(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 2 757 939 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
24.10.2018 Bulletin 2018/43

(21) Application number: **12833644.3**

(22) Date of filing: **19.09.2012**

(51) Int Cl.:
A61B 5/00 *(2006.01)* ***A61B 5/08*** *(2006.01)*

(86) International application number:
PCT/IB2012/002550

(87) International publication number:
WO 2013/041973 (28.03.2013 Gazette 2013/13)

(54) NON-INVASIVE INTRACRANIAL PRESSURE SYSTEM

NICHTINVASIVES SYSTEM FÜR DEN INTRAKRANIELLEN DRUCK

SYSTÈME DE PRESSION INTRACRÂNIEN NON INVASIF

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **19.09.2011 US 201161536347 P**
17.09.2012 US 201213621635

(43) Date of publication of application:
30.07.2014 Bulletin 2014/31

(73) Proprietor: **BRAINCARE DESENVOLVIMENTO E INOVAÇÃO TECNOLÓGICA LTDA.**
13.562-400 São Carlos SP (BR)

(72) Inventor: **HENRIQUE FRIGIERI VILELA, Gustavo**
Araraquara - SP 14811-070 (BR)

(74) Representative: **Capasso, Olga et al**
De Simone & Partners SpA
Via Vincenzo Bellini, 20
00198 Roma (IT)

(56) References cited:
WO-A1-92/02174
WO-A1-2010/056401
GB-A- 2 156 997
US-A- 5 617 873
US-A1- 2009 177 279
US-A1- 2009 234 245
US-A1- 2010 161 004
US-B2- 6 746 410
US-B2- 6 773 407

EP 2 757 939 B1

Description

[0001] The present patent application claims benefit from US2013085400 filed September 17, 2012, and US9826934 filed September 19, 2011.

I. Technical Field

[0002] The technical field includes machine, manufacture, article, process, and product produced thereby, as well as necessary intermediates, which in some cases, pertains to noninvasive intracranial pressure detection and/or monitoring and use of data with respect thereto.

II. SUMMARY

[0003] Depending on the implementation, there is apparatus, a method for use and method for making, and corresponding products produced thereby, as well as data structures, articles, computer-readable media tangibly embodying program instructions, manufactures, and necessary intermediates of the foregoing, each pertaining to non-invasively detecting and/or monitoring intracranial pressure, e.g., in animals, humans, which may be in ex-vivo and/or invivo conditions.

[0004] The invention is defined by the claims. The embodiments described later are merely for illustrative purpose, not necessarily forming part of the invention.

III. FIGURES

[0005]

Figure 1 is an illustrative architecture for embodiment with respect to intracranial pressure monitoring system.

Figure 2 is an illustrative embodiment including a brain strap with a corresponding sensor housing, oriented to a human patient's head.

Figure 3 is an illustrative embodiment of a strap with a sensor housing and an adjustment means.

Figure 4 is an illustrative embodiment of the housing for the sensor.

Figure 5 is another illustrative embodiment of a housing for a sensor.

Figure 6 is another illustrative embodiment of components within the housing.

Figure 7 is another illustrative embodiment of the components within the housing.

Figure 8 is another illustrative embodiment of the components within the housing.

Figure 9 is another illustrative embodiment of the components within the housing.

Figure 10 is another illustrative embodiment of the components within the housing.

Figure 11 is an illustrative embodiment including a brain helmet with a corresponding sensor.

Figure 12 is another illustrative embodiment of the brain helmet.

Figure 13 is an illustrative embodiment of a spring configuration.

Figure 14 is an illustrative of another embodiment of a spring configuration.

Figure 15 is an illustrative embodiment of a computer system.

Figure 16 is an illustrative embodiment of logic flow.

Figure 17 is an illustrative embodiment of an intracranial pressure signal.

Figure 18 is an illustrative embodiment of an intracranial pressure monitor display.

Figure 19 is an illustrative embodiment of an intracranial pressure monitor signal display.

Figure 20 is an illustrative embodiment of a display of intracranial pressure monitoring of a jugular maneuver.

Figure 21 is an illustrative embodiment of a display of intracranial pressure monitoring of epileptic seizures.

Figure 22 is an illustrative embodiment of a display of diagnostic of hydrocephaly.

Figure 23 is an illustrative embodiment of a display with respect to an intravenous use of Sodium Thiopental in pigs.

Figure 24 is an illustrative embodiment of a display with respect to rats having received dipyrone.

Figure 25 is an illustrative embodiment of a display with respect to a response to adrenaline.

Figure 26 is an illustrative embodiment of a display with respect to an intracranial tumor.

Figure 27 is an illustrative embodiment of a display with respect to hydrocephaly and evaluating the performance of shunts.

Figure 28 is an illustrative ICP waveform monitored with the ICPNI monitor.

IV. MODES

[0006] Intracranial Pressure (ICP) is the relation between the volume of the intracranial space and its components: Cerebral spinal fluid (CSF), blood and brain parenchyma. ICP monitoring can be used in the diagnosis and prognostics of various disorders such as neurological disorders, e.g., stroke, hydrocephalus, tumors well as trauma. Rather than using an invasive technique, i.e., requiring shaving, incision in the patient's head, trepanation of the skull bone and sensor insertion in the brain tissue, embodiments herein involve noninvasive embodiments, e.g., for monitoring this medical parameter, through the cranial bone.

[0007] Generally, there can be at least one sensor located to detect intracranial pressure noninvasively, in contrast to being directed to a sensor located invasively, e.g., within a skull or under the skin or where the skin has been removed, e.g., by incision. (The following discussion refers to "sensor" in the singular, with the understanding that embodiments can be configured with one

or more sensors.) The sensor can be located with a strap, as an example of a non-invasive manner of locating the sensor with respect to the subject's head. In some embodiments, the sensor can be detecting intracranial pressure by a spring located between the sensor and the patient's head. In any case, the sensor detects intracranial pressure with signals that can be communicated to equipment. Equipment processes the received signals as signal data. That is, if the signals are analog signals, they are converted to digital signal data. In any case, the signal data is saved to a memory configured to store the signal data. The signal data can be processed and also saved in memory configured to store the processed signal data, and can be rendered at a display.

[0008] The embodiments can be such as to non-invasively detect and/or monitor what is happening directly inside the central nervous system, e.g., in the patient's head, for such variables otherwise not known to be observable without invasive methods. The central nervous system observations are unique because of the many physiological barriers such as bloodbrain-barriers of complex nature containing biochemical, electrophysiological and other components. Peripherical measurements of the arterial or venous pressure or haemodynamic variables normally used in present medical procedures do not necessarily correspond to the corresponding variables monitored by embodiments herein described.

[0009] The accompanying figures and discussion of embodiments are intended to illustrate and exemplify in a teaching manner, by way of the prophetic teachings. With this in mind, turn to Figure 1 and consider that equipment 1 can include sensor device 2 can noninvasively located adjacent and proximate to the head of a subject, such as a human "patient". Sensor device 2, can be located, for example, so as to allow movement by the patient, e.g., with a strap 3. In another embodiment, sensor device 2 can be located, for example, so as to immobilize the patient or in a helmet.

[0010] In some embodiments, the sensor device 2 can detect skull deformation by such as by an electric strain gage, an optical sensor, an optical fiber, a magnetic sensor, an interferometric sensor, or any other device which detects and/or monitors the skull deformation without trichotomy or surgical incision. Sensor device 2 can, but need not, be configured to be disposable or reusable after use by the patient in a detecting session.

[0011] Generally, equipment 1 associates the skull deformation with intracranial pressure detection and changes. Equipment 1 can, but need not, include a signal amplifier 4 to amplify signals received from sensor device 2. Equipment 1 can, but need not, include an analog to digital converter 6. That is, if an analog implementation is carried out, there can be a conversion of the analog signals into digital signals, e.g., signal data. Equipment 1 can be powered by regular utility electricity, e.g., an AC power source, or by battery power, e.g., to allow and/or protect monitoring during a power failure or to under conditions where regular electrical utilities are unavailable, e.g., in an ambulance. The equipment 1 has a capability of receiving signals from at least one, and in some embodiments, multiple sensors, and working with different acquisition frequencies.

[0012] Equipment 1 can include a processor 8, e.g., in a multiparametric monitor, computer, etc, which processes the signal data to produce output data that is stored in memory operably associated with the processor 8, e.g., a digital memory 10. The digital memory (device) 10 can have a database configured to store the signal data and/or the output data. The signal data and/or the output data can be rendered on an internal display 12 and/or on an external display 14.

[0013] The equipment 1 can be configured so that an intracranial pressure apparatus, whatever be the implementation desired, produces output which can include real-time curves of physiological parameters such as intracranial pressure, respiratory and cardiac cycles, and the like on an internal display 12 and/or an external display 14. The equipment 1 can save the data the patient's time series, e.g., for subsequent review and/or processing, in memory 10.

[0014] Consider now the embodiment illustrated in Figures 2 and 3, wherein a noninvasive sensor device 2 for detecting or monitoring ICP includes a sensor device 2, which is configured to provide protection and location for at least one ICP monitoring sensor (not shown in Figure 2). The sensor device 2 can be attached to the patient's head with a strap 3 which can be produced, for example, from an elastic or rigid material and configured to provide dimensional adjustment to the patient's head.

[0015] The strap 3 can be coupled to the sensor device 2 through fittings or other means, e.g., at both ends, such as direct affixing in an upper portion of the sensor housing (Figure 3). The strap 3 can locate one or more of sensor device 2. The strap 3 can, but need not, include an adjustment system 5.

[0016] Helmets, hoods, or arcs may instead be used to affix a sensor device 2 with respect to the patient's head, or other means can be used to provide an equivalent function as the strap 3.

[0017] In the illustration of Figure 4, there can be a sensor housing comprising a lid 7 and a sensor box base 9. Attached to the base 9, there can be a support 11 for a sensor bar 13, adapted for stabilizing and affixing the strain sensor 15 with respect to the base 9.

[0018] At an end of sensing bar 13 (opposite the support 11) there can be a pin 16 configured for contacting the patient's head. This pin 16 can be fixed to bar 13 to communicate changes in skull volume to sensor 15.

[0019] Components such as 7, 9, 11, 13, and 16 can be produced out of metal, polymer, carbon, glass fibers, and any combination thereof.

[0020] Alterations in ICP cause changes in cranial volume, detected by pin 16. The pin 16 of the sensor 15 contacts the surface of the patient's head, to detect variations in the volume of the skull. Pin 16 causes a defor-

mation in, or communicated by, bar 13, and the deformation is captured by the sensor 15 adjacent to an opposite end of the bar 13. Accordingly, the device 2, and methods of its use, can be used to detect and/or monitor ICP in humans or animals, even in diverse situations, such as trauma, hydrocephalus, intracranial tumors, stroke, pharmacological studies, etc.

[0021] So in the illustrated embodiments illustrated in Figures 2-12, there can be one or more noninvasive sensor devices 2, a strap 3 or the like, and equipment 1, which can is communicatively arranged with the sensor 15, e.g., via wires, wireless communication technologies, etc. The equipment 1 filters and amplifies signals from sensor 15, may in some embodiments digitalize the signal from the sensor 15, and can send the signal or other output to a printer, computer, tablet, mobile phone, medical monitor, its own display 12, etc.. There can be a digital memory 10 in equipment 1, e.g., a memory card, to store the digital data, allowing for later analysis.

[0022] The noninvasive monitor can facilitate adjusting equipment 1 for sensitivity to acquire the characteristic morphology of intracranial pressure waves, with their peaks P1, P2, and P3 (Figure 28). The sensor 15 used may, for example, be a full-bridge, a quarter-bridge, or half-bridge sensor, presenting values of electrical resistance in a system detecting ICP.

[0023] Figure 2 illustrates a brain strap embodiment in which the sensor device 2 is noninvasively contacting a surface of a patient's head, proximate to the skull bone, with a band 3. The strap and/or band can, but need not, be configured to be disposable than be reused after use by the patient in a detecting session. In such an embodiment, the band 3 can be of a material that is non-rigid, such as a polymer or metallic, for example, foil, strip, tape, or the like. Sensor device 2 can be attached to, or positioned with respect to, the material and the patient's head so as to allow for detection of ICP.

[0024] In such embodiments, there can be a connector, such as a wire or other means (not shown in the Figures), communicating the signals from the sensor device to the equipment 1. (In other embodiments, the sensor device(s) can be communicatively associated with the equipment 1 by Bluetooth, ZigBee, or any other remote communication systems.)

[0025] Note that a configuration fixes the sensor 15 and sensor device 2 on the patient's head, without trichotomy or surgical incision, allowing his or her (or its) movement during the intracranial pressure detecting and monitoring.

[0026] Figure 11 and Figure 12 illustrate more of a helmet-type embodiment in which the sensor 15 is non-invasively contacting a surface of a patient's head, proximate to the skull bone, with a helmet device 17. Device 17, e.g., with a stereotaxic apparatus, can be such as to immobilize the head of the patient with respect to the sensor device 2 in a fixed position contacting with the surface of the patient's head. One may, but need not, use such a configuration where certain patient movement is not of particular interest, or for reproducibility of detecting and/or monitoring a condition where position is held constant. In such an embodiment, there can also be a portion of a strap 3, with the sensor device 2, that can, but need not, be configured to be disposable rather than be reused after use by the patient in a detecting session.

[0027] As illustrated more particularly in Figure 12, device 17 can be a stereotaxic apparatus to fix the patient's position geometrically in the system (17a - support for temporal regions, 17b - support for forehead, and 17c - support for the chin). In some such embodiments, there can be quantitative numerical marks on the bars that regulate the supports (17a, 17b, and 17c) for reference. As illustrated by comparison of Figures 11 and 12, the device 17 can comprise movable arms 18 that locate the patient, or in another way of thinking the sensor 15, with respect to each other.

[0028] The strap embodiments, or the more helmet-type embodiments, can use the flexible material approach discussed above, e.g., such as foil, with a (e.g., strain gage) sensor 15, e.g., configured in connection with device 17. Another approach is to use a sensor 15 with a spring (see Figures 13 and 14), e.g., in a housing 20.

[0029] Turning to Figures 13 and 14, the noninvasive sensor can use one or more springs 19 in detecting the intracranial pressure. One end of the spring 19 can be adjacent to an upper end of housing 20. A pin 16 is urged by the spring 19 into contact with the head of the patient. Figures 13 and 14 show various configurations of the noninvasive sensor 15 in communication via the spring 19 with a pin 16 locatable into contact with the patient's head.

[0030] There can be various embodiments hereinafter. In one embodiment, the output or raw data can also be stored and rendered via polygraph system.

[0031] Illustratively, embodiments can be carried out by such as the following.

[0032] In one embodiment, the equipment 1 can be used, for example, with the brain strap sensor approach, by:

1 - Placing the sensor 15 tip 16 over the adequate region of the skull bone, for instance the parietal bone region;

2 - Using an elastic strap 3 to fix the sensor device 2 on the head of the patient, e.g., as shown in Figure 2;

3 - Connecting the sensor device 2 to the equipment 1 using wires (or connecting by wireless protocols);

4 - Commencing detection and/or monitoring procedure to obtain intracranial pressure signals;

5 - Processing, including by a processor 8, the intracranial pressure signals to produce intracranial pressure data;

6 - Storing the intracranial pressure data in a database configured to store the intracranial pressure data, the database in a memory 10 operably asso-

ciated with the processor 8; and
7 - Displaying 12 / 14 the intracranial pressure data.

[0033] In some embodiments, there can be such as:

1 - Communicating signals from the sensor 15, i.e., a full detected signal, to the equipment 1, the full signal can be a sum of cardiologic, respiratory, ICP signals - and others, if so desired;
2 - Receiving, the full signal (e.g., in microvolts) at an amplifier 4 and amplifying the microvolts to volts (1000x);
3 - Converting, by an analog-to-digital converter 6, the analog signal into a digital data;
4 - Processing the digital data with such as mathematical analyses to produce output;
5 - Storing the digital data and at least some of the output in the database;
6 - Rendering the output or communicating it to be output, to a display 12 / 14.

[0034] With respect to the processing, the equipment 1 can carry out mathematical processing, such as Fourier Transform, to separate the signals, which can then be stored and rendered, e.g., via an output device such as a printer and/or display 12 / 14. In some embodiments, the equipment 1 renders signals such as the filtered signal via an output device, such as a multiparametric monitor, printer, computer or monitor, computer-to-computer communication device, such as a router or gateway.

[0035] As mentioned above, in other embodiments, equipment 1 has a processor 8, and in some but not all embodiments, the processor 8 can be a processor (a processor can be multiple processors working in cooperation) of a computer system as is illustratively represented in Figure 15. In another configuration, a computer system can be operably associated or in communication with a processor 8 of a multiparametric monitor, and either or both can be in communication with another computer system.

[0036] More particularly, by way of example, there can be a computer system 21, which in some embodiments can include processor 8 and in other embodiments can receive data from equipment 1. In either case, computer system 21 can interact with another computer system 22, via a network 23. As used herein, the term "computer" generally refers to hardware or hardware in combination with one or more program(s), such as can be implemented in software. Computers can be implemented as general-purpose computers, specialized devices, or a combination of general-purpose and specialized computing devices. Computing devices can be implemented electrically, optically, quantumly, biologically, and/or mechanically or in any combination of these technologies. A computer as used herein can be viewed as at least one computer having all functionality or as multiple computers with functionality separated to collectively cooperate to bring about the functionality, e.g., the functions shown as being carried out by a single computer can be carried out by more than one computer, and the functions shown as being carried out by more than one computer can be carried out by a single computer, without departing from the present intent. In some, but not all embodiments, the computer 24 can include a single processor, such as processor 8 and/or multi-processor 8 implementations of a computer. A processor 8 can include any device that processes information or executes instructions. Computer logic flow and operations can be used in processing devices, including but not limited to: signal processors, data processors, microprocessors, and communication processors. Logic flow can be implemented in discrete circuits, combinational logic, ASICs, FPGAs, reconfigurable logic, programmed computers, or an equivalent.

[0037] Computer-readable media or medium, as used herein, includes any technology that includes a characteristic of memory, e.g., tangibly embodying a program of instructions executable by a computer to perform operations according to an embodiment herein. Memory technologies can be implemented using magnetic, optical, mechanical, or biological characteristics of materials. Common examples of memory are RAM, ROM, PROM, EPROM, FPGA, and floppy or hard disks. Communications medium or connection, as used herein, is any pathway or conduit in which information can be communicated or exchanged. The pathway or conduit can be wired, optical, fluidic, acoustic, wireless, or any combination of the foregoing.

