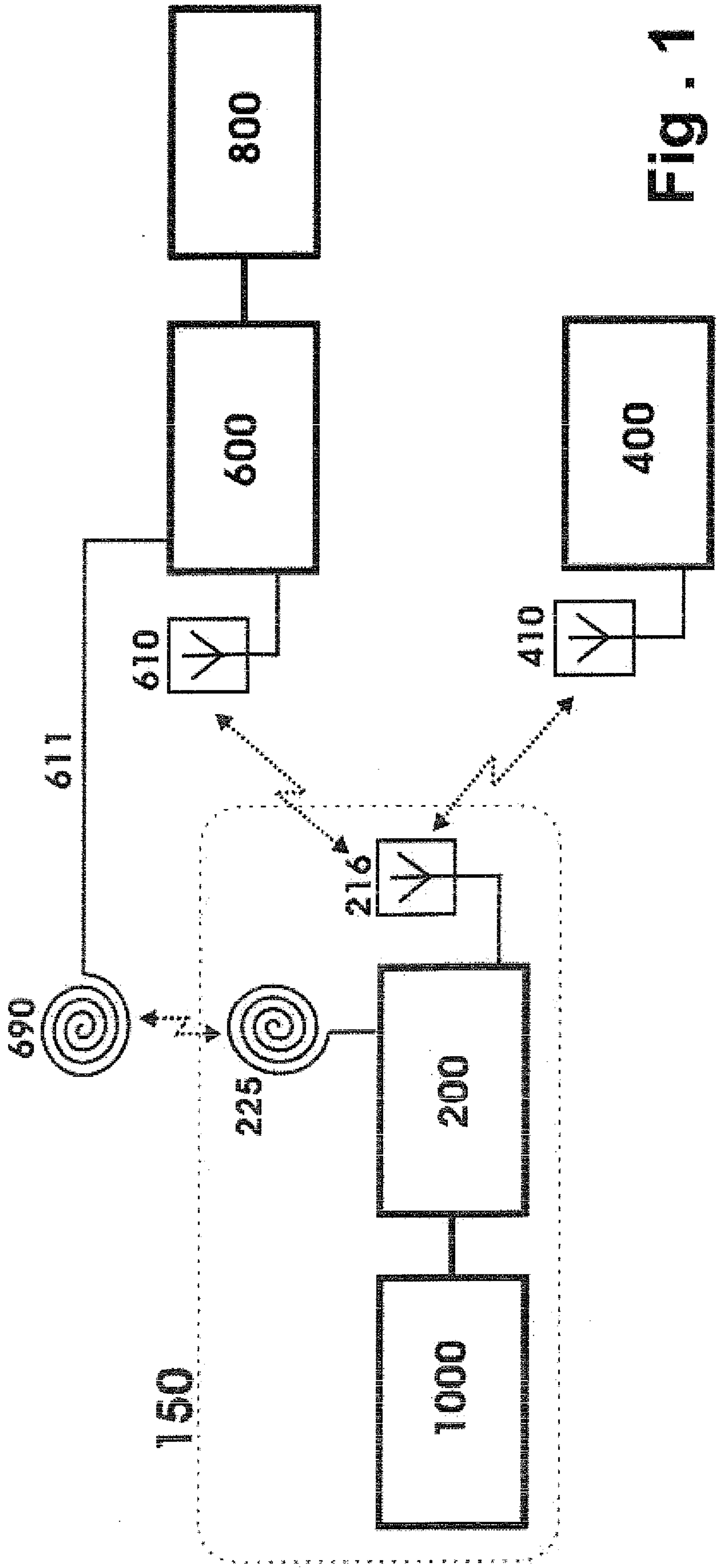


Fig. 1