[0038] A "computer" or "computer system(s)" as used herein can include one or more computers, which illustratively can be PC systems, server systems, mobile devices, and any combination of the foregoing. Depending on the implementation, a computer can be adapted to communicate among themselves, or over a network such as the Internet. Programs, as used herein, are instructions that when executed by a processing device causes the processor to perform specified operations. Programs can be written in various languages, including but not limited to assembly, COBOL, FORTRAN, BASIC, C, C++, Java, or JavaScript. Languages can be object-oriented like C++ and Java, for example. The programming language can be interpreted or compiled, or a combination of both. The programs are usually processed by a computing system having an operating system. An operating system can be processor-specific, like an RTOS (real time operating system) used in cell phones, or commercial like Mac OS X, UNIX, Windows, or Linux. An operating system or program can be hardwired, firmware, reside in memory, or implemented in an FPGA or reconfigurable logic.

[0039] A "network" as described here can be a preconfigured network, like a local area network ("LAN") of computers, servers, and peripheral devices in a single office, or an ad hoc network caused by the temporary interconnection of computers over the Internet, by modem, via telephone, cable television, radio communication, combinations of these (like a telephone call made in response

to a television solicitation), or otherwise to conduct a particular transaction. In the latter sense, the computers in the network do not need to all be linked up at once; as few as two of them can be linked at a time. The link can be a formal link or a casual link, as by sending e-mails or other communications from one computer to the other, or logging one computer into a website maintained on another via the Internet.

[0040] The network or Internet-type network connections or communication paths described above can be made in various ways. In one embodiment, the Internet connection can be enabled by a series of devices and transmission lines or paths including: a first computer; a modem connected to the first computer; a telephone (regular or DSL) or cable television transmission line or radio communication channel connected with or generated by a transmitter associated with the modem; a first Internet Service Provider (ISP) receiving the communication; the Internet, to which the first ISP is connected; a second ISP connected to the Internet, receiving the communication; a telephone or cable television transmission line or radio communication channel connected with or generated by the ISP; a modem connected to the second computer; and the second computer.

[0041] For example, a computer system 21 and/or 22 can each comprise a computer 24 (e.g., a Lenovo, HP, Apple, or other personal computer; an enterprise server computer; distributed computing; etc.) with one or more processors 8 (e.g., an Intel or AMD processor or the like), memory 10 (e.g., RAM, a hard drive, disk drive, etc.) not shown in Figure 15, one or more input devices 25 (e.g., keyboard, mouse, modem, sensor 15, e.g., via amplifier 4 and analog to digital converter 6 or the like (see Figure 1)), and one or more output devices 26 (e.g., a modem, a printer, a display 12 monitor, external display 14, and/or other such output devices). Note that a gateway 27 or modem 28 or router 29 are each illustrative of a computer-to-computer communication device that can operate as an input/output device. To provide other illustrative embodiments, the computer system(s) 21 / 22 can comprise at least one of a desktop computer, a telephonic device, a console, a laptop computer, a tablet, and a mobile communication device. The mobile communication device can comprise at least one of a cellular telephone, laptop, a PDA, and a smartphone-type device such as an iPhone. Communications between devices may be wired (e.g., cabled Ethernet home or office network), wireless (e.g., IEEE 802.11 A/B/G/N network transceivers), or near-field radio-frequency communications (e.g., Bluetooth), or optical (e.g., infrared). Networking between devices may be through WANs, LANs, Intranets, Internet or peer-to-peer arrangements, or in a combination of them. The network 23 may include, for example, gateways, routers, bridges, switches, frontend and back-end servers, ISPs (Internet Service Providers), which may interact with content provider servers, scanners, copiers, printers, and user computing devices. Devices on the network may include interfaces that can be simple, such as a keyboard with an LCD screen, or can be complex, such as a web interface. Web interfaces are presented in a web browser environment. Web browsers render XML or HTML containing pictures, video, audio, interactive media, and links in the display of a computer. Firefox, Internet Explorer, Safari, Chrome, and Opera are examples of well-known web browsers that are available for PCs and mobile devices. Network 23 can be the Internet.

[0042] Figure 16 illustrates, again in a teaching rather than in a limiting manner, logic flow of at least one computer system configured to carry out an embodiment. In the embodiment illustrated, not in a limiting manner, sensor 15 provides a full signal to amplifier 4 which amplifies the full signal to produce an amplified full signal. The amplified full signal is communicated to analog-to-digital converter 6, which converts the amplified full signal to produce signal data. The signal data is communicated to processor 8, which can process and transform the signal data, e.g., by applying a Fourier Transform 30 and/or Fast Fourier Transform filters 31, wavelets 32 and/or statistical tolls 33. Fourier filters decompose a sequence of values into components of different frequencies, for example, most people present a heart rate between 50 and 120 bpm, and these filters can detect the signals in this frequency range and exhibit such as heartbeat signals. The filters can, but need not, be such as origin, matlab, qtiplot, or other signal analysis filter, some of which may use methods such as fast fourier transforms, wavelet processing, and statistical methods for signal analysis and interpretation. The filtering can be carried out to display, or to isolate, physiological components such as cardiologic, respiratory and intracranial pressure data.

[0043] The signal data is processed or transformed by the Fourier Transform 30 to produce a frequency spectrum data 34. The signal data is processed or transformed by the Fast Fourier Transform filters 31, wavelets 32 and/or statistical tolls 33 to separate out and produce intracranial pressure signal data 35, cardiac signal data 36, and respiratory signal data 37.

[0044] The frequency spectrum data 34, intracranial pressure data 35, cardiac data 36, and respiratory data 37 are communicated to memory 10 and display 12 and/or 14 and/or other output device. Memory 10 includes a database configured to store the frequency spectrum data 34, intracranial pressure data 35, cardiac data 36, and respiratory data 37. In some, but not all, embodiments, computer system 21 associates or further processes some or all of data 34, 35, 36, and 37, into further output, e.g., which can in some embodiments be communicated as illustrated in Figure 15 from computer system 21 to computer system 22, either of which can further process or transform some or all of the output received so as to produce yet further output.

[0045] So for example, though not illustrated in Figure 15, in some but not all embodiments, the equipment 1 is used to produce output which is then inserted by at least one of computer systems 21 and 22 into a report (or other document), such as a medical record. The report or med-

ical record can be generated and configured so that some or all of data 34, 35, 36, and 37 is located contextually into the report or medical record, which can then be stored e.g., in computer-readable memory, displayed electronically, communicated over a network, or output in hard copy at an output device, e.g., printer. The report or medical record can be generated so that some or all of data 34, 35, 36, and 37 is located in a preconfigured location in the report or medical record and associated, by at least one of computer systems 21 and 22 with other data. So for example, the report can be generated and configured such that some of data 34, 35, 36, and 37 is electronically located in the report or medical record in association with data one or more of neurological, physiological, pharmacological, endocrinological data, obtained from a memory, such as memory operably associated with at least one of computer systems 21 and 22, e.g., having been previously input. In some embodiments, computer system 21 or 22 is programmed to request and capture patient data (e.g., name, age, identification of the patient, hospital registration number, pathology(ies), and other such data in forming, or combining the data 34, 35, 36, and 37 into the report or medical record.

[0046] Figure 17 illustrates the output at, e.g., display 12 and/or 14. The illustrated output is the signal data, e.g., prior to the Fourier Transform 30 or the Fast Fourier Transform Filters 31. The signal data shows raw digital signal data of intracranial pressure. The display shows the full signal from the sensor 15, i.e., the ICP signal, the respiratory signal and frequency, and the cardiac signal and frequency.

[0047] Figure 18 illustrates a display 12/14 of raw data includes 34, 35, 36, and 37, during a real-time monitoring, in connection with other data output. This display also shows the heart and respiratory rate. (Display 12/14 can also be adapted to display the real-time curves, e.g., on the computer 21 display or, through an adapter, to a multiparametric monitor.)

[0048] Figure 19 illustrates the results of Fast Fourier filters 31 applied to the raw signal data, after the use of mathematical tools which divide the signal data into the ICP 35, cardiac data 36, and respiratory 37 data.

[0049] Embodiments herein can, therefore, include the non-invasive equipment, or parts thereof or operably associated therewith, and methods to detect intracranial pressure (ICP) and use the detected ICP and related data. Any of this data can be processed and analyzed, for medical, pathological, and/or physiological situations, for diagnosis and treatment responsive to the detecting and output from the detecting, especially to identify an initial condition, identify how a patient is responding to a treatment and/or how to adjust a subsequent treatment based on the patient's detected reaction to the treatment, and when to cease the treatment because a target condition has been detected. This has application in the diagnoses of one or more pathologies, e.g., in the vascular, cardiac, respiratory, and central nervous system disorders, and responses to administrations of treatment.

[0050] To exemplify the foregoing, a display, e.g., display 14, is presented in Figure 20 to illustrate the variation of physiologic parameters during a jugular compression. Figure 20 illustrates a baseline to the left of the peaks on the lower curves, a peak that illustrates an abnormality associated with jugular blood flow, and after administration of a treatment, a return to normal ranges, suggesting that further or alternative treatment is not needed or that the treatment has been sufficient. This is an example of the behavior of intracranial pressure in situations such as hemorrhagic stroke (increase of pressure -jugular compression) and the return (after jugular release) to baseline after treatment (e.g., decompressive craniotomy). The ICP value returns below the baseline, due to the body's defense mechanisms, which tries to maintain body's homeostasis by activating defense mechanisms.

[0051] In another teaching embodiment, detection of epilepsy seizures in Wistar rats is illustrated in Figure 21. Figure 21 illustrates detecting and diagnostics for the seizures (above reference squares added to the bottom axis of the display) and the detected the physiological parameters. The output signals illustrate an epileptic's aura, the sign before the external symptoms. These results show variations in cardiologic, respiratory and ICP signals, monitored inside the skull. Variations in these signals may collaborate diagnosis and treatment monitoring of epileptic patients.

[0052] In another teaching embodiment, the equipment 1 can be used in the diagnostics of hydrocephaly, and to check for proper operation of the shunts. Figure 22 shows the results of the equipment 1 monitoring illustrative of hydrocephaly patients.

[0053] Hydrocephalus is a disease diagnosed using imaging techniques; these devices are expensive and not available for the entire population. The equipment presented here is able to indicate a diagnosis of hydrocephalus through the analysis of low frequency waves on ICP (0 to 0.2 Hz), which vary greatly in amplitude in patients with hydrocephalus, as shown in Figure 22. It's possible see in this graph that patients after insertion of shunts show a decrease in the amplitude of these oscillations. An appropriate periodic monitoring routine now is possible with the equipment described herein.

[0054] In still another teaching embodiment, the sensor 15 and processing related thereto can detect and/or monitor the real-time drug effects, e.g., to determine the dosage and effect, the drug absorption, etc. In some embodiments, especially in children, in old age and patients require drug multi-therapy, and the detecting can be used to determine treatment, e.g., administer more of one or another medication, and determine, from the detected response of the patient, whether to adjust or cease the treatment, etc. For example, drugs can decrease the metabolism, or physiological parameters such as blood pressure, resulting in an intracranial pressure decrease that is detectable according to embodiments herein. Similarly, the reverse effect can be observed in drugs that

raise blood pressure or body metabolism.

[0055] Monitoring of drugs can be exemplified in the three cases described below.

[0056] The Figure 23 illustrates a display, e.g., display 12 and/or display 14, with respect to an intravenous use of Sodium Thiopental in pigs with 4 Kg (dosage = 7mg/kg body weight), a barbiturate general anesthetic. The Figure 23 illustrates a decrease in intracranial pressure after the use of this anesthetic (black arrow), thereby illustrating how the sensor 15 and processing related thereto can detect and/or monitor in connection with anesthesia, important information during surgical procedures.

[0057] Figure 23 is illustrative of detecting and/or monitoring of the depth of anesthesia, e.g., on a patient. A black arrow inserted into Figure 23 shows the use of Sodium Thiopental.

[0058] Dipyrone is an analgesic. The decrease in blood pressure caused by this drug can be the subject of the sensor 15 and processing related thereto, e.g., with respect to ICP. In Figure 24 a display, e.g., display 12 and/or display 14, with respect to rats with approximately 300g, are illustrated as having received dipyrone by gavage (5mg/kg body weight). The detecting and/or monitoring, in real time, of the action of the drugs is illustrative of maintenance of patients in intensive care units. Accordingly, embodiments herein can be configured and used to increasing, decrease, supplement, or cease administration of one or more pharmaceuticals or other treatments.

[0059] Figure 24 is illustrative of detecting and/or monitoring the effect of dipyrone, e.g., on a patient. Decreased intracranial pressure detected or monitored after the injection of analgesic.

[0060] There are substances that can increase the metabolism and the patient's blood pressure, such as adrenaline. The detecting and/or monitoring the effect of such drugs on a patient can be implemented with respect to maintaining of patient's homeostasis, and embodiments herein, are accordingly illustrated in Figure 25 (rats with 300g, adrenaline dosage of 0.01mg/Kg body weight). Accordingly, this effect can be detected or monitored via the sensor 15 and processing related thereto, e.g., with respect to ICPICP, as illustrated in the Figure 25 display, e.g., display 12 and/or display 14.

[0061] Figure 25 is illustrative of detecting and/or monitoring a response to adrenaline, e.g., in a patient. The black arrow indicates the injection of the drug.

[0062] The sensor 15 and processing related thereto, e.g., with respect to ICP. In Figures 26 and 27, each show a display, e.g., display 12 and/or display 14, with respect to diagnosing and monitoring diseases such as intracranial tumors, hydrocephalus, and others previously discussed herein, as well as in processes in which detections of a patient are used to determine treatment of the patient, e.g., by detected patient response to the treatment. Figures 26 and 27 illustrate a diagnosis simulated with respect to animal experimentation.

[0063] Figure 26 is illustrative of (via a simulation) of intracranial tumor in rabbits (1.5 kg). For example, a rubber balloon can be inserted into the subdural space, the balloon connected to a cannula, so as to be able to inflate the balloon, e.g., with water. The Figure 26 display, e.g., display 12 and/or display 14, is illustrated as monitoring or detecting changes due to the increase in the balloon, which represents a tumor growth. This teaching illustration is provided to indicate the ability to diagnose and monitor disease progression, as well as the efficacy of treatments such as chemotherapy and radiotherapy.

[0064] Figure 26 provides a tumor simulation, e.g., in a patient.

[0065] Another teaching embodiment is directed to diagnosing hydrocephaly and evaluating the performance of shunts. The Figure 27 display, e.g., display 12 and/or display 14, is illustrated as detecting and/or monitoring of the disease by an experimental animal model (rats with 300g) in which rats received saline injection into the spinal canal, thus simulating the accumulation of cerebrospinal fluid, characteristic of this disease. The display in Figure 27 is illustrated as showing in real time the increase in intracranial pressure resulting from this volume variation, e.g., in a patient.

[0066] Figure 27 provides a hydrocephaly simulation. Depending on the embodiment for the desired application, the sensor 15 and processing related thereto, can be configured and used to detect and/or monitor the intracranial pressure in patients with trauma, hydrocephaly, tumors, epilepsy, stroke, etc. so as to produce diagnostic data related to the corresponding medical condition and/or to produce data corresponding to a patient's reaction to treatment of that condition, e.g., so as to adjust the treatment responsive to what is detected. (Note that embodiments are not limited to human patient embodiments, and thus can include embodiments configured for animals, especially in connection with veterinary medicine and surgery.) Other examples include hydrocephaly diagnoses, and evaluating the functioning of hydrocephaly shunts, edemas, chronic pain, migraine, etc. (e.g., to evaluate the action of drugs and their half-life in the patient's brain). Still further examples include diagnostics and treatment of brain symptoms related to cerebral fluid flow, labyrinthits, nausea, secondary injury, and treatment thereof. And treatment can, for example, include administering medication, surgery, etc., in connection with the data or display or other output indicating a patient condition and response to the treatment.

[0067] Figure 28 is an illustrative embodiment of a display with respect to ICPNI Monitoring. The ICP wave has typical morphological characteristics, this wave is composed by P1 that is the result of the systolic wave of arterial blood pressure, P2 that is consequence of the cardiac valve closure and P3 that show the accommodation of blood pressure wave in the central nervous system.

[0068] Additional examples include diagnosing proper operation of a stent, analyzing cardiac and respiratory parameters with respect to the central nervous system,

analyzing cardiologic, respiratory, cardiac and vascular parameters using maneuvers (postural changes, jugular compress, valsava maneuver and physical activity), etc.

[0069] Yet further examples include diagnostics and analyses of time series of the intracranial pressure, e.g., to determine the drug dosage required for the adequate homeostasis of the brain pressure. Additional examples include pharmaceutical clinical trials, detecting/monitoring/ evaluating the depth of anesthesia procedures in general surgery and making adjustments thereto in response to the data. Yet still further examples include detecting or monitoring the efficiency of chemotherapy and radiotherapy in intracranial and/or skull tumors, cardiologic, and respiratory analyses related to the intracranial pressure signal, etc. and treatment adjustments in response to what is detected.

[0070] Other embodiments can similarly be configured for producing the data in connection with exercise physiology, gymnastics, etc. to monitor the effect of physical activity in the brain.

[0071] Due to the non-invasive aspects of embodiments herein, the detecting or monitoring can be carried out with respect to cases of loss consciousness (syncope) during space and flight situations, or in cases of pressure changes, such as divers, climbers or other activities with pressure changes.

[0072] In sum, appreciation is requested for the robust range of possibilities flowing from the core teaching herein. More broadly, however, the terms and expressions which have been employed herein are used as terms of teaching and not of limitation, and there is no intention, in the use of such terms and expressions, of excluding equivalents of the features shown and described, or portions thereof, it being recognized that various modifications are possible within the scope of the embodiments contemplated and suggested herein. Further, various embodiments are as described and suggested herein. Although the disclosure herein has been described with reference to specific embodiments, the disclosures are intended to be illustrative and are not intended to be limiting. Various modifications and applications may occur to those skilled in the art without departing from the scope defined herein.

[0073] Thus, although illustrative embodiments have been described in detail above, it is respectfully requested that appreciation be given for the modifications that can be made based on the exemplary embodiments, implementations, and variations, without materially departing from the novel teachings and advantages herein. Accordingly, such modifications are intended to be included within the scope defined by claims. In the claims, and otherwise herein, meansplus-function language is intended to cover the structures described herein as performing the recited function and not only structural equivalents, but also equivalent structures. Thus, although a nail and a screw may not be structural equivalents in that a nail employs a cylindrical surface to secure wooden parts together, whereas a screw employs a helical surface, in the environment fastening wooden parts, a nail and a screw may be equivalent structures.

Claims

1. A method to digitally produce and communicate intracranial pressure data from skull deformation electric signals, the method **characterized by** including:

   receiving, from at least one sensor (2) noninvasively located on a patient, detected skull deformation electric signals at electrical equipment (1) configured to transform and process the skull deformation signals that are received;
   transforming and processing, by the electrical equipment_(1), the received skull deformation electric signals to produce digital intracranial pressure data;
   outputting, by the electrical equipment (1), the digital intracranial pressure data via an output device (1) operably associated with the electrical equipment (1) to render the digital intracranial pressure data_(35),
   wherein the skull deformation electric signals are analog signals, and the electrical equipment (1) includes an amplifier_(4), an analog-to-digital converter (6), a processor (8), a memory (10), and a monitor (12), and wherein the transforming and processing includes:

      amplifying, by the amplifier (4), the skull deformation electric signals that are received from said at least one sensor (2) to produce amplified analog skull deformation signals;
      converting, by the analog-to-digital converter (6), the amplified skull deformation signals from analog form into digital form skull deformation electric signals;
      applying, including with said processor (8), a Fourier Transform, a Fast Fourier Transform, or both on the digital form skull deformation electric signals to produce the digital intracranial pressure data (35); and
      storing, in the memory (10), the digital intracranial pressure data (35) in a database.

2. The method of claim 1, wherein the at least one sensor (2) includes at least one strain gage sensor_(15).

3. The method of claim 2, wherein the at least one strain gage (15) is noninvasively located by a strap, band, hat, or helmet; and the outputting includes displaying, on the monitor_(12), the rendered digital intracranial pressure data.

4. The method of claim 1, further including communicating at least some of said output such that at least

some of the digital intracranial pressure data is communicated to a digital device remote from a medical facility where the electrical equipment (1) is located or digitally inserting at least some of said output such that at least some of the digital intracranial pressure data is digitally inserted into a report or medical record which is replayed to a digital device remote from a medical facility where the electrical equipment (1) is located.

5. The method of claim 1, further including communicating at least some of said output such that at least some of the digital intracranial pressure data is digitally inserted into a medical record in association with data indicative of one or more of a trauma, a stroke, epilepsy, an intracranial hemorrhage, a hydrocephalus, a migraine headache, a headache, a tumor, a postural change, a cardiologic disease, a lie or falsehood, a neuroparasitosis, cystocercosis, craniosynostosis, hydrocephalus, a jugular blood flow abnormality, a pharmacologically induced change in intracranial pressure, an anesthetic, an analgesic, a hormone, a dynamical effect of a neurologic actives drug, a dynamical effect of a disease, an onset of ictus of a seizure, a ventricle-peritoneal shunt problem, a lumbar puncture, a brain death.

6. The method of claim 1, further including communicating at least some of said output such that at least some of the digital intracranial pressure data is digitally inserted into a report or medical record in association with data indicative of an evaluation of one or more of physiology of: exercise, a shock to a head, a rapid acceleration or deceleration, microgravity, a pilot's intracranial pressure during flying, an effect of an explosion or shock wave, a physiologic parameter associated with temperature, and a physiologic parameter associated with humidity.

7. An apparatus to digitally produce and communicate intracranial pressure data from skull deformation electric signals, the apparatus **characterized by** including:

at least one non-invasive sensor (2) of skull deformation electric signals;
electrical equipment (1) arranged to receive the skull deformation electric signals and configured to transform and process the skull deformation signals that are received to produce digital intracranial pressure data_(35);
an output device (26) operably associated with the electrical equipment so as to output the digital intracranial pressure data, wherein the electrical equipment (1) includes:

an amplifier (4) arranged to amplify the skull deformation electric signals that are received from said at least one sensor (2) to produce amplified analog skull deformation signals;
an analog-to-digital converter (6) arranged to convert the amplified skull deformation signals from analog form into digital form skull deformation electric signals;
a processor (8) arranged and programmed to apply a Fourier Transform, a Fast Fourier Transform, or both on the digital form skull deformation electric signals to produce the digital intracranial pressure data_(35); and
a memory (10) arranged to store the digital intracranial pressure data (35) in a database.

8. The apparatus of claim 7, wherein_said at least one sensor (2) includes at least one strain gage and wherein:
the output device (26) includes a monitor;

the detected skull deformation electric signals correspond to a human or an animal;
said at least one sensor (2) is noninvasively locatable by a strap, band, hat or helmet or said at least one sensor is noninvasively locatable by a stationary apparatus which substantially fixes the patient's position with respect to said at least one sensor (2).

9. The apparatus of claim 7, wherein said output digital intracranial pressure data (35) is digitally inserted into a report or medical record or at least some of said output digital intracranial pressure data is communicated to a digital device remote from a medical facility where the electrical equipment is located.

10. The apparatus of claim 7, wherein the digital intracranial pressure data includes (35) data showing an abnormality in a wave morphology corresponding to changes in the intracranial pressure or wherein the electrical equipment (1) is configured to perform mathematical analyses using signal analysis ad pattern recognition sufficient to show an abnormality in wave morphology.

11. The apparatus of claim 7, wherein the electrical equipment (1) is configured to communicate at least some of the digital intracranial pressure data such that said at least some of the digital intracranial pressure data is digitally inserted into a report or medical record preconfigured in association with one or more of neurological, physiological, pathological, pharmacological, psychological, and endocrinological data.

12. The apparatus of claim 7, wherein the electrical equipment (1) is configured to communicate at least some of said output such that at least some of the

digital intracranial pressure data is digitally inserted into a medical record in association with data indicative of one or more of a diagnosis, a treatment, a treatment adjustment, and a treatment cessation.

13. The apparatus of claim 7, wherein the electrical equipment (1) is configured to communicate at least some of said output such that at least some of the digital intracranial pressure data is digitally inserted into a medical record in association with data indicative of one or more of a trauma, a stroke, epilepsy, an intracranial hemorrhage, a hydrocephalus, a migraine headache, a headache, a tumor, a postural change, a cardiologic disease, a lie or falsehood, a neuroparasitosis, cystocercosis, craniosynostosis, hydrocephalus, a jugular blood flow abnormality, a pharmacologically induced change in intracranial pressure, an anesthetic, an analgesic, a hormone, a dynamical effect of a neurologic actives drug, a dynamical effect of a disease, an onset of ictus of a seizure, a ventricle-peritoneal shunt problem, a lumbar puncture, a brain death.

14. The apparatus of claim 7, wherein said output of said digital intracranial pressure data comprises a digital insertion into a report or medical record in association with data indicative of an evaluation of one or more of physiology of: exercise, a shock to a head, a rapid acceleration or deceleration, microgravity, a pilot's intracranial pressure during flying, an effect of an explosion or shock wave, a physiologic parameter associated with temperature, and a physiologic parameter associated with humidity.

15. The apparatus of claim 7, wherein the electrical equipment (1) is arranged to monitor the digital intracranial pressure data for a threshold, such that if the threshold is encountered, an alarm is triggered.

Patentansprüche

1. Verfahren zur digitalen Darstellung und Kommunikation von intrakraniellen Druckdaten aus elektrischen Schädelverformungssignalen, wobei das Verfahren **dadurch gekennzeichnet ist, dass** es umfasst:

Empfangen, von mindestens einem Sensor (2), der nicht-invasiv an einem Patienten lokalisiert ist, von detektierten elektrischen Schädelverformungssignalen an einer elektrischen Ausrüstung (1), die ausgelegt ist, die Schädelverformungssignale, die empfangen werden, zu transformieren und zu verarbeiten;
Transformieren und Verarbeiten, durch die elektrische Ausrüstung (1), der empfangenen elektrischen Schädelverformungssignale, um digitale intrakranielle Druckdaten zu erzeugen;
Ausgeben, durch die elektrische Ausrüstung (1), der digitalen intrakraniellen Druckdaten über eine Ausgabevorrichtung (1), die betreibbar mit der elektrischen Ausrüstung (1) assoziiert ist, um die digitalen intrakraniellen Druckdaten (35) zu rendern, wobei die elektrischen Schädelverformungssignale analoge Signale sind, und die elektrische Ausrüstung (1) einen Verstärker (4), einen Analog-Digital-Wandler (6), einen Prozessor (8), einen Speicher (10) und einen Monitor (12) aufweist, und wobei das Transformieren und Verarbeiten umfasst:

Verstärken, durch den Verstärker (4), der elektrischen Schädelverformungssignale, die von dem mindestens einen Sensor (2) empfangen werden, um verstärkte analoge Schädelverformungssignale zu erzeugen;
Umwandeln, durch den Analog-Digital-Wandler (6), der verstärkten Schädelverformungssignale von einer analogen Form in eine digitale Form der Schädelverformungssignale;
Anlegen, einschließlich mit dem Prozessor (8), von einer Fourier-Transformation, einer schnellen Fourier-Transformation oder beiden an die digitale Form der elektrischen Schädelverformungssignale, um die digitalen intrakraniellen Druckdaten (35) zu erzeugen; und
Speichern, in dem Speicher (10), der digitalen intrakraniellen Druckdaten (35) in einer Datenbank.

2. Verfahren nach Anspruch 1, wobei der mindestens eine Sensor (2) mindestens einen Dehnungsmessersensor (15) aufweist.

3. Verfahren nach Anspruch 2, wobei der mindestens eine Dehnungssensor (15) nicht-invasiv durch einen Riemen, ein Band, einen Hut oder einen Helm lokalisiert wird; und das Ausgeben ein Anzeigen, auf dem Monitor (12), der gerenderten digitalen intrakraniellen Druckdaten umfasst.

4. Verfahren nach Anspruch 1, ferner umfassend ein Kommunizieren mindestens eines Teils der Ausgabe, so dass mindestens ein Teil der digitalen intrakraniellen Druckdaten zu einer digitalen Vorrichtung entfernt von einer medizinischen Einrichtung kommuniziert wird, wo die elektrische Ausrüstung (1) lokalisiert ist, oder digitales Einfügen mindestens eines Teils der Ausgabe, so dass mindestens ein Teil der digitalen intrakraniellen Druckdaten digital in einen Bericht oder medizinischen Befund eingefügt wird, der auf einer digitalen Vorrichtung entfernt von einer medizinischen Einrichtung, wo die elektrische

Ausrüstung (1) lokalisiert ist, wiedergegeben wird.

5. Verfahren nach Anspruch 1, ferner umfassend ein Kommunizieren mindestens eines Teils des Ausgangs, so dass mindestens ein Teil der digitalen intrakraniellen Druckdaten digital in einen medizinischen Befund in Assoziation mit Daten eingefügt wird, die eines oder mehrere anzeigen von einem Trauma, einem Schlaganfall, Epilepsie, einer intrakraniellen Blutung, einem Hydrocephalus, Migränekopfschmerzen, Kopfschmerzen, einem Tumor, einer Haltungsänderung, einer kardiologischen Erkrankung, einer Lüge oder Unwahrheit, einer Neuroparasitose, Cysticercose, Craniosynostose, Hydrocephalus, einer jugularen Durchblutungsabnormalität, einer pharmakologisch induzierten Änderung des intrakraniellen Drucks, einem Anästhetikum, einem Analgetikum, einem Hormon, einem dynamischen Effekt eines neurologisch aktiven Arzneimittels, einem dynamischen Effekt einer Erkrankung, einem Einsetzen des Ictus eines Anfalls, einem Ventrikel-peritonealen Shunt-Problem, einer Lumbalpunktion, einem Hirntod.

6. Verfahren nach Anspruch 1, ferner umfassend ein Kommunizieren mindestens eines Teils der Ausgabe, so dass mindestens ein Teil der digitalen intrakraniellen Druckdaten digital in einen Bericht oder medizinischen Befund in Assoziation mit Daten eingefügt wird, die eine Evaluierung einer oder mehrerer Physiologien anzeigen von: einer körperlichen Betätigung, einem Schlag auf den Kopf, einer raschen Beschleunigung oder Entschleunigung, einer Mikrogravitation, einem intrakraniellen Druck eines Piloten während des Flugs, einem Effekt einer Explosion oder Stoßwelle, einem physiologischen Parameter, der mit der Temperatur assoziiert ist, und einem physiologischen Parameter, der mit Feuchtigkeit assoziiert ist.

7. Vorrichtung zur digitalen Darstellung und Kommunikation von intrakraniellen Druckdaten aus elektrischen Schädelverformungssignalen, wobei die Vorrichtung **dadurch gekennzeichnet ist, dass** sie umfasst:

mindestens einen nicht-invasiven Sensor (2) von elektrischen Schädelverformungssignalen;
eine elektrische Ausrüstung (1), die eingerichtet ist, die elektrischen Schädelverformungssignale zu empfangen, und ausgelegt ist, die Schädelverformungssignale, die empfangen werden, zu transformieren und zu verarbeiten, um digitale intrakranielle Druckdaten (35) zu erzeugen;
eine Ausgabevorrichtung (26), die betreibbar mit der elektrischen Ausrüstung assoziiert ist, um so die digitalen intrakraniellen Druckdaten auszugeben, wobei die elektrische Ausrüstung (1) umfasst:

einen Verstärker (4), der eingerichtet ist, die elektrischen Schädelverformungssignale, die von dem mindestens einen Sensor (2) empfangen werden, zu verstärken, um verstärkte analoge Schädelverformungssignale zu erzeugen;
einen Analog-Digital-Wandler (6), der eingerichtet ist, die verstärkten Schädelverformungssignale von einer analogen Form in eine digitale Form der elektrischen Schädelverformungssignale umzuwandeln;
einen Prozessor (8), der eingerichtet und programmiert ist, eine Fourier-Transformation, eine schnelle Fourier-Transformation oder beide an die digitale Form der elektrischen Schädelverformungssignale anzulegen, um die digitalen intrakraniellen Druckdaten (35) zu erzeugen; und
einen Speicher (10), der eingerichtet ist, die digitalen intrakraniellen Druckdaten (35) in einer Datenbank zu speichern.

8. Vorrichtung nach Anspruch 7, wobei der mindestens eine Sensor (2) mindestens einen Dehnungsmesser aufweist, und wobei:

die Ausgabevorrichtung (26) einen Monitor aufweist;
die detektierten elektrischen Schädelverformungssignale einem Menschen oder einem Tier entsprechen;
der mindestens eine Sensor (2) nicht-invasiv durch einen Riemen, ein Band, einen Hut oder einen Helm lokalisierbar ist, oder der mindestens eine Sensor nicht-invasiv durch eine stationäre Vorrichtung lokalisierbar ist, welche die Position eines Patienten in Bezug auf den mindestens einen Sensor (2) im Wesentlichen fixiert.

9. Vorrichtung nach Anspruch 7, wobei die ausgegebenen digitalen intrakraniellen Druckdaten (35) digital in einen Bericht oder medizinischen Befund eingefügt werden, oder mindestens ein Teil der ausgegebenen digitalen intrakraniellen Druckdaten zu einer digitalen Vorrichtung entfernt von einer medizinischen Einrichtung kommuniziert wird, wo die elektrische Ausrüstung lokalisiert ist.

10. Vorrichtung nach Anspruch 7, wobei die digitalen intrakraniellen Druckdaten (35) Daten umfassen, welche eine Abnormalität in einer Wellenmorphologie zeigen, die Änderungen in dem intrakraniellen Druck entspricht, oder wobei die elektrische Ausrüstung (1) ausgelegt ist, mathematische Analysen unter Verwendung einer Signalanalyse und Mustererkennung

vorzunehmen, die ausreichen, um eine Abnormalität in der Wellenmorphologie zu zeigen.

11. Vorrichtung nach Anspruch 7, wobei die elektrische Ausrüstung (1) ausgelegt ist, mindestens einen Teil der digitalen intrakraniellen Druckdaten zu kommunizieren, so dass mindestens ein Teil der digitalen intrakraniellen Druckdaten digital in einen Bericht oder medizinischen Befund eingefügt wird, der in Assoziation mit einem oder mehreren von neurologischen, physiologischen, pathologischen, pharmakologischen, psychologischen und endokrinologischen Daten vorausgelegt sind.

12. Vorrichtung nach Anspruch 7, wobei die elektrische Ausrüstung (1) ausgelegt ist, mindestens einen Teil der Ausgabe zu kommunizieren, so dass mindestens ein Teil der digitalen intrakraniellen Druckdaten digital in einen medizinischen Befund in Assoziation mit Daten eingefügt wird, die eines oder mehrere von einer Diagnose, einer Behandlung, einer Behandlungseinstellung und einem Behandlungsende anzeigen.

13. Vorrichtung nach Anspruch 7, wobei die elektrische Ausrüstung (1) ausgelegt ist, mindestens einen Teil der Ausgabe zu kommunizieren, so dass mindestens ein Teil der digitalen intrakraniellen Druckdaten digital in einen medizinischen Befund in Assoziation mit Daten eingefügt wird, die eines oder mehrere anzeigen von einem Trauma, einem Schlaganfall, Epilepsie, einer intrakraniellen Blutung, einem Hydrocephalus, Migränekopfschmerzen, Kopfschmerzen, einem Tumor, einer Haltungsänderung, einer kardiologischen Erkrankung, einer Lüge oder Unwahrheit, einer Neuroparasitose, Cysticercose, Craniosynostose, Hydrocephalus, einer jugularen Durchblutungsabnormalität, einer pharmakologisch induzierten Änderung des intrakraniellen Drucks, einem Anästhetikum, einem Analgetikum, einem Hormon, einem dynamischen Effekt eines neurologisch aktiven Arzneimittels, einem dynamischen Effekt einer Erkrankung, einem Einsetzen des Ictus eines Anfalls, einem Ventrikel-peritonealen Shunt-Problem, einer Lumbalpunktion, einem Hirntod.