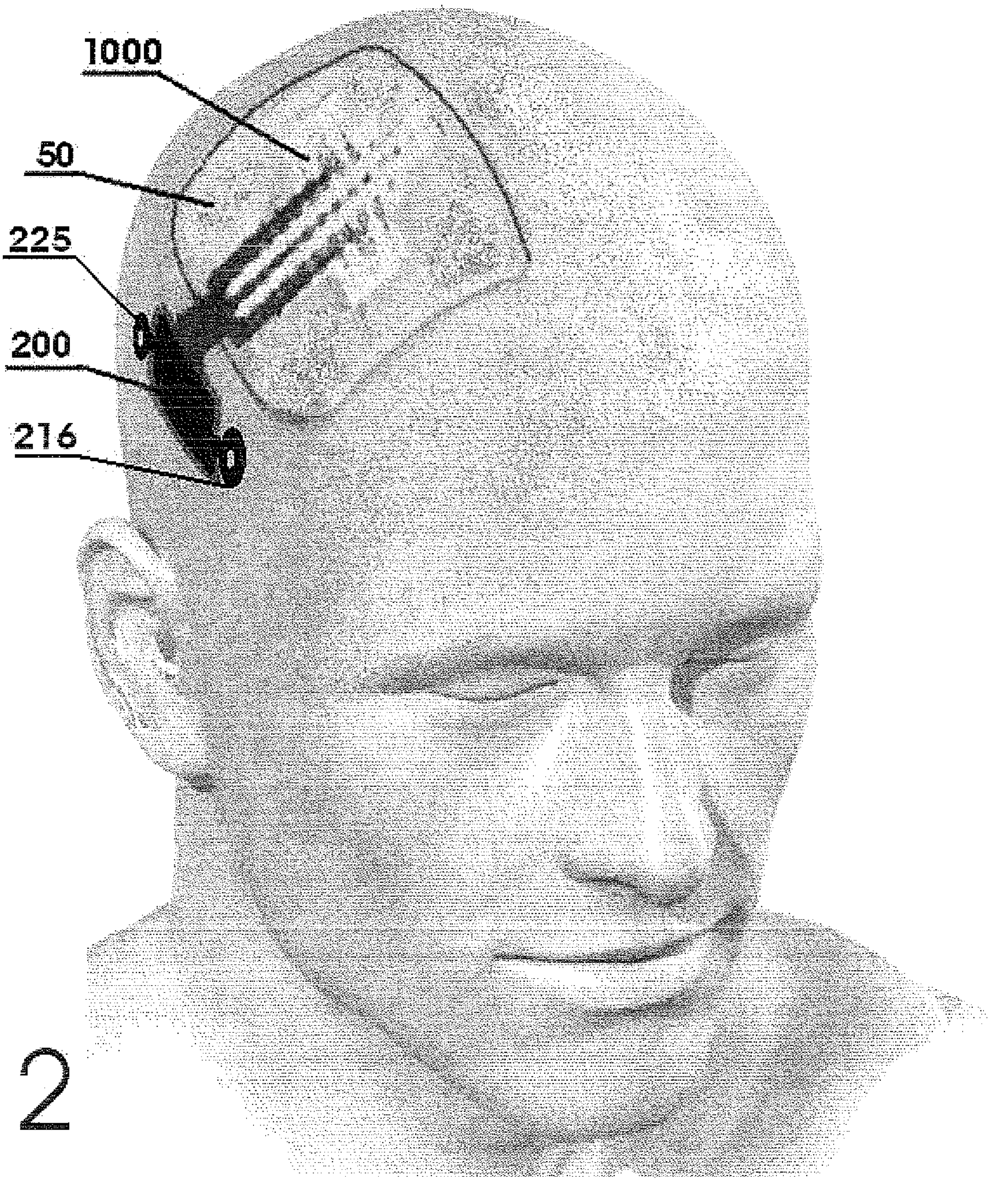


Fig. 2