14. Vorrichtung nach Anspruch 7, wobei die Ausgabe der digitalen intrakraniellen Druckdaten ein digitales Einfügen in einen Bericht oder medizinischen Befund in Assoziation mit Daten umfasst, die eine Evaluierung einer oder mehrerer Physiologien anzeigen von: einer körperlichen Bewegung, einem Schlag auf den Kopf, einer raschen Beschleunigung oder Entschleunigung, einer Mikrogravitation, einem intrakraniellen Druck eines Piloten während des Flugs, einem Effekt einer Explosion oder Stoßwelle, einem physiologischen Parameter, der mit der Temperatur assoziiert ist, und einem physiologischen Parameter, der mit Feuchtigkeit assoziiert ist.

15. Vorrichtung nach Anspruch 7, wobei die elektrische Ausrüstung (1) eingerichtet ist, die digitalen intrakraniellen Druckdaten für eine Schwelle zu überwachen, so dass, wenn die Schwelle angetroffen wird, ein Alarm ausgelöst wird.

Revendications

1. Procédé pour numériquement produire et communiquer des données de pression intracrânienne à partir de signaux électriques de déformation du crâne, le procédé **caractérisé en ce qu'**il inclut :

la réception, d'au moins un capteur (2) positionné de façon non invasive sur un patient, de signaux électriques de déformation du crâne détectés au niveau de l'équipement électrique (1) configuré pour transformer et traiter les signaux de déformation du crâne qui sont reçus ;
la transformation et le traitement, par l'équipement électrique (1), des signaux électriques de déformation du crâne reçus pour produire des données numériques de pression intracrânienne ;
l'émission, par l'équipement électrique (1), des données numériques de pression intracrânienne via un dispositif d'émission (1) fonctionnellement associé à l'équipement électrique (1) pour restituer les données numériques de pression intracrânienne (35),
dans lequel les signaux électriques de déformation du crâne sont des signaux analogiques, et l'équipement électrique (1) comprend un amplificateur (4), un convertisseur analogique-numérique (6), un processeur (8), une mémoire (10), et un moniteur (12), et dans lequel la transformation et le traitement comprennent :

l'amplification, par l'amplificateur (4), des signaux électriques de déformation du crâne qui sont reçus dudit au moins un capteur (2) pour produire des signaux analogiques amplifiés de déformation du crâne ;
la conversion, par le convertisseur analogique-numérique (6), des signaux amplifiés de déformation du crâne de la forme analogique en signaux électriques de déformation du crâne sous la forme numérique ;
l'application, y compris avec ledit processeur (8), d'une transformée de Fourier, d'une transformée de Fourier rapide, ou des deux aux signaux électriques de déformation du crâne sous forme numérique pour produire les données numériques de pression intracrânienne (35) ; et

le stockage, dans la mémoire (10), des données numériques de pression intracrânienne (35) dans une base de données.

2. Procédé selon la revendication 1, dans lequel l'au moins un capteur (2) comprend au moins un capteur à jauge de contrainte (15).

3. Procédé selon la revendication 2, dans lequel l'au moins une jauge de contrainte (15) est positionnée de façon non invasive par une sangle, une bande, un chapeau, ou un casque ; et l'émission comprend l'affichage, sur le moniteur (12), des données numériques de pression intracrânienne restituées.

4. Procédé selon la revendication 1, comprenant en outre la communication d'au moins une partie de ladite émission de telle sorte qu'au moins certaines des données numériques de pression intracrânienne sont communiquées à un dispositif numérique distant d'une installation médicale où l'équipement électrique (1) est positionné ou l'insertion numérique d'au moins une partie de ladite émission de manière à ce qu'au moins certaines des données numériques de pression intracrânienne soient numériquement insérées dans un rapport ou un dossier médical qui est retransmis à un dispositif numérique distant d'une installation médicale où est positionné l'équipement électrique (1).

5. Procédé selon la revendication 1, comprenant en outre la communication d'au moins une partie de ladite émission de manière à ce qu'au moins certaines des données numériques de pression intracrânienne soient numériquement insérées dans un dossier médical en association avec des données indiquant un ou plusieurs traumatisme, accident vasculaire cérébral, épilepsie, hémorragie intracrânienne, hydrocéphalie, migraines, céphalées, tumeur, modification de posture, maladie cardique, mensonge ou supercherie, neuroparasitose, cystocercose, craniosynostose, hydrocéphalie, anomalie de la circulation sanguine jugulaire, modification de la pression intracrânienne induite par traitement pharmacologique, produit anesthésiant, produit analgésique, hormone, effet dynamique d'un médicament actif sur le système neurologique, effet dynamique d'une maladie, début de crise d'ictus, problème de dérivation ventriculopéritonéale, ponction lombaire, mort cérébrale.

6. Procédé selon la revendication 1, comprenant en outre la communication d'au moins une partie de ladite émission de manière à ce qu'au moins certaines des données numériques de pression intracrânienne soient numériquement insérées dans un rapport ou un dossier médical en association avec des données indiquant une évaluation d'une ou plusieurs physiologie : de l'exercice, d'un choc à la tête, d'une accélération ou décélération rapide, de microgravité, de la pression intracrânienne d'un pilote durant un vol, d'un effet d'une onde d'explosion ou de choc, d'un paramètre physiologique associé à la température, et d'un paramètre physiologique associé à l'humidité.

7. Appareil pour numériquement produire et communiquer des données de pression intracrânienne de signaux électriques de déformation du crâne, l'appareil étant **caractérisé en ce qu'**il comprend :

au moins un capteur non invasif (2) de signaux électriques de déformation du crâne ;
un équipement électrique (1) agencé pour recevoir les signaux électriques de déformation du crâne et configuré pour transformer et traiter les signaux de déformation du crâne qui sont reçus pour produire les données numériques de pression intracrânienne (35) ;
un dispositif d'émission (26) fonctionnellement associé à l'équipement électrique de manière à émettre les données numériques de pression intracrânienne, dans lequel l'équipement électrique (1) comprend :

un amplificateur (4) agencé pour amplifier les signaux électriques de déformation du crâne qui sont reçus dudit au moins un capteur (2) pour produire des signaux analogiques amplifiés de déformation du crâne ;
un convertisseur analogique-numérique (6) agencé pour convertir les signaux amplifiés de déformation du crâne de la forme analogique en signaux électriques de déformation du crâne sous forme numérique ;
un processeur (8) agencé et programmé pour appliquer une transformée de Fourier, une transformée de Fourier rapide, ou les deux aux signaux électriques de déformation du crâne sous forme numérique pour produire les données numériques de pression intracrânienne (35) ; et
une mémoire (10) agencée pour stocker les données numériques de pression intracrânienne (35) dans une base de données.

8. Appareil selon la revendication 7, dans lequel ledit au moins un capteur (2) comprend au moins une jauge de pression et dans lequel :

le dispositif d'émission (26) comprend un moniteur ;
les signaux électriques de déformation du crâne détectés correspondent à un être humain ou un animal ;
ledit au moins un capteur (2) est positionné de

façon non invasive par une sangle, une bande, un chapeau ou un casque ou ledit au moins un capteur est positionné de façon non invasive par un appareil stationnaire qui fixe sensiblement la position du patient relativement au dit au moins un capteur (2).

9. Appareil selon la revendication 7, dans lequel lesdites données numériques de pression intracrânienne émises (35) sont numériquement insérées dans un rapport ou un dossier médical ou au moins certaines desdites données numériques de pression intracrânienne sont communiquées à un dispositif numérique distant d'une installation médicale où l'équipement électrique se trouve.

10. Appareil selon la revendication 7, dans lequel les données numériques de pression intracrânienne comprennent (35) des données présentant une anomalie dans une morphologie d'onde correspondant à des modifications de la pression intracrânienne ou dans lequel l'équipement électrique (1) est configuré pour réaliser des analyses mathématiques en utilisant une analyse de signal et une reconnaissance de forme suffisantes pour mettre en évidence une anomalie dans la morphologie d'onde.

11. Appareil selon la revendication 7, dans lequel l'équipement électrique (1) est configuré pour communiquer au moins certaines des données numériques de pression intracrânienne de manière à ce que lesdites au moins certaines des données numériques de pression intracrânienne soient insérées numériquement dans un rapport ou un dossier médical préconfiguré en association avec une ou plusieurs données neurologiques, physiologiques, pathologiques, pharmacologiques, phycologiques, et endocrinologiques.

12. Appareil selon la revendication 7, dans lequel l'équipement électrique (1) est configuré pour communiquer au moins une partie de ladite émission de manière à ce qu'au moins certaines des données numériques de pression intracrânienne soient numériquement insérées dans un dossier médical en association avec des données indiquant un ou plusieurs diagnostic, traitement, ajustement de traitement, et arrêt de traitement.

13. Appareil selon la revendication 7, dans lequel l'équipement électrique (1) est configuré pour communiquer au moins une partie de ladite émission de manière à ce qu'au moins certaines des données numériques de pression intracrânienne soient numériquement insérées dans un dossier médical en association avec des données indiquant un ou plusieurs traumatisme, accident vasculaire cérébral, épilepsie, hémorragie intracrânienne, hydrocéphalie, migraines, céphalées, tumeur, modification de posture, maladie cardique, mensonge ou supercherie, neuroparasitose, cystocercose, crâniosynostose, hydrocéphalie, anomalie de la circulation sanguine jugulaire, modification de la pression intracrânienne induite par traitement pharmacologique, produit anesthésiant, produit analgésique, hormone, effet dynamique d'un médicament actif sur le système neurologique, effet dynamique d'une maladie, début de crise d'ictus, problème de dérivation ventriculopéritonéale, ponction lombaire, mort cérébrale.

14. Appareil selon la revendication 7, dans lequel ladite émission desdites données numériques de pression intracrânienne comprend une insertion numérique dans un rapport ou un dossier médical en association avec des données indiquant une évaluation d'une ou plusieurs physiologie : de l'exercice, d'un choc à la tête, d'une accélération ou décélération rapide, de microgravité, de la pression intracrânienne d'un pilote durant un vol, d'un effet d'une onde d'explosion ou de choc, d'un paramètre physiologique associé à la température, et d'un paramètre physiologique associé à l'humidité.

15. Appareil selon la revendication 7, dans lequel l'équipement électrique (1) est agencé pour surveiller les données numériques de pression intracrânienne par rapport à un seuil, de telle sorte que si le seuil est atteint, une alarme est déclenchée.

Figure 1

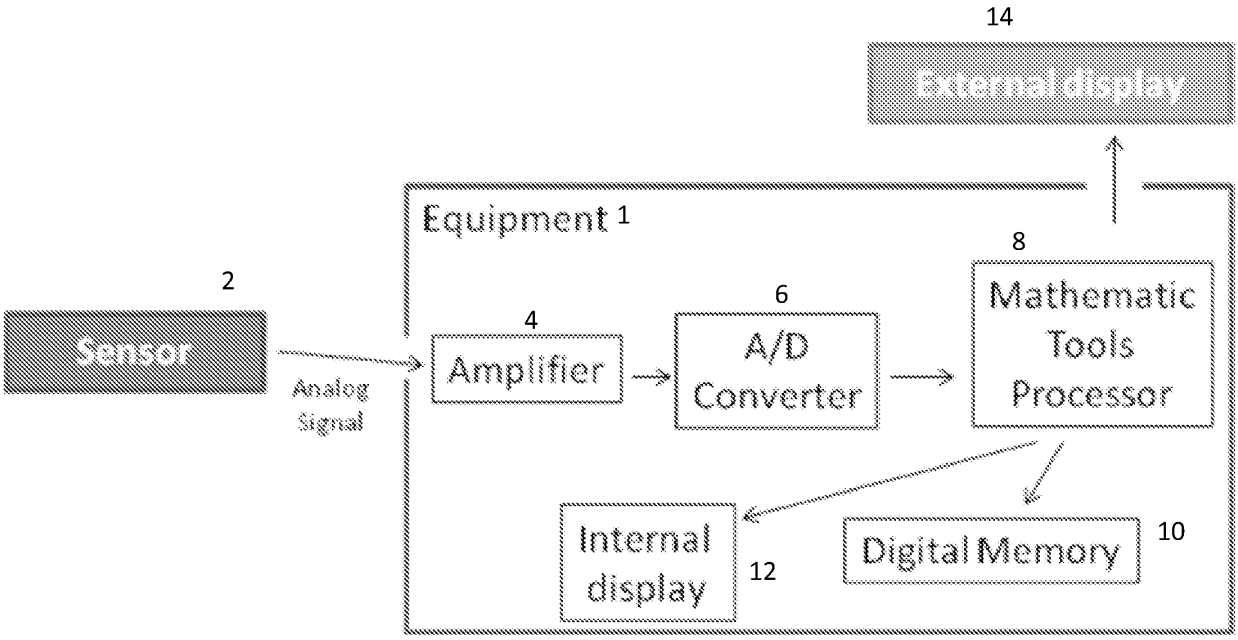

14
External display
Equipment 1
8
2
6
4
Mathematic Tools Processor
Sensor
Amplifier
A/D Converter
Analog Signal
Internal display
12
Digital Memory
10

Figure 2

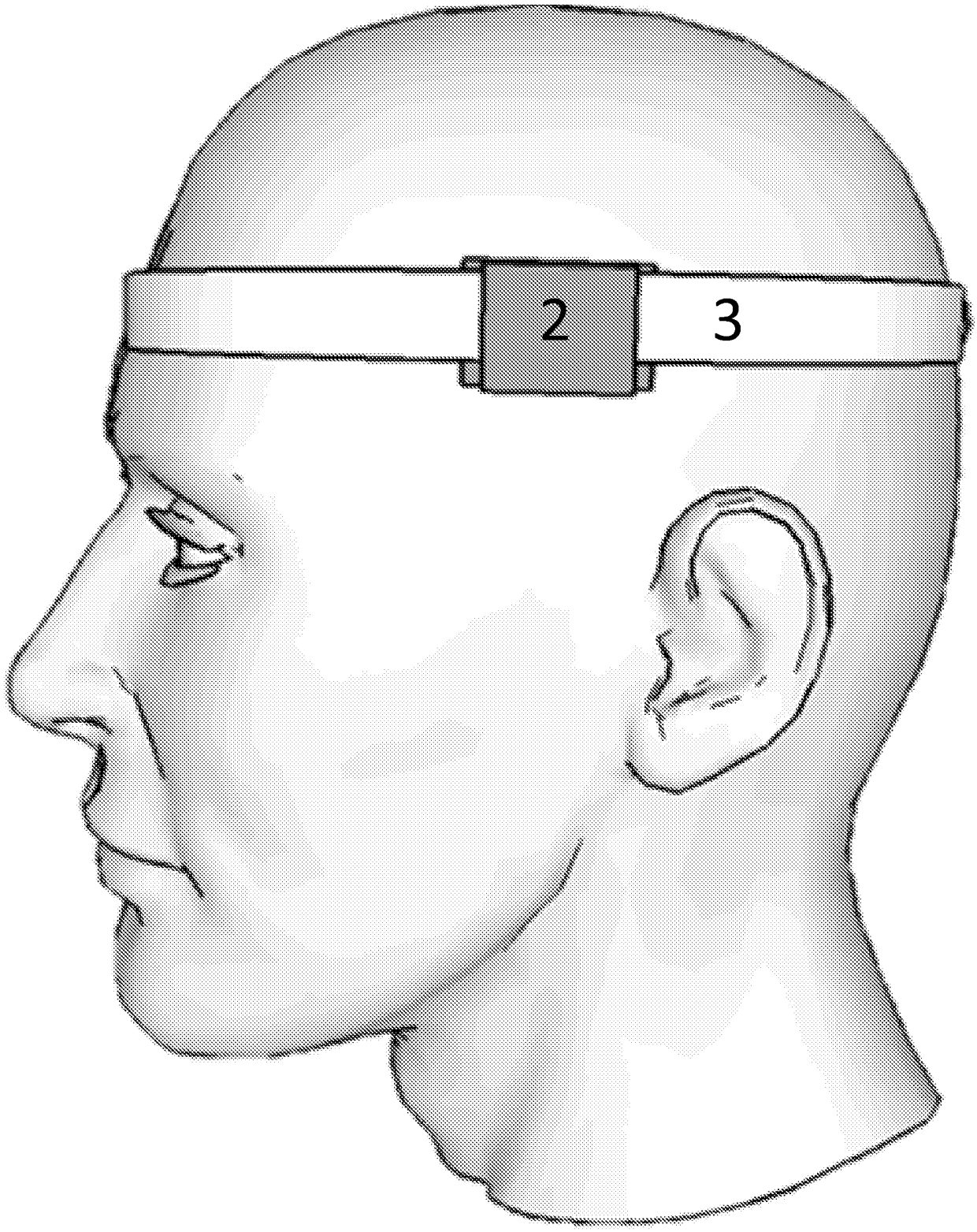


Figure 3

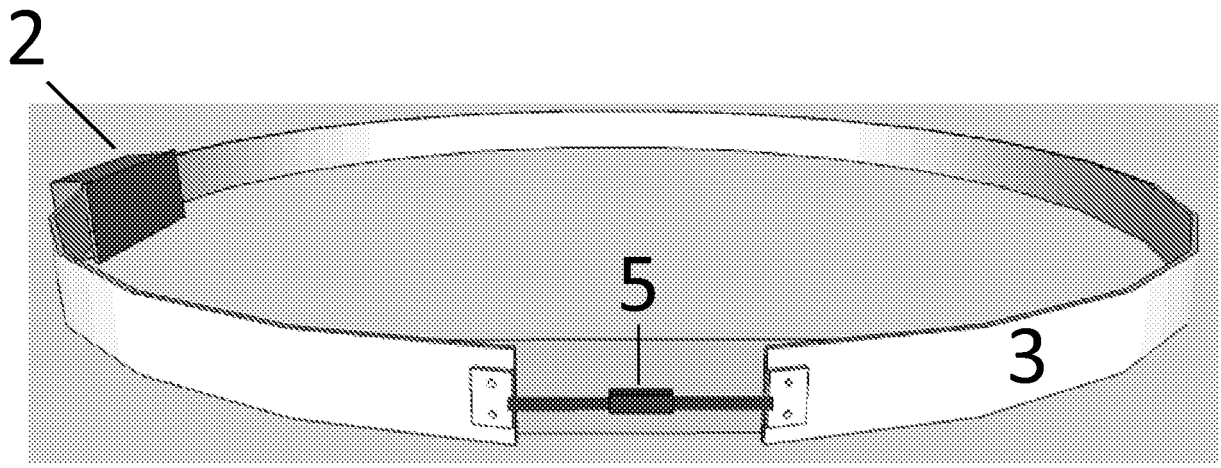


Figure 4

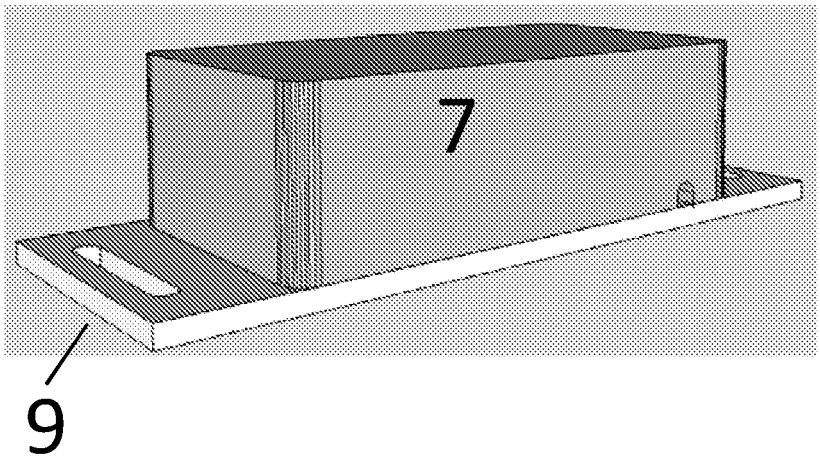


Figure 5

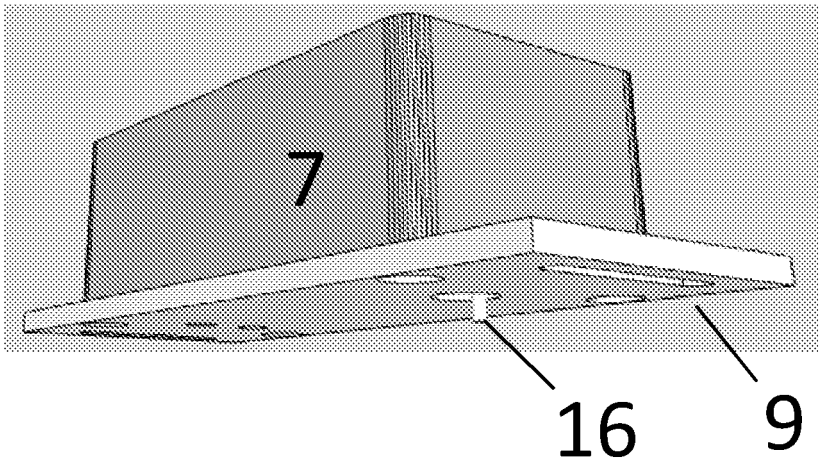


Figure 6

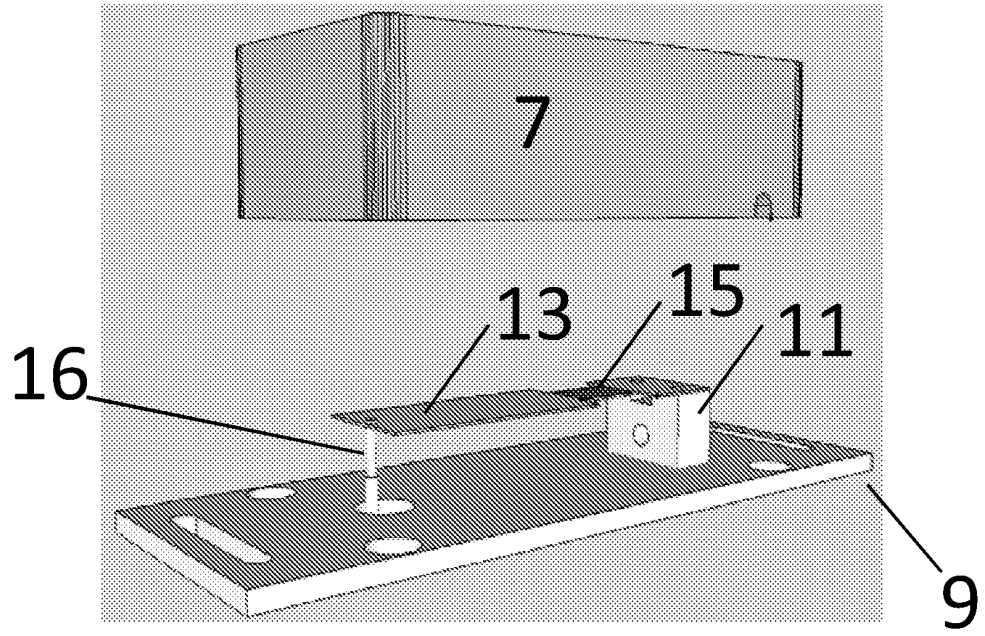


Figure 7

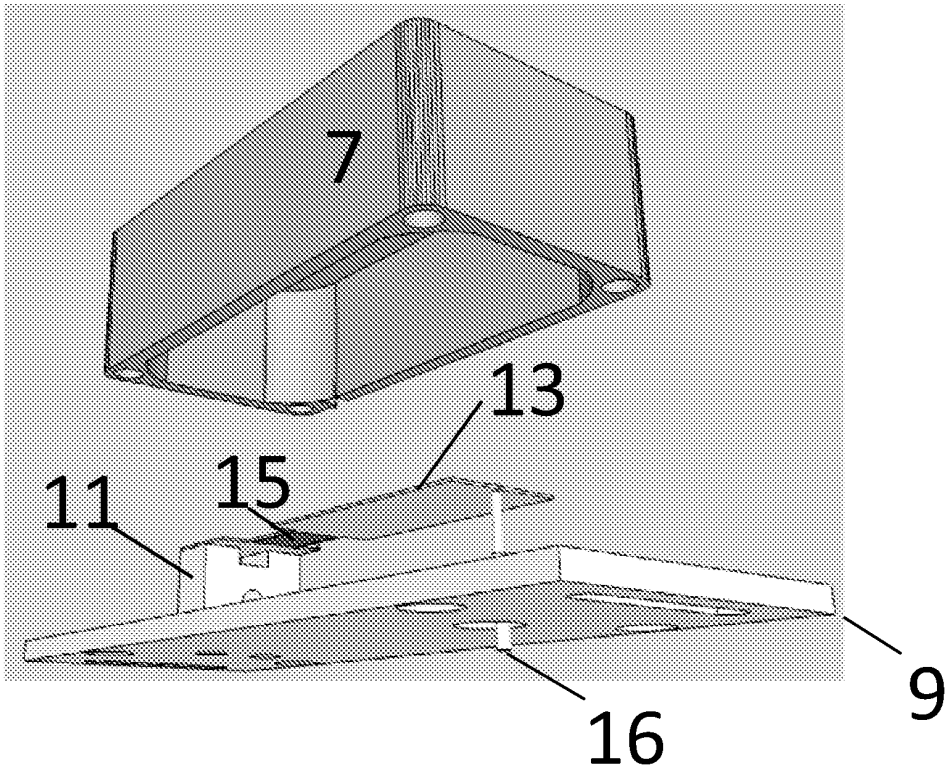


Figure 8

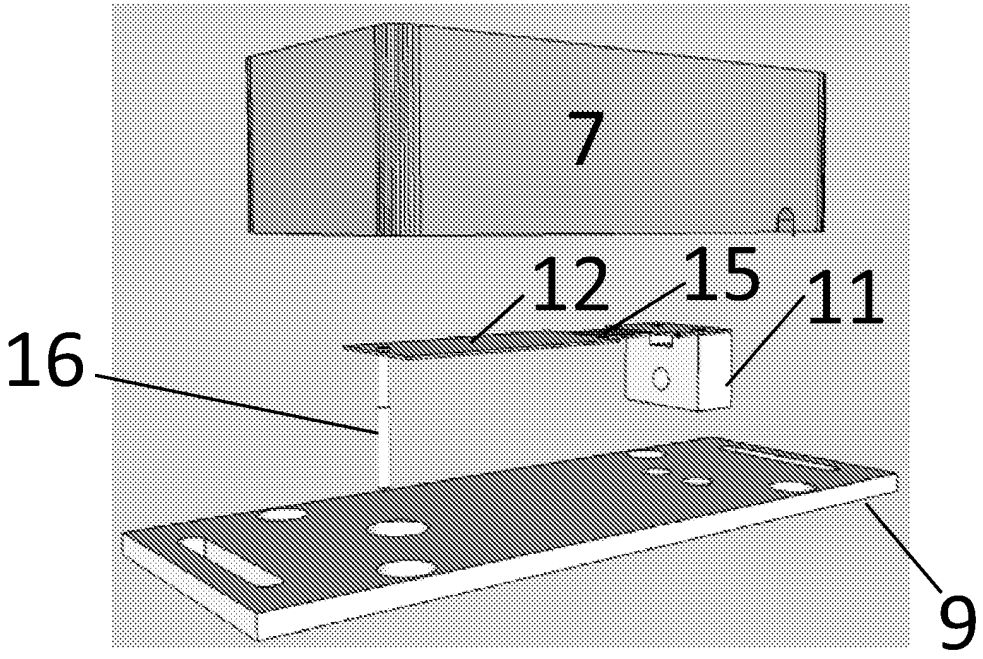


Figure 9

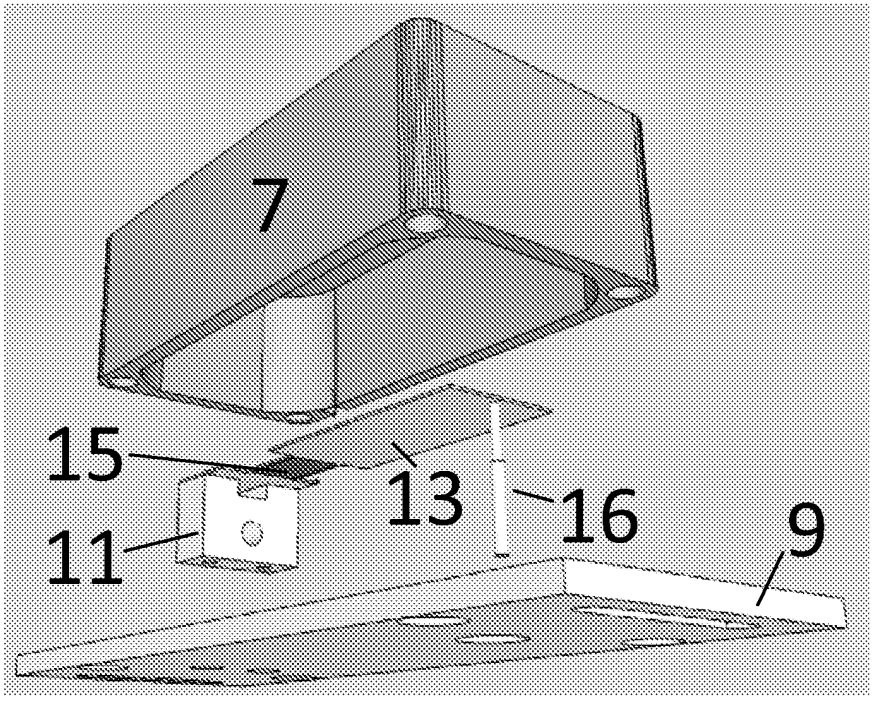


Figure 10

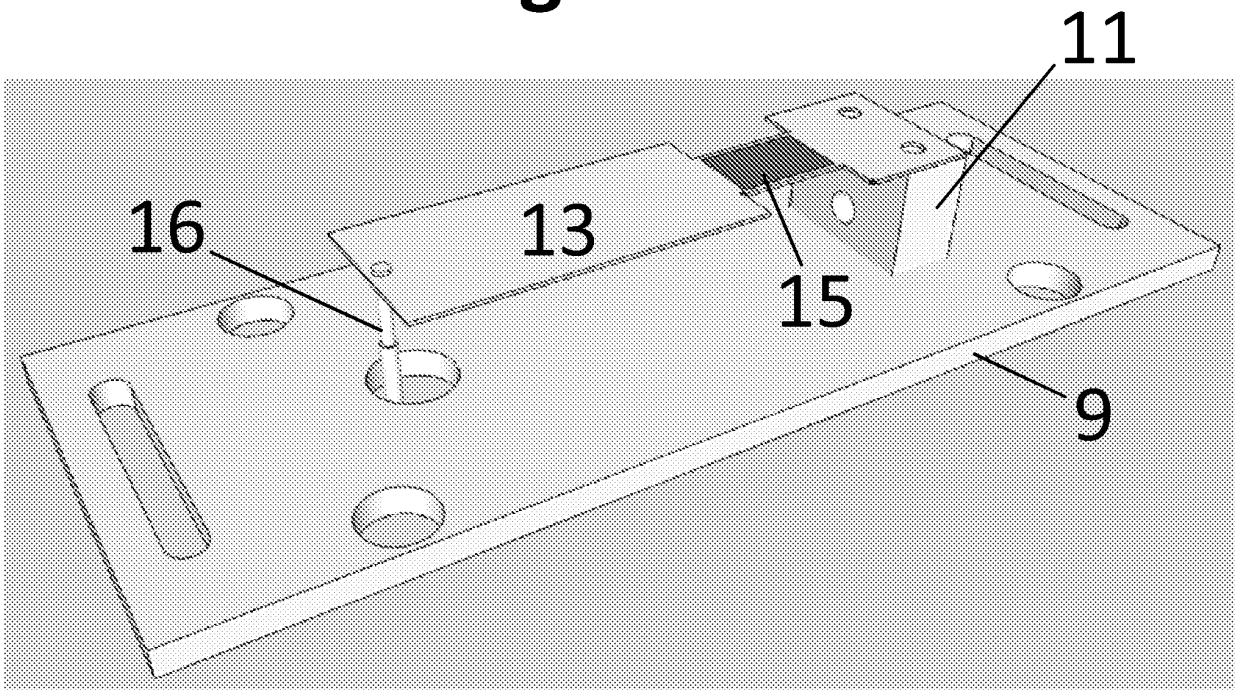


Figure 11

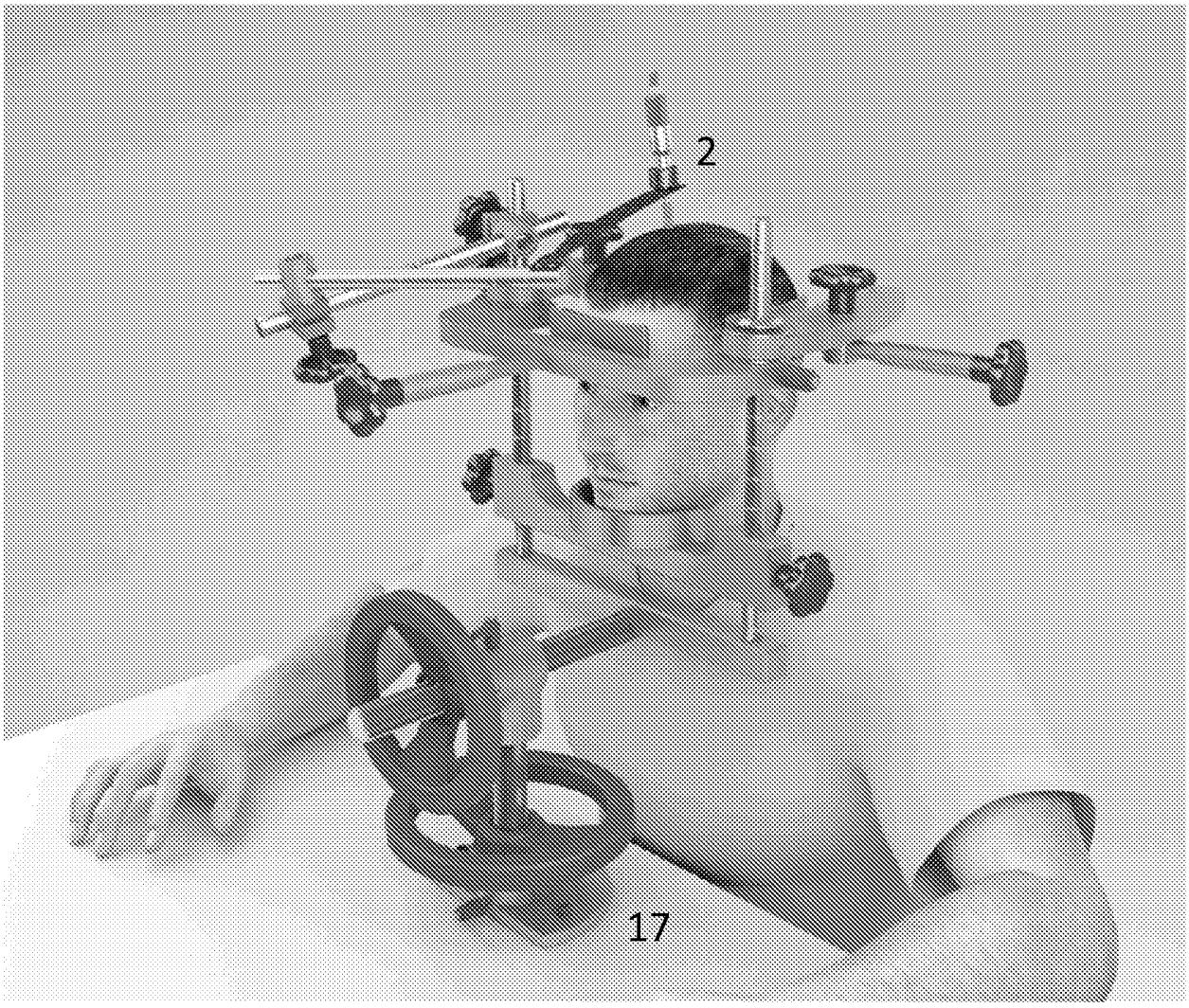


Figure 12

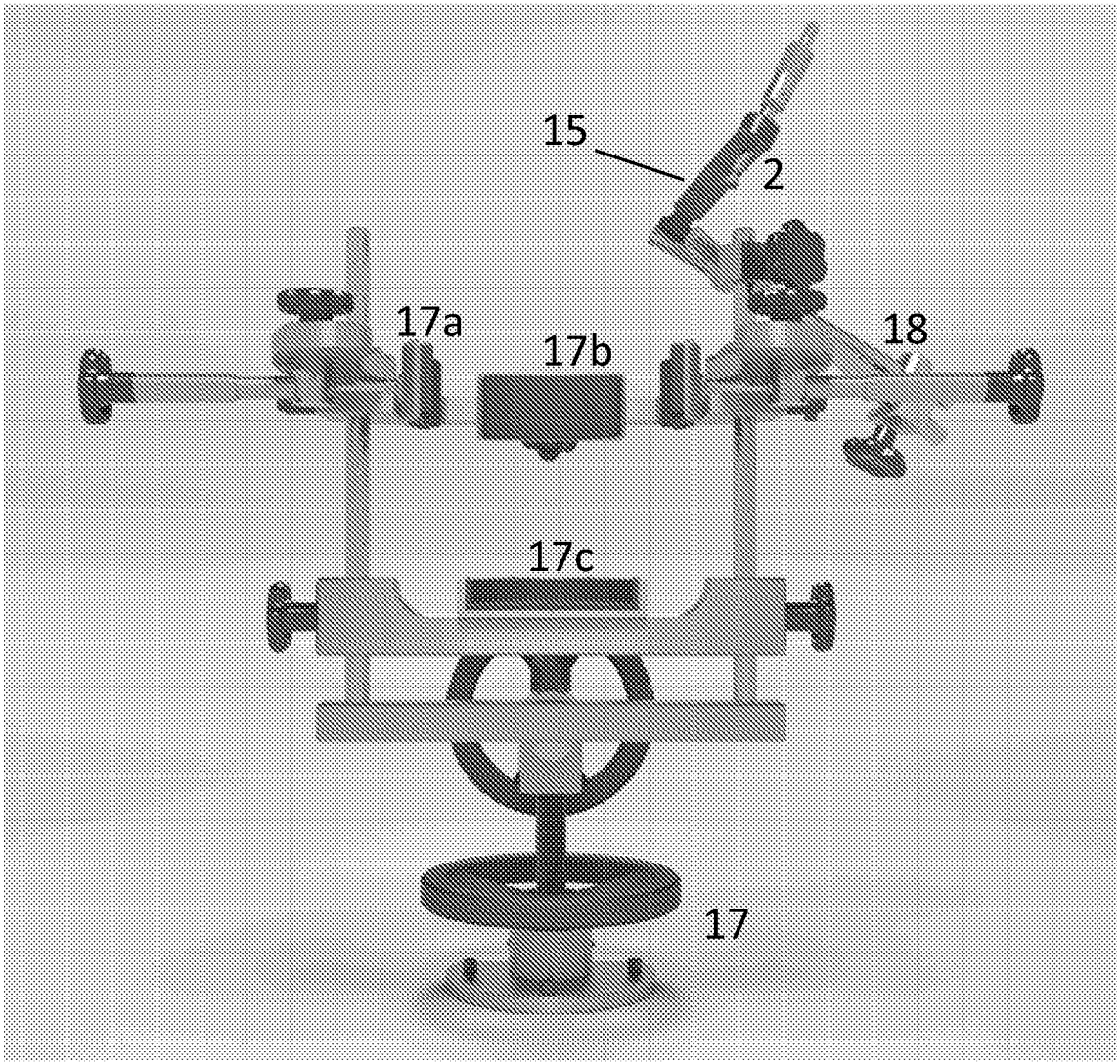


Figure 13

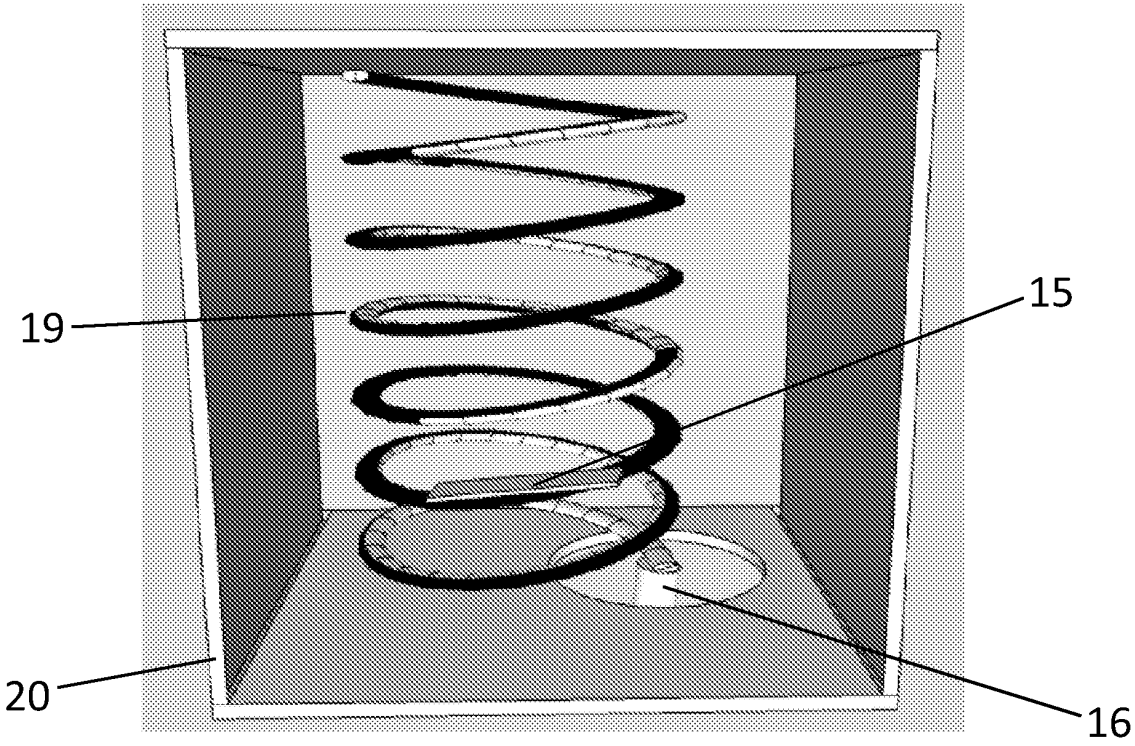


Figure 14

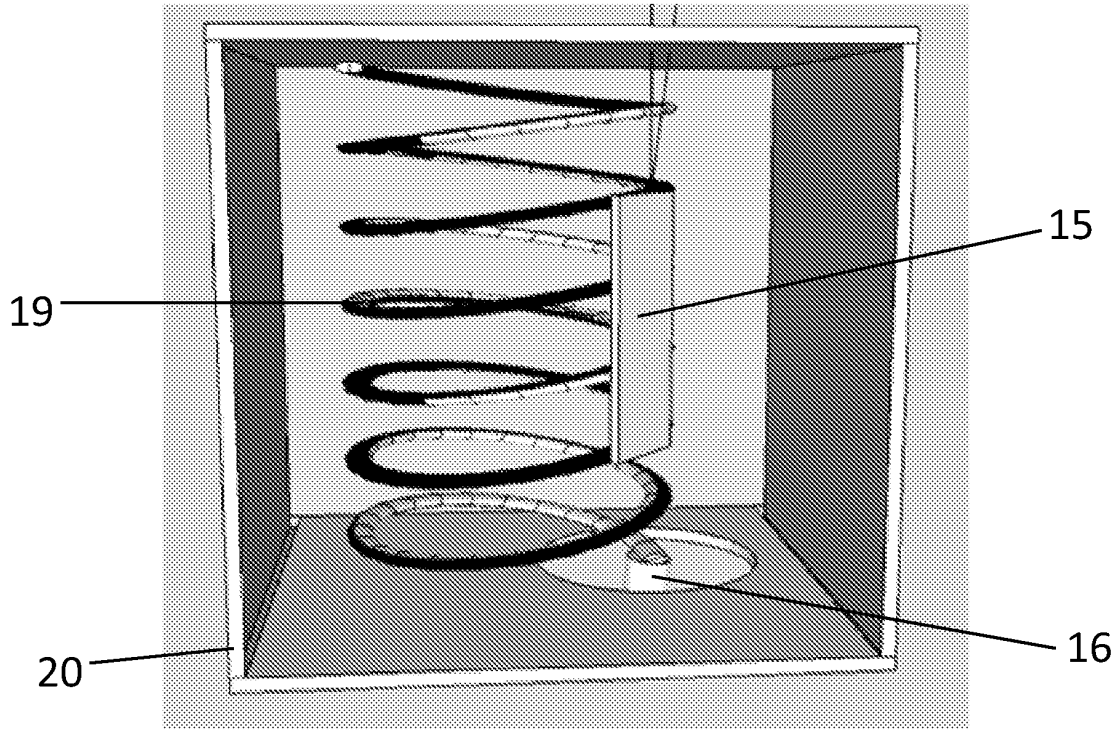


Figure 15