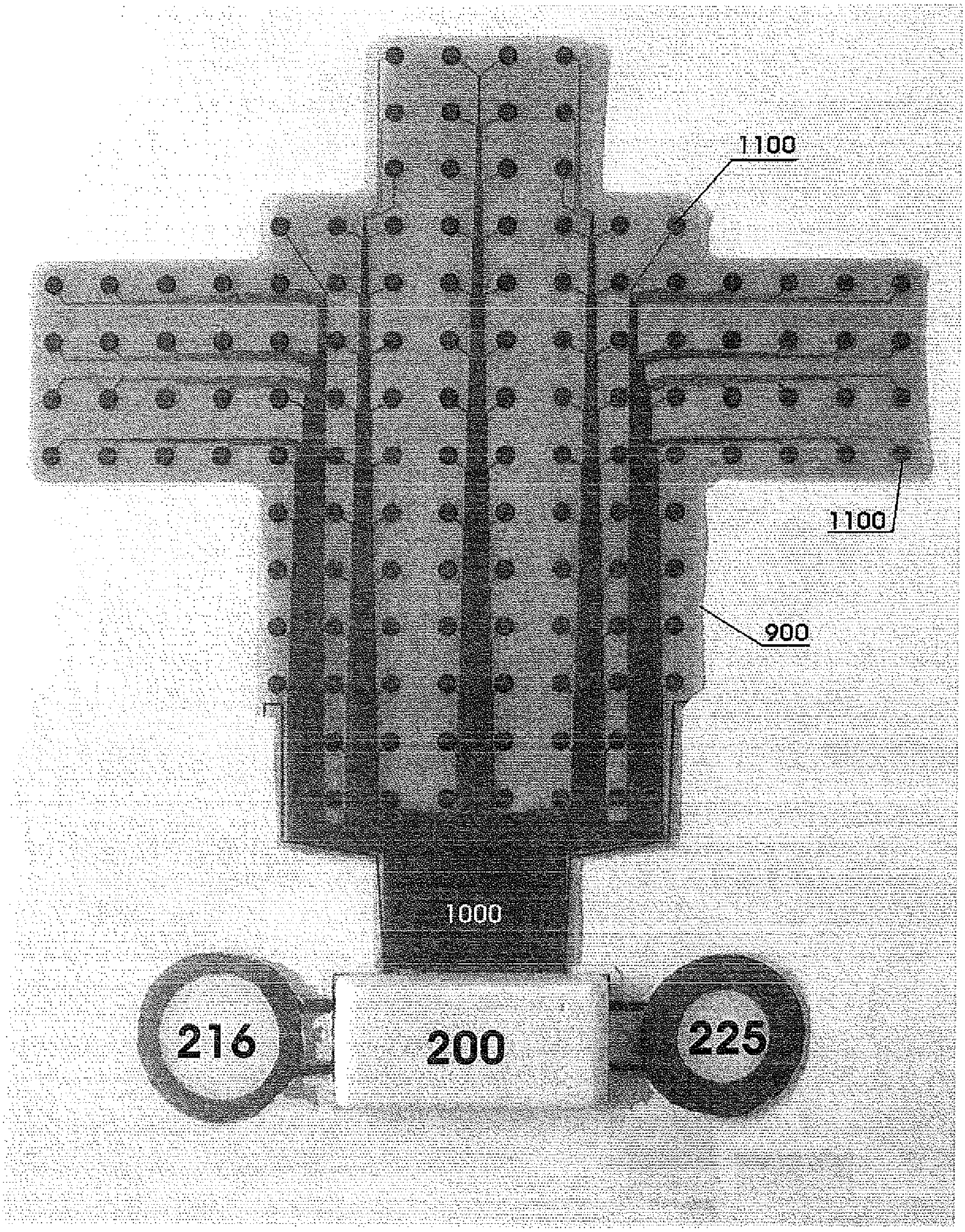


Fig. 3a

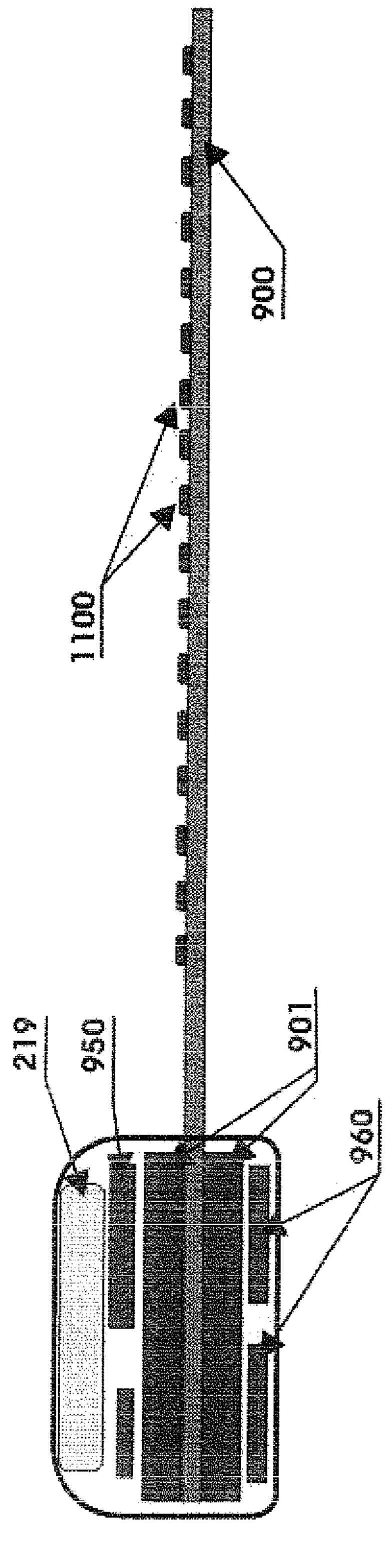