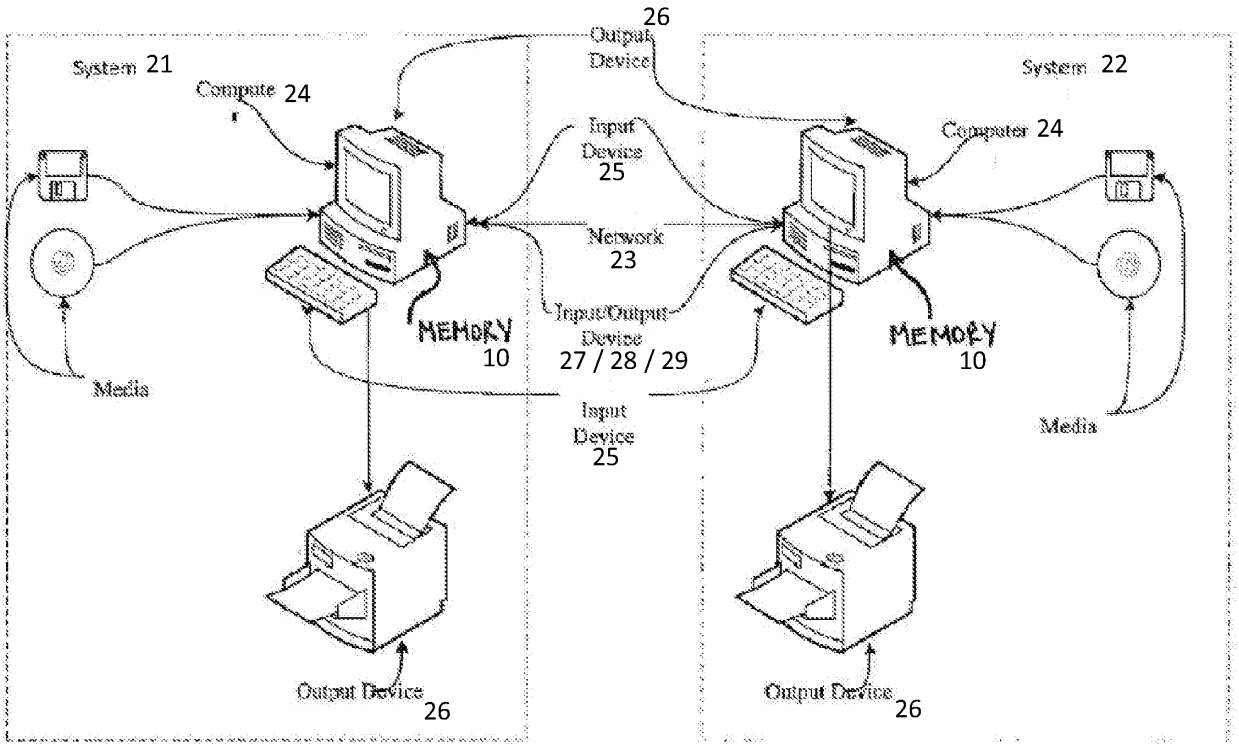

26
Output Device
System 21
Compute 24
Input Device 25
Network 23
Input/Output Device 27 / 28 / 29
MEMORY 10
Media
Input Device 25
Output Device 26
System 22
Computer 24
MEMORY 10
Media
Output Device 26

Figure 16

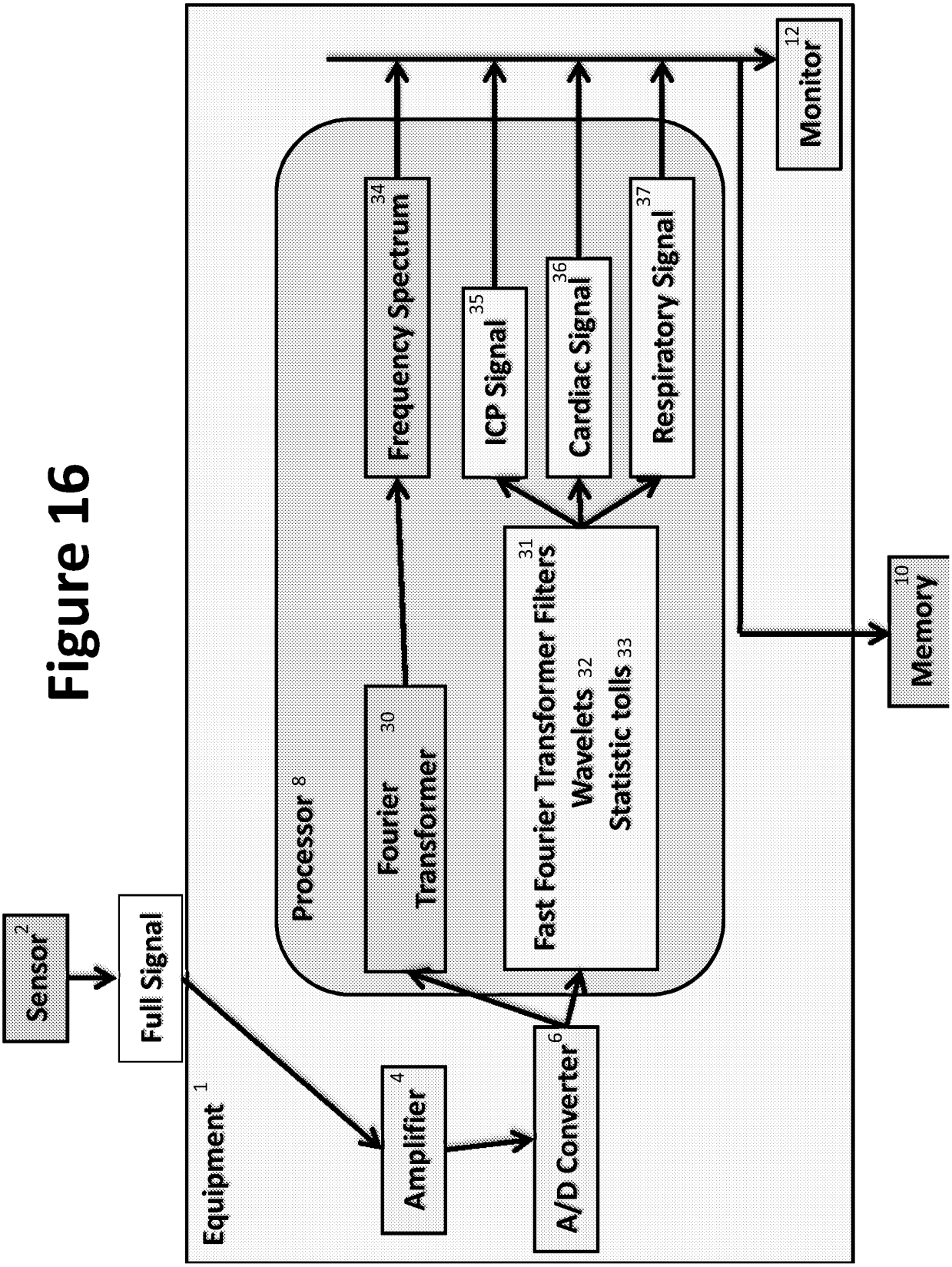

Sensor 2
Full Signal
Equipment 1
Amplifier 4
A/D Converter 6
Processor 8
Fourier Transformer 30
Fast Fourier Transformer Filters 31
Wavelets 32
Statistic tolls 33
Frequency Spectrum 34
ICP Signal 35
Cardiac Signal 36
Respiratory Signal 37
Monitor 12
Memory 10

Figure 17

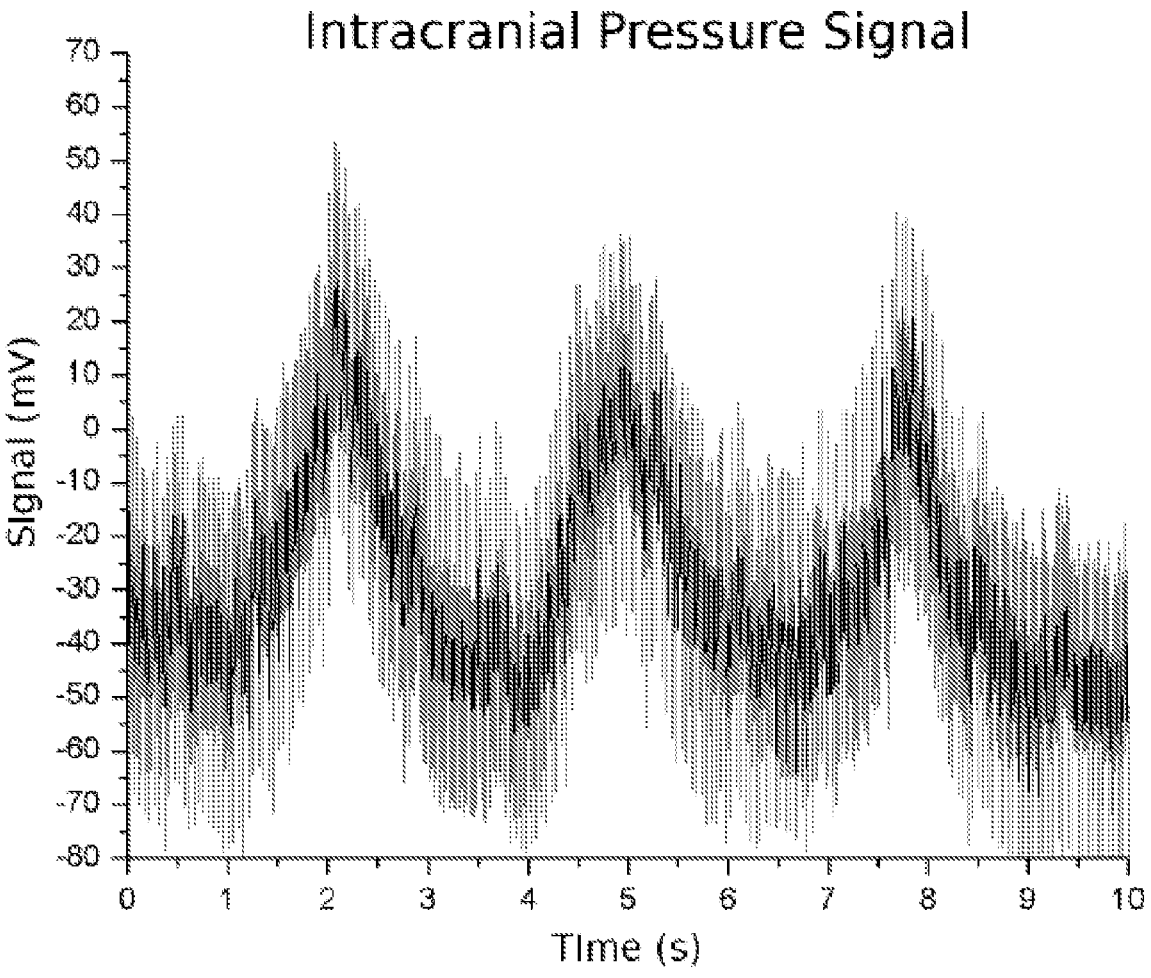

Intracranial Pressure Signal
Signal (mV)
70
60
50
40
30
20
10
0
-10
-20
-30
-40
-50
-60
-70
-80
0
1
2
3
4
5
6
7
8
9
10
Time (s)

Figure 18

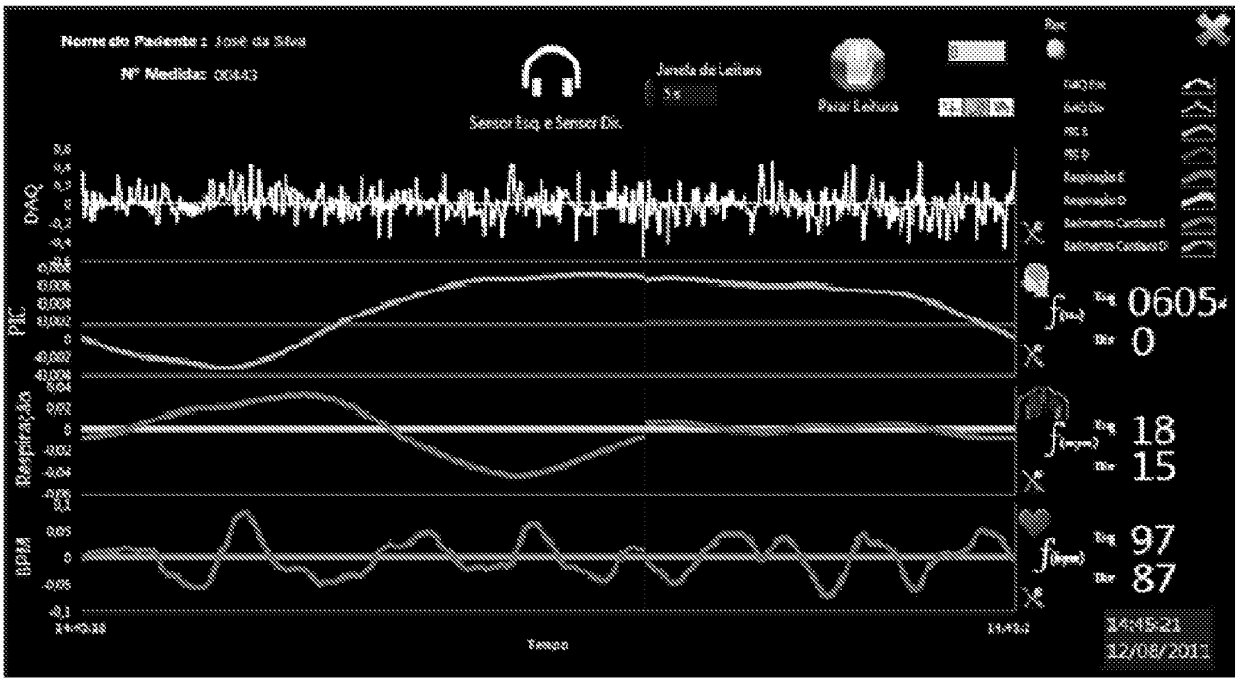

Nome do Paciente : José da Silva
Nº Medidas: 00003
Sensor Esq. e Sensor Dir.
Pausa Leitura
DAQ
PIC
Respiração
BPM
Tempo
0605
0
18
15
97
87
12/09/2011

Figure 19

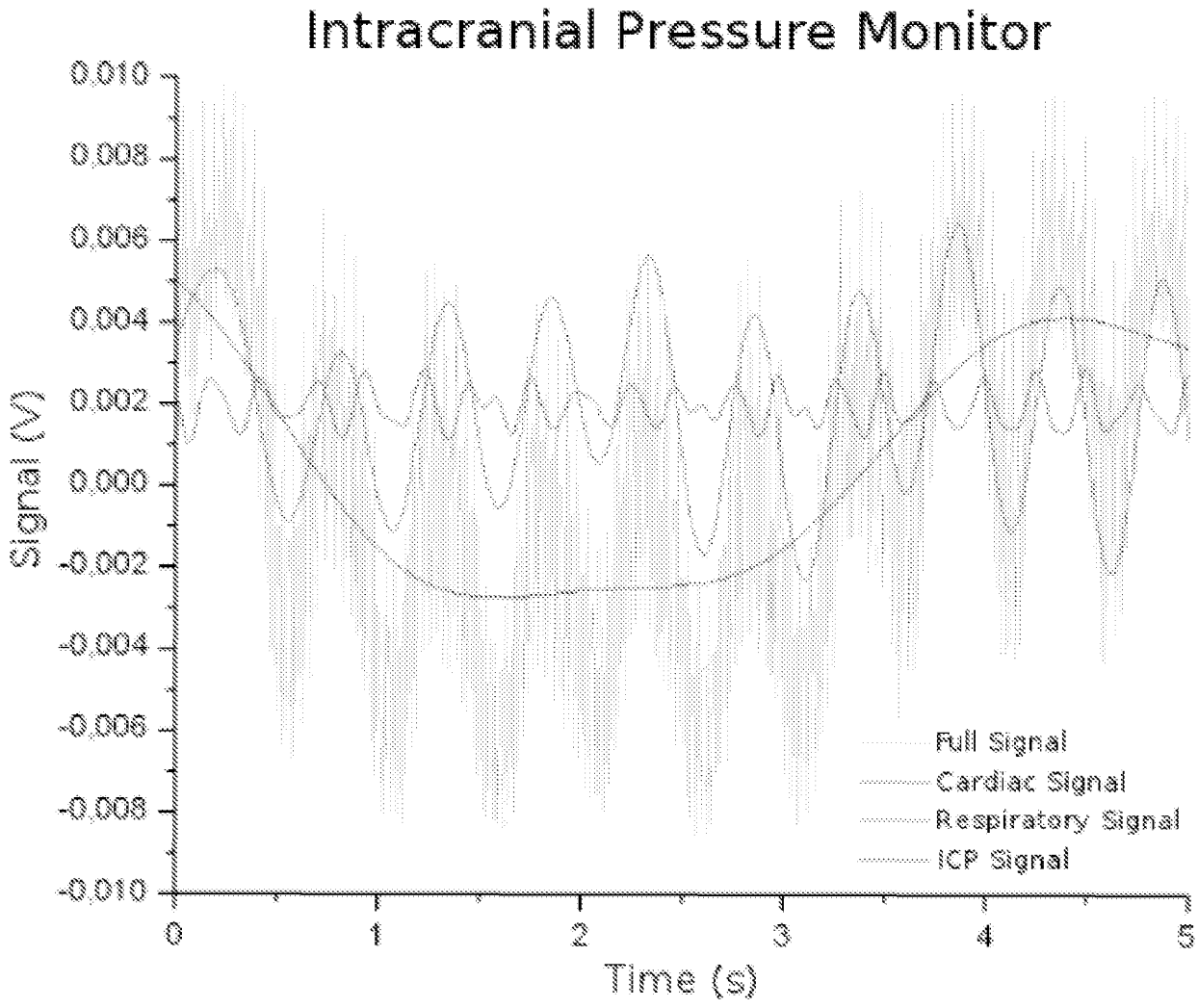

Intracranial Pressure Monitor
Signal (V)
0.010
0.008
0.006
0.004
0.002
0.000
-0.002
-0.004
-0.006
-0.008
-0.010
0
1
2
3
4
5
Time (s)
Full Signal
Cardiac Signal
Respiratory Signal
ICP Signal

Figure 20

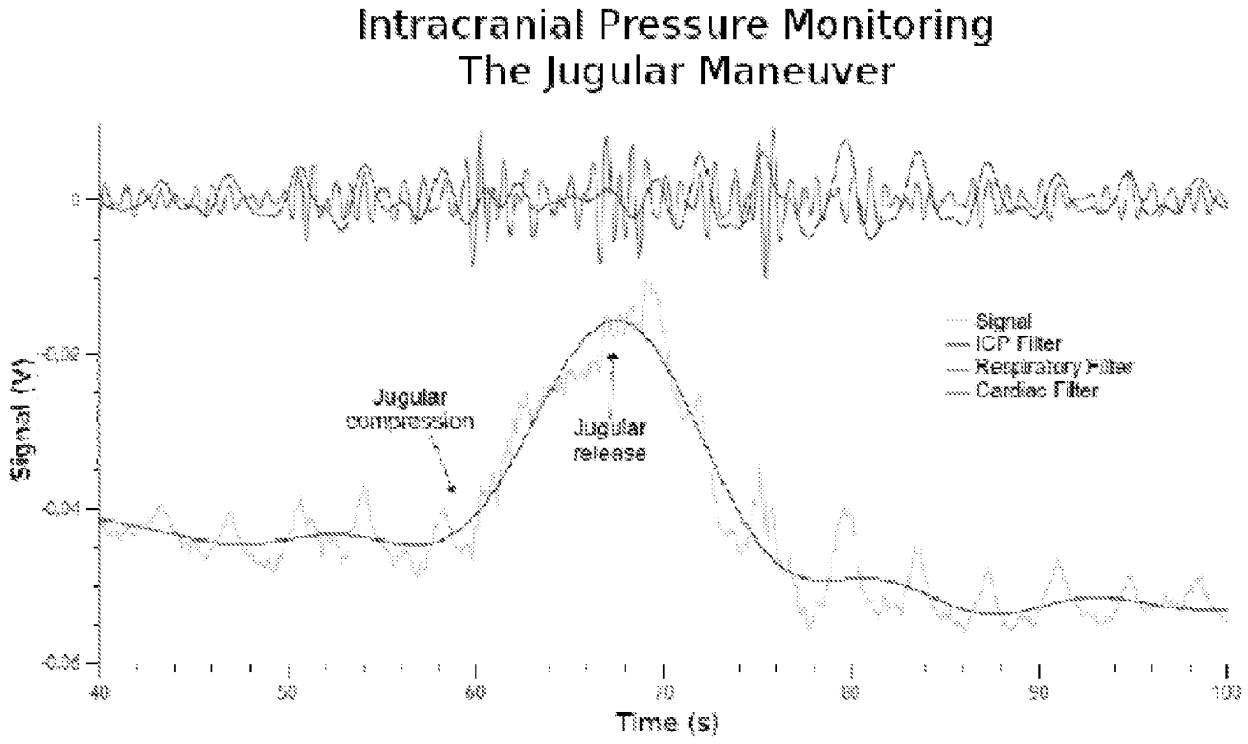

Intracranial Pressure Monitoring
The Jugular Maneuver
Signal
ICP Filter
Respiratory Filter
Cardiac Filter
Jugular compression
Jugular release
Signal (V)
Time (s)

Figure 21

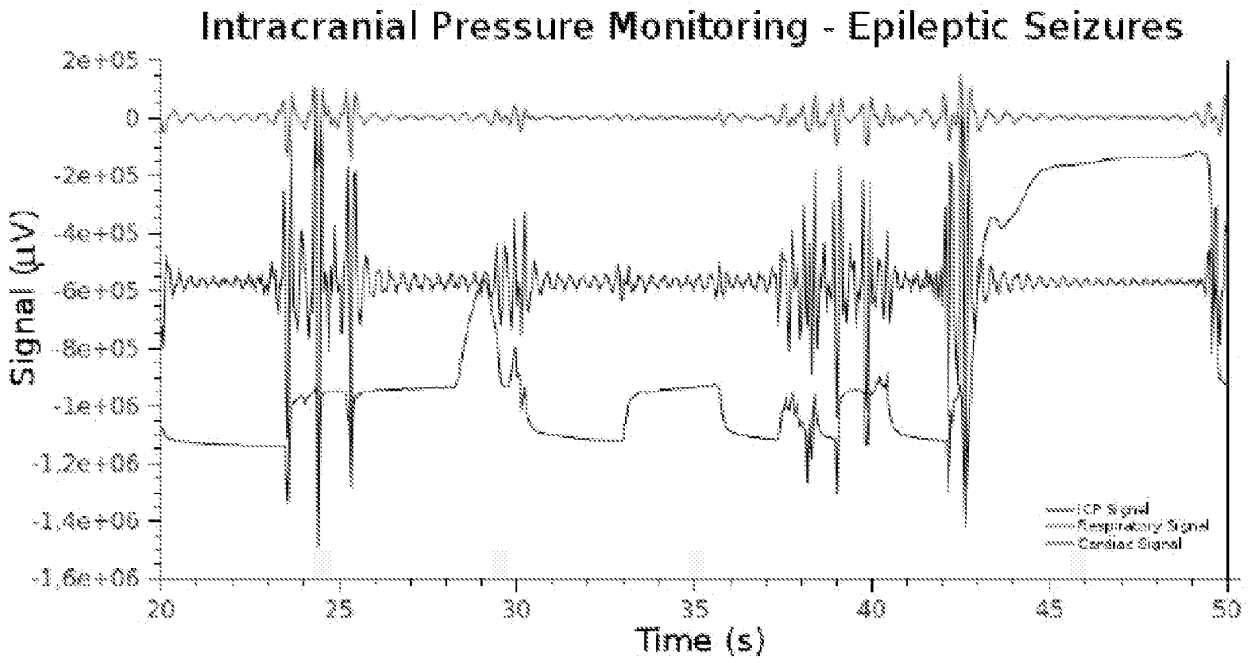

Intracranial Pressure Monitoring - Epileptic Seizures
Signal (µV)
2e+05
0
-2e+05
-4e+05
-6e+05
-8e+05
-1e+06
-1.2e+06
-1.4e+06
-1.6e+06
20
25
30
35
40
45
50
Time (s)
ICP Signal
Respiratory Signal
Cardiac Signal

Figure 22

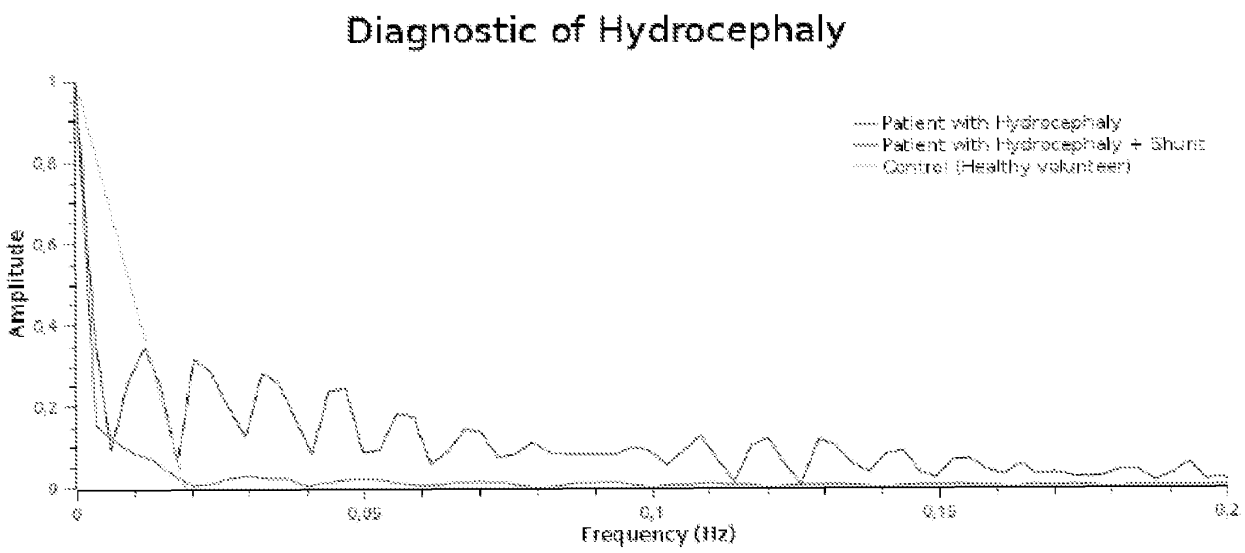

Diagnostic of Hydrocephaly
Patient with Hydrocephaly
Patient with Hydrocephaly + Shunt
Control (Healthy volunteer)
Amplitude
Frequency (Hz)
0
0,05
0,1
0,15
0,2