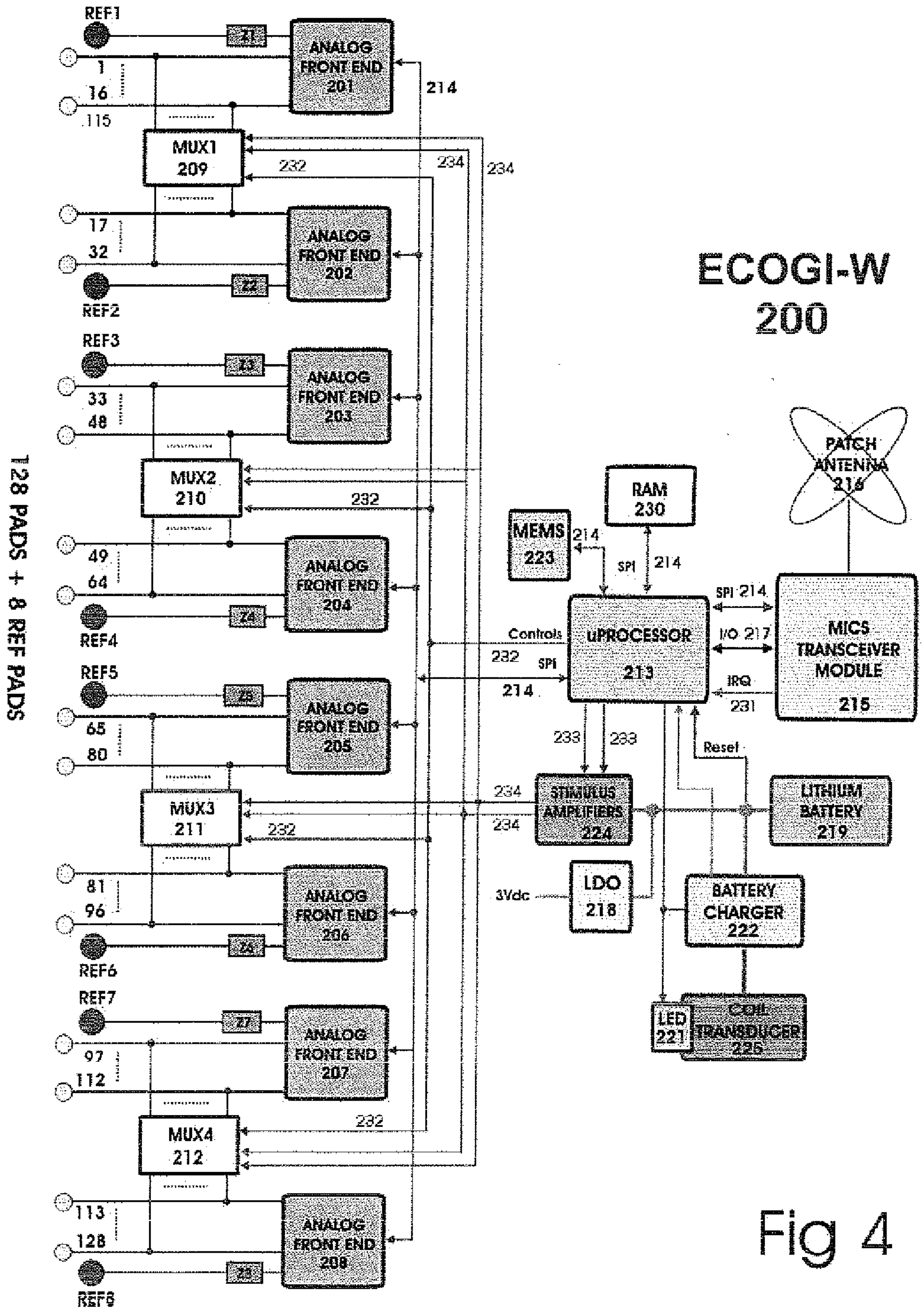