Figure 23

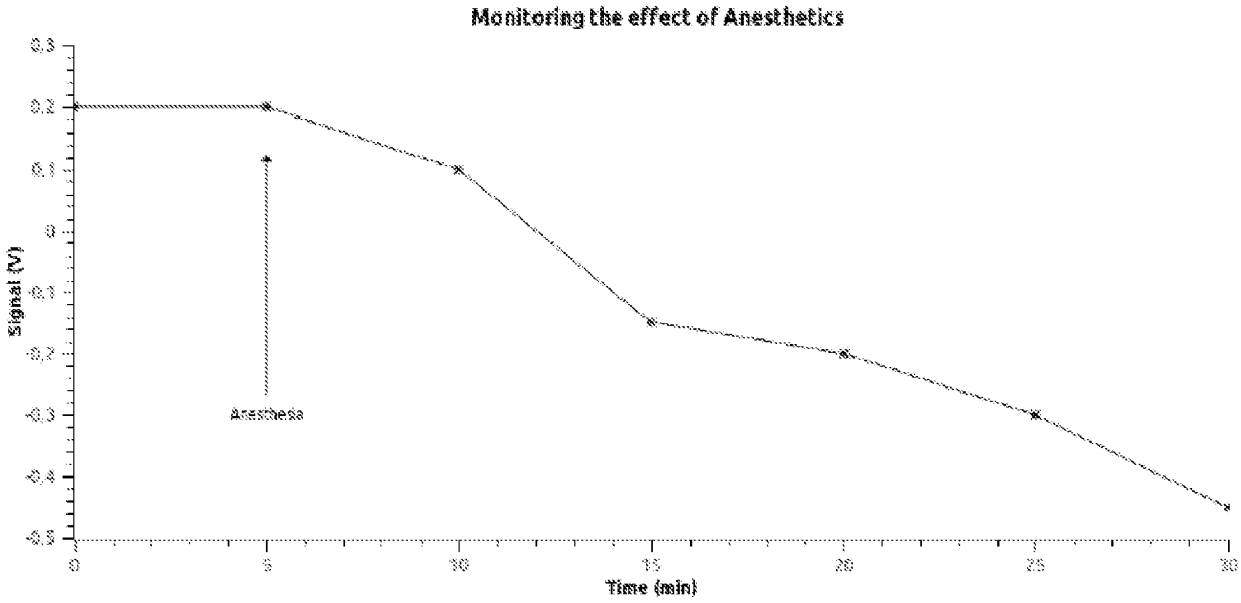

Monitoring the effect of Anesthetics
Signal (V)
Anesthesia
Time (min)
0
5
10
15
20
25
30

Figure 24

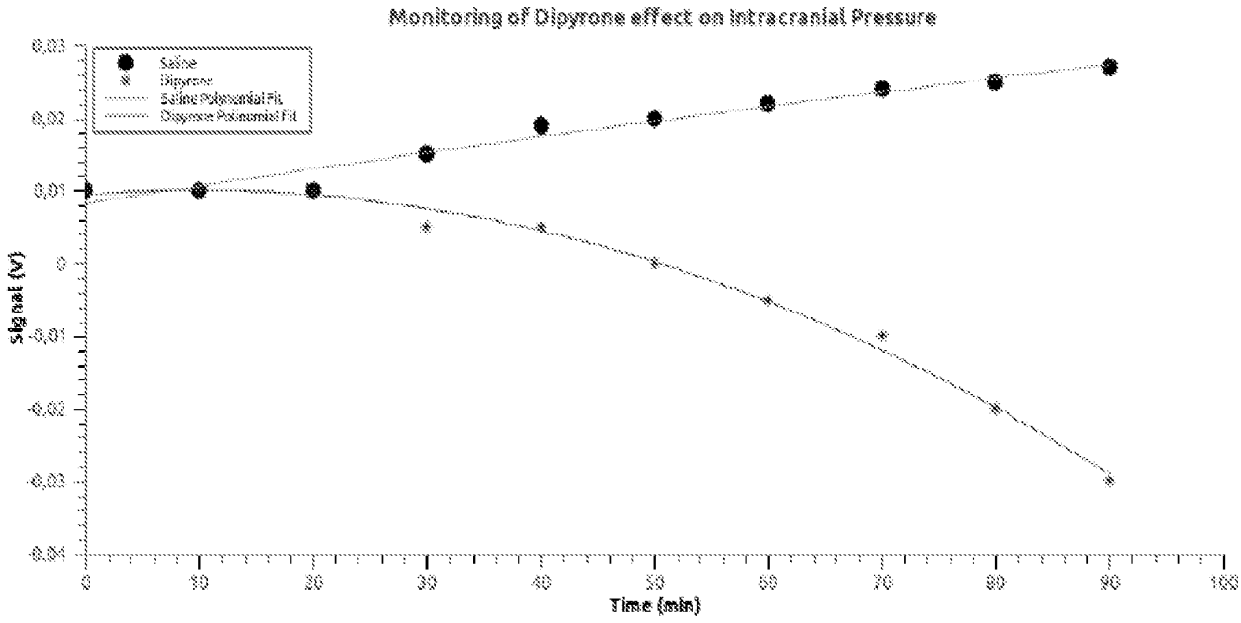

Monitoring of Dipyrone effect on Intracranial Pressure
Saline
Dipyrone
Saline Polynomial Fit
Dipyrone Polynomial Fit
Signal (V)
0,03
0,02
0,01
0
-0,01
-0,02
-0,03
-0,04
0
10
20
30
40
50
60
70
80
90
100
Time (min)

Figure 25

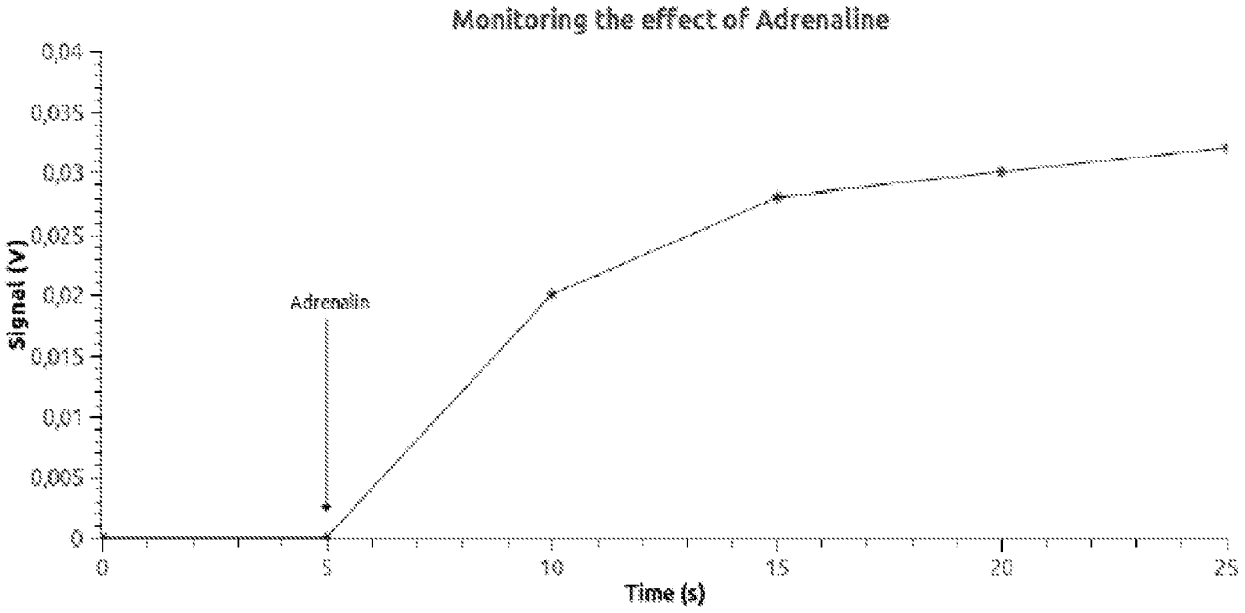

Monitoring the effect of Adrenaline
Signal (V)
0,04
0,035
0,03
0,025
0,02
0,015
0,01
0,005
0
Adrenalin
0
5
10
15
20
25
Time (s)

Figure 26

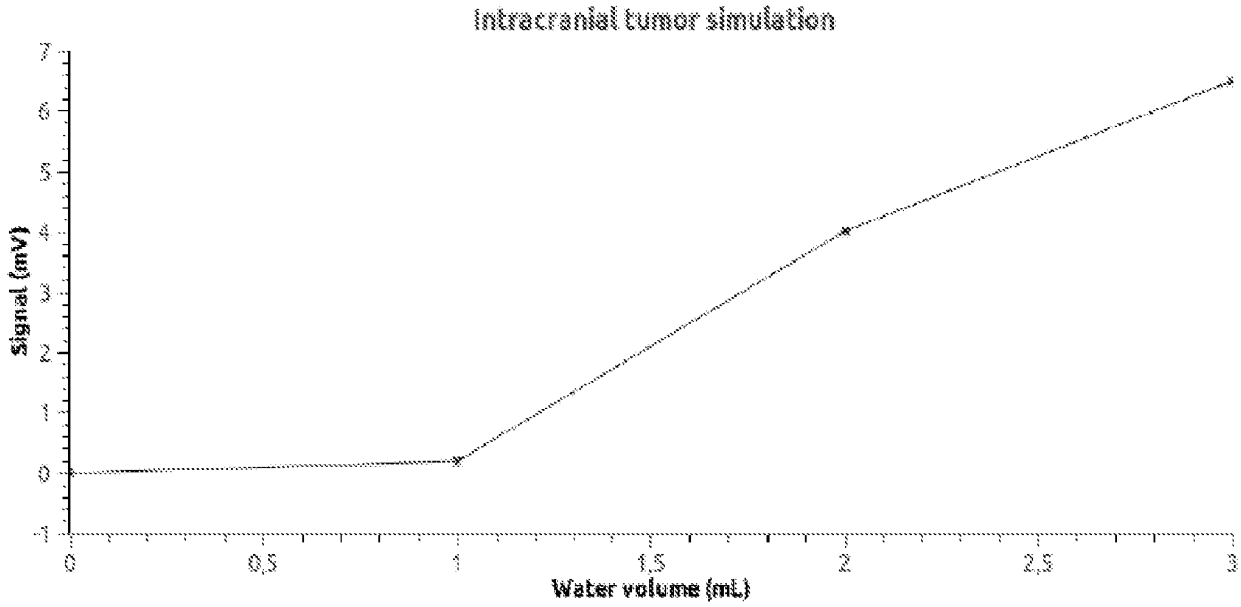

Intracranial tumor simulation
Signal (mV)
Water volume (mL)
0
0,5
1
1,5
2
2,5
3

Figure 27

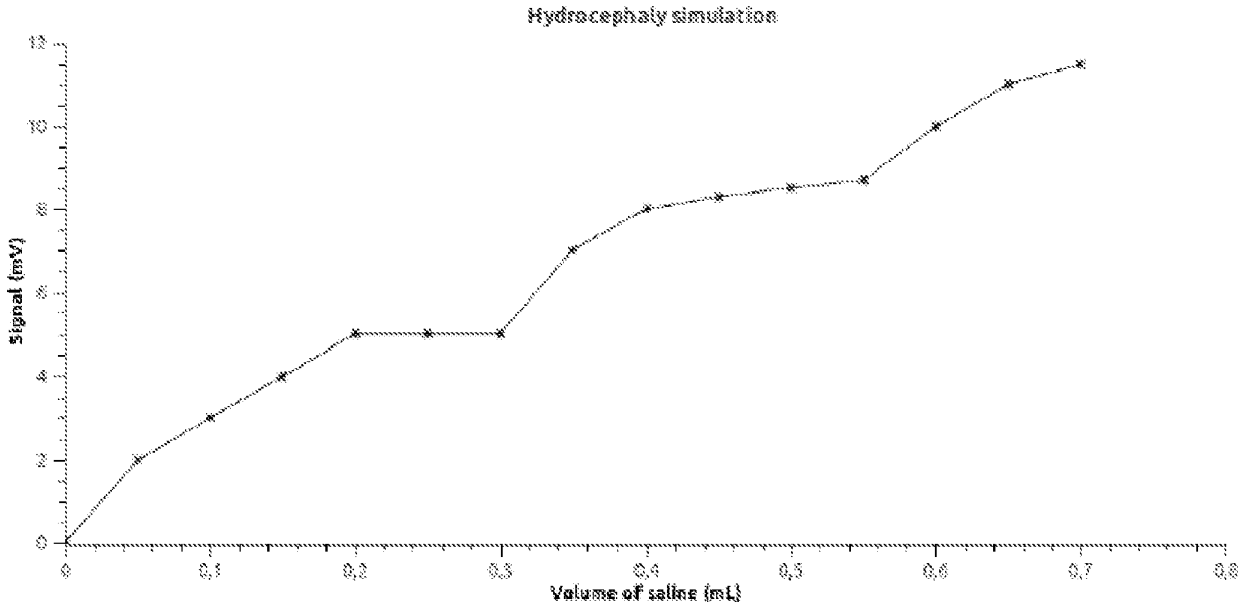
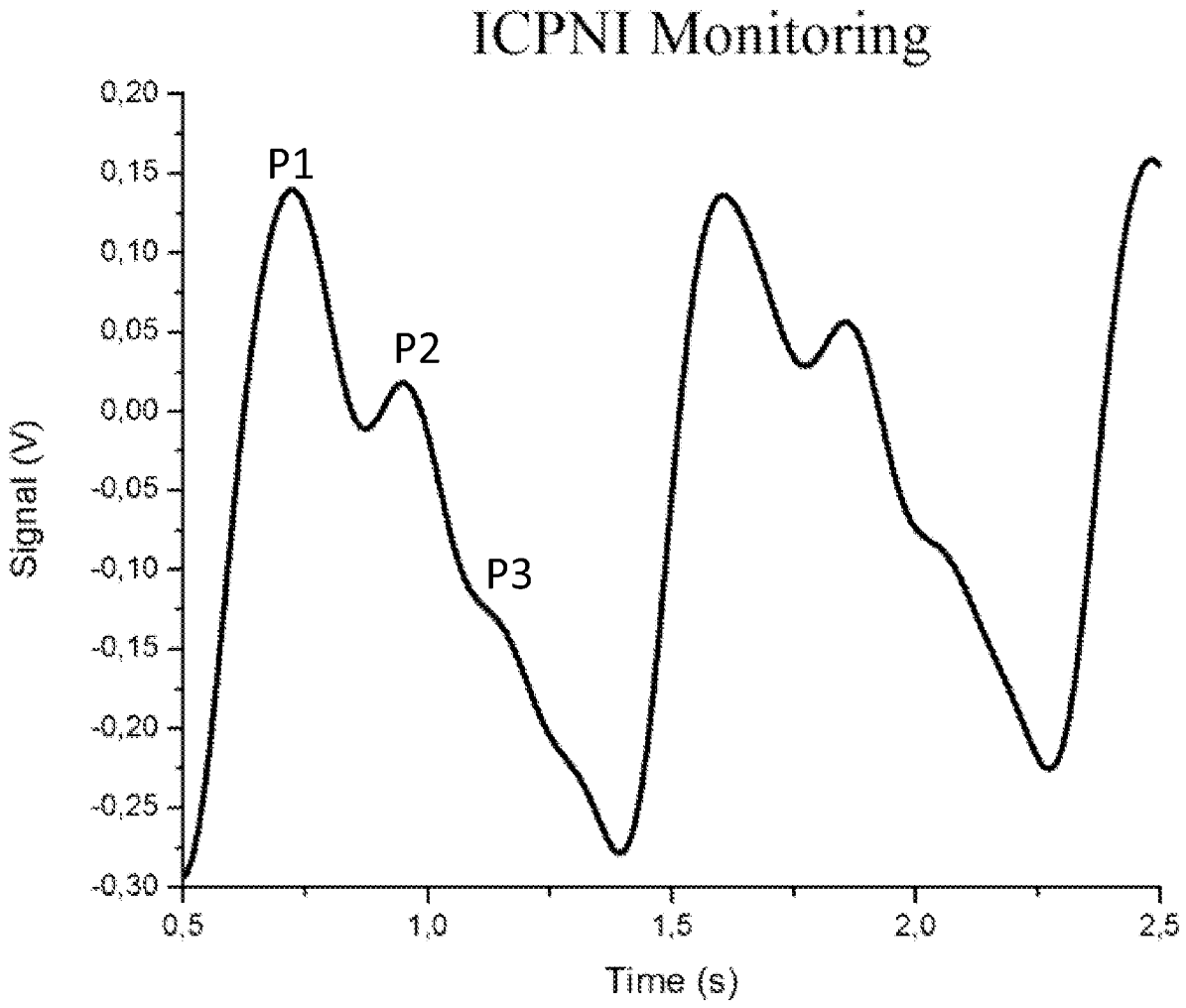

Hydrocephaly simulation
Signal (mV)
Volume of saline (mL)
0
0,1
0,2
0,3
0,4
0,5
0,6
0,7
0,8

Figure 28


ICPNI Monitoring
P1
P2
P3
Signal (V)
Time (s)
0,20
0,15
0,10
0,05
0,00
-0,05
-0,10
-0,15
-0,20
-0,25
-0,30
0,5
1,0
1,5
2,0
2,5

REFERENCES CITED IN THE DESCRIPTION

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

Patent documents cited in the description

- US 2013085400 A **[0001]**
- US 9826934 B **[0001]**

专利名称(译)	非侵入性颅内压系统		
公开(公告)号	EP2757939B1	公开(公告)日	2018-10-24
申请号	EP2012833644	申请日	2012-09-19
[标]申请(专利权)人(译)	OLIVEIRA SERGIO亚什		
申请(专利权)人(译)	OLIVEIRA奥马斯卡雷，塞尔吉奥		
[标]发明人	HENRIQUE FRIGIERI VILELA GUSTAVO		
发明人	HENRIQUE FRIGIERI VILELA, GUSTAVO		
IPC分类号	A61B5/00 A61B5/08		
CPC分类号	A61B5/031 A61B5/4094 A61B5/6814 A61B5/6831 A61B5/0205 A61B5/02438 A61B5/0816 A61B5/11 A61B5/4064 A61B5/4504 A61B5/4538 A61B5/4821 A61B5/4848 A61B5/6803 A61B5/7257 A61B5/7278 A61B5/7282 A61B5/7425 A61B5/743 A61B5/746 A61B2503/40 A61B2505/09 A61B2560/0475 A61B2562/0209 A61B2562/0223 A61B2562/0233 A61B2562/06		
优先权	61/536347 2011-09-19 US 13/621635 2012-09-17 US		
其他公开文献	EP2757939A4 EP2757939A2		
外部链接	Espacenet		

摘要(译)

非侵入性颅内压检测和/或监测和使用与其相关的数据。说明性地，关于方法，可以存在一种从颅骨变形电信号数字地产生和传递颅内压数据的方法，该方法包括：从至少一个传感器接收被配置为变换的电气设备处的检测到的颅骨变形电信号。并处理收到的颅骨变形信号;通过电气设备转换和处理接收到的颅骨变形电信号，产生数字颅内压数据;电气设备通过可操作地与电气设备相关联的输出设备输出数字颅内压数据，以提供数字颅内压数据。

Figure 1