Fig. 3b



ECOGI-W
200
128 PADS + 8 REF PADS
REF1
REF2
REF3
REF4
REF5
REF6
REF7
REF8
ANALOG FRONT END 201
ANALOG FRONT END 202
ANALOG FRONT END 203
ANALOG FRONT END 204
ANALOG FRONT END 205
ANALOG FRONT END 206
ANALOG FRONT END 207
ANALOG FRONT END 208
MUX1 209
MUX2 210
MUX3 211
MUX4 212
214
232
234
PATCH ANTENNA 216
RAM 230
MEMS 223
SPI
uPROCESSOR 213
Controls
MICS TRANSCEIVER MODULE 215
I/O 217
IRQ
231
233
Reset
STIMULUS AMPLIFIERS 224
LITHIUM BATTERY 219
3Vdc
LDO 218
BATTERY CHARGER 222
LED 221
COIL TRANSDUCER 225

Fig 4

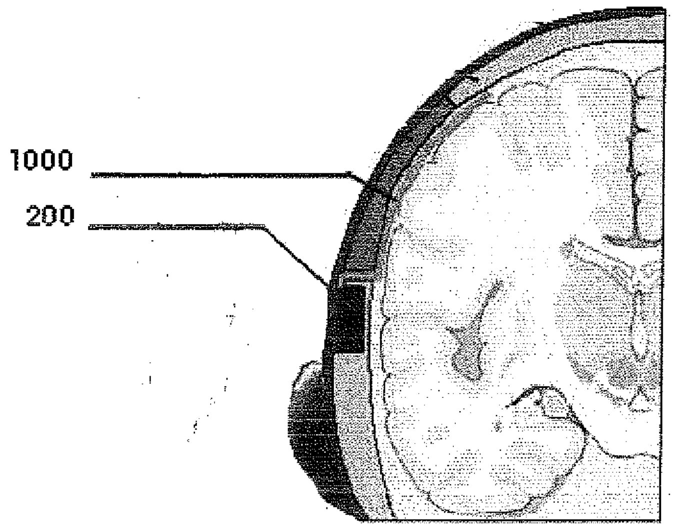


Fig. 5

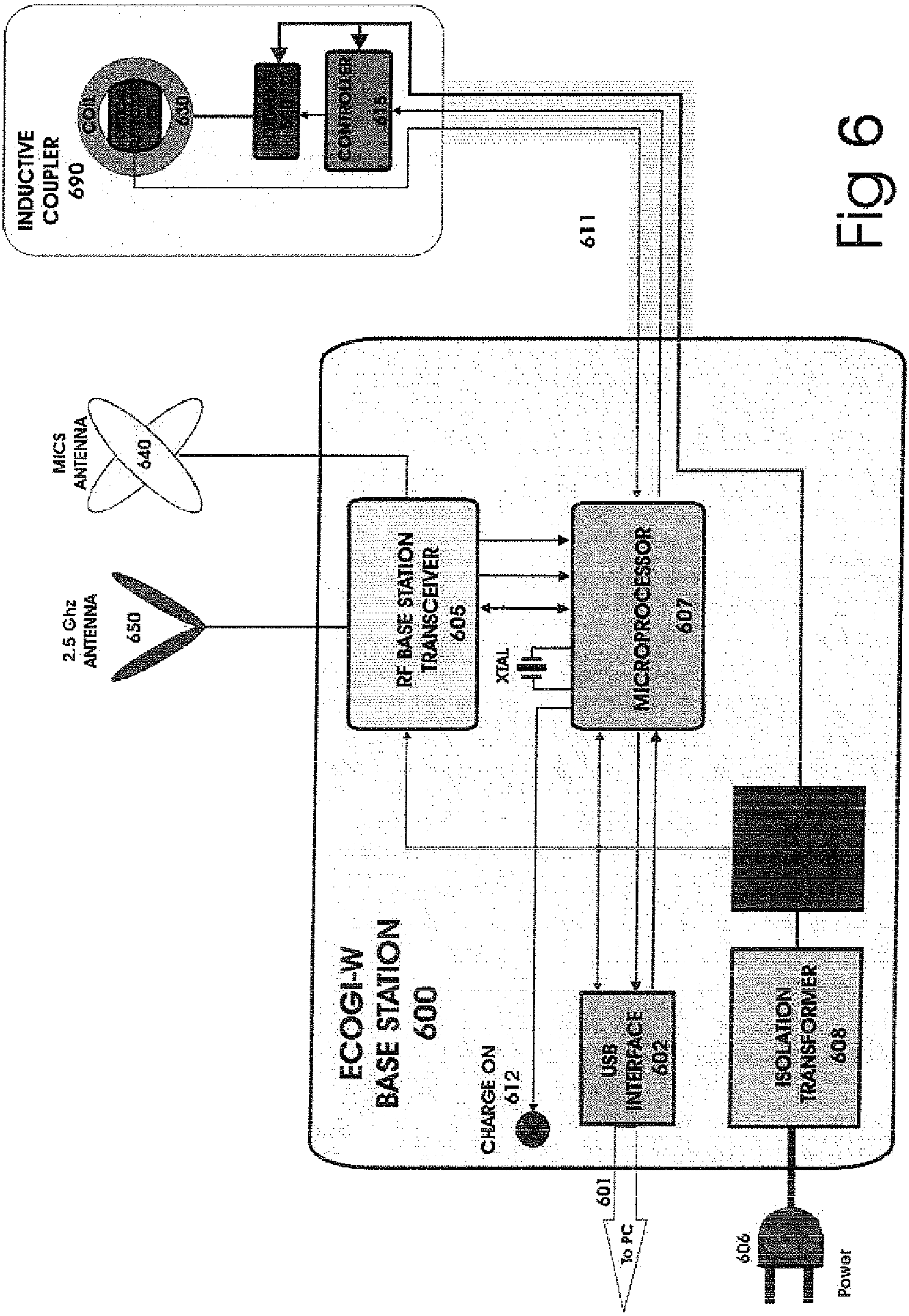

INDUCTIVE
COUPLER
690
COIL
630
CONTROLLER
615
611
MICS
ANTENNA
640
2.5 Ghz
ANTENNA
650
RF BASE STATION
TRANSCEIVER
605
XTAL
MICROPROCESSOR
607
ECOGI-W
BASE STATION
600
CHARGE ON
612
USB
INTERFACE
602
ISOLATION
TRANSFORMER
608
601
To PC
606
Power

Fig 6

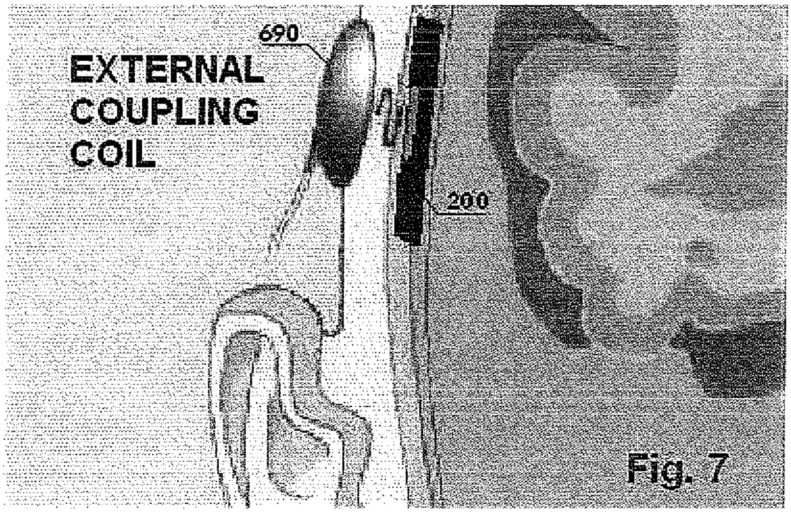


Fig. 7

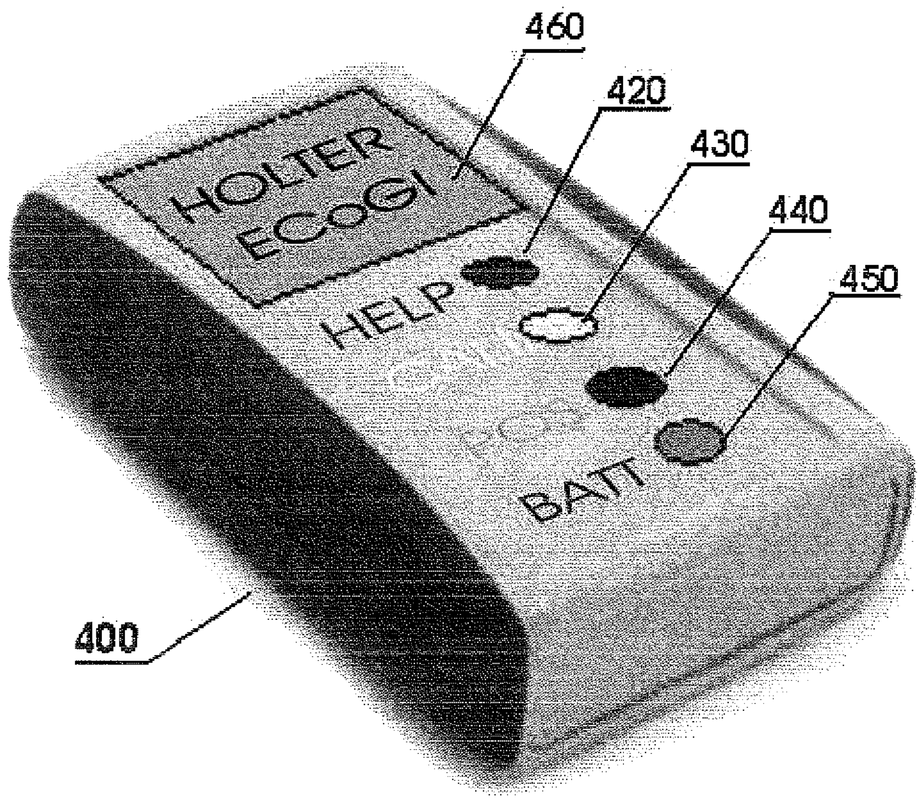


Fig. 8

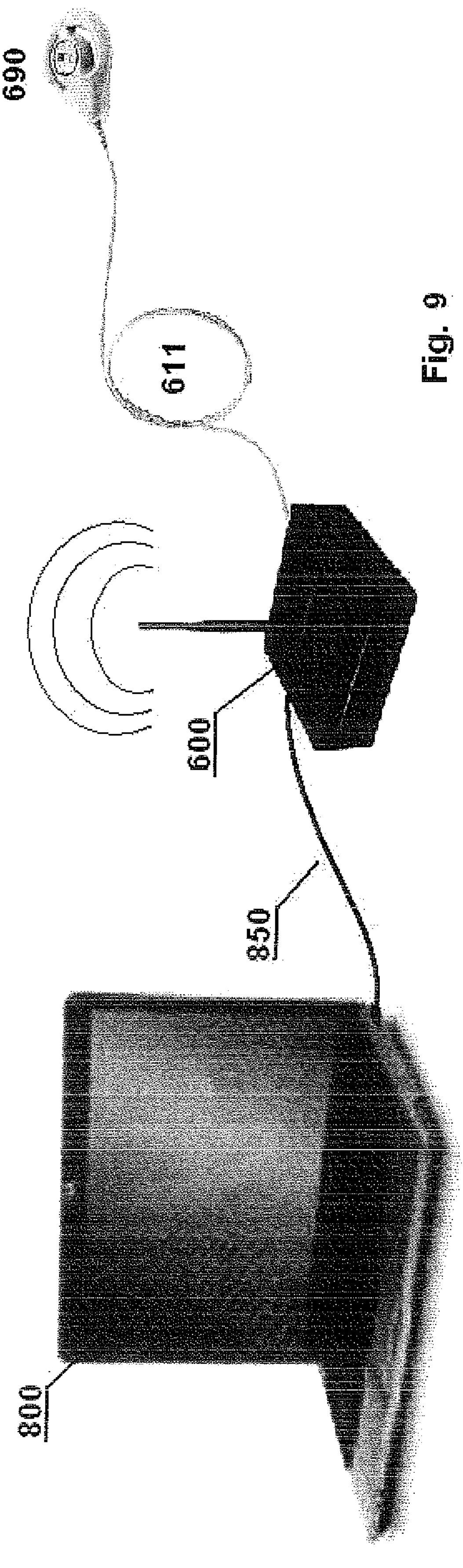


Fig. 9

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 20080234598 A1 **[0011]**

专利名称(译)	用于获取和监测脑生物电信号和颅内刺激的可植入装置		
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CPC分类号	A61N1/36064 A61B5/0031 A61B5/0476 A61B5/6868 A61N1/0476 A61N1/0529 A61N1/0531		
优先权	RM2011000206 2011-04-21 IT		
其他公开文献	EP2699145A1		
外部链接	Espacenet		

摘要(译)

本发明涉及一种用于获取和监测脑生物电信号的可植入装置（150），包括适合于检测脑生物电信号的多个有效电极（1100），所述有源电极（1100）布置在连接的网格（1000）上根据预定义的模式到可植入装置（150）的电子模块（200）。有源电极（1100）通过形成在所述电网（1000）上的相应路径（115）连接到所述电子模块（200）的微处理器（213），并连接到至少一个模拟输入单元（201,202,203，204,205,206,207,208），布置在电子模块（200）中，所述至少一个模拟输入单元又通过数据总线（214）连接到至少一个无源电极（REF1，REF2，REF3，REF4，REF5，REF6，REF7，REF8）和所述微处理器（213）。至少一个模拟输入单元（201,202,203,204,205,206,207,208）包括用于与其连接的每个有源电极（1100）的模数转换器。由于这些特征，可以并行地并且同时获取由每个有源电极检测的生物电信号，这导致脑疾病焦点的定位和映射的准确性的提高。本发明还涉及一种数据采集和处理系统，其包括可植入装置（150）。