(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
11 June 2009 (11.06.2009)

PCT

(10) International Publication Number
WO 2009/073615 A1

(51) International Patent Classification:
A61B 5/0215 (2006.01) *H01B 5/00* (2006.01)

(21) International Application Number:
PCT/US2008/085155

(22) International Filing Date:
1 December 2008 (01.12.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/004,508 29 November 2007 (29.11.2007) US
61/008,202 19 December 2007 (19.12.2007) US

(71) Applicant *(for all designated States except US)*: **INTEGRATED SENSING SYSTEMS, INC.** [US/US]; 391 Airport Industrial Drive, Ypsilanti, Michigan 48198 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **NAJAFI, Nader** [US/US]; 1240 Severn Court, Ann Arbor, Michigan 48105 (US). **HOOK-MORGAN, Catherine** [US/US]; 1119 Olivia Avenue, Ann Arbor, Michigan 48104 (US). **GOETZINGER, David Joseph** [US/US]; 16000 Riverside, Livonia, Michigan 48154 (US). **MASSOUD-ANSARI, Sonbol** [US/US]; 4040 Harlington Circle, El Dorado Hills, California 95762 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(54) **Title:** SENSOR UNIT AND PROCEDURE FOR MONITORING INTRACRANIAL PHYSIOLOGICAL PROPERTIES

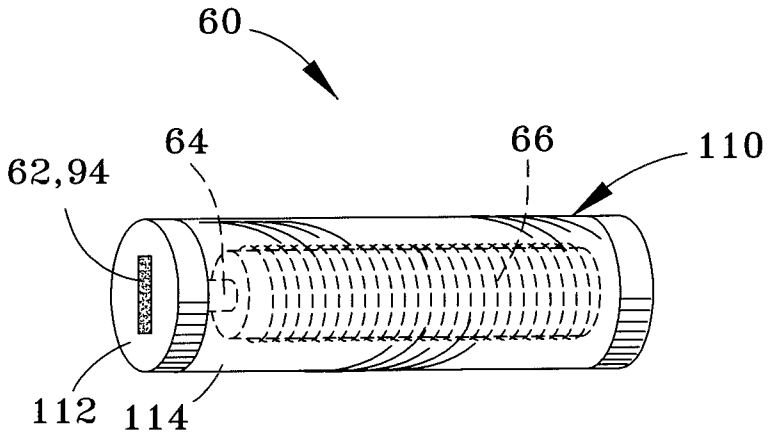


FIG.4

(57) **Abstract:** An anchor for an implantable sensing device, a sensor unit formed by the anchor and sensing device, and a surgical procedure for implanting the sensor unit for monitoring a physiological parameter within a cavity of a living body, such as an intracranial physiological property. The anchor includes a shank portion and a head portion. The shank portion defines a distal end of the anchor and has a bore defining an opening at the distal end. The head portion defines a proximal end of the anchor and has a larger cross-sectional dimension than the shank portion. The sensor unit comprises the anchor and the sensing device placed and secured within the bore of the anchor so that a sensing element of the sensing device is exposed for sensing the physiological parameter within the cavity.

WO 2009/073615 A1

SENSOR UNIT AND PROCEDURE FOR MONITORING INTRACRANIAL PHYSIOLOGICAL PROPERTIES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application Nos. 61/004,508 filed November 29, 2007, and 61/008,202 filed December 19, 2007. The contents of these prior patent applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention generally relates to implantable medical devices, monitoring systems and associated procedures. More particularly, this invention relates to a sensor unit comprising an anchor and an implantable medical sensing device, and to a procedure for implanting the sensing device for monitoring intracranial physiological properties.

[0003] Wireless devices such as pressure sensors have been implanted and used to monitor heart, brain, bladder and ocular function. With this technology, capacitive pressure sensors are often used, by which changes in pressure cause a corresponding change in the capacitance of an implanted capacitor (tuning capacitor). The change in capacitance can be sensed, for example, by sensing a change in the resonant frequency of a tank or other circuit coupled to the implanted capacitor.

[0004] Telemetric implantable sensors that have been proposed include batteryless pressure sensors developed by CardioMEMS, Inc., Remon Medical, and the assignee of the present invention, Integrated Sensing Systems, Inc. (ISSYS). For example, see commonly-assigned U.S. Patent Nos. 6,926,670 and 6,968,734 to Rich et al., and N. Najafi

and A. Ludomirsky, "Initial Animal Studies of a Wireless, Batteryless, MEMS Implant for Cardiovascular Applications," Biomedical Microdevices, 6:1, p. 61-65 (2004). With such technologies, pressure changes are typically sensed with an implant equipped with a mechanical (tuning) capacitor having a fixed electrode and a moving electrode, for example, on a diaphragm that deflects in response to pressure changes. The implant is further equipped with an inductor in the form of a fixed coil that serves as an antenna for the implant, such that the implant is able to receive a radio frequency (RF) signal transmitted from outside the patient to power the circuit, and also transmit the resonant frequency as an output of the circuit that can be sensed by a reader outside the patient. The implant can be placed with a catheter, for example, directly within the heart chamber whose pressure is to be monitored, or in an intermediary structure, for example, the atrial or ventricular septum of the heart.

[0005] Presently in the United States, roughly one million people are treated for head injuries each year, with over a quarter million of these being moderate or severe injuries. Traumatic brain injuries currently account for approximately 70,000 deaths each year in the United States, with an additional 80,000 patients having severe long-term disabilities. Monitoring intracranial pressure (ICP) to identify intracranial hypertension (ICH) is one of the most important steps in treatment of severe head injuries. The ability to accurately monitor and identify high ICP levels enables physicians to diagnose and treat the underlying causes and significantly reduce the morbidity and mortality rates of these patients.

[0006] ICP is currently measured and recorded through a variety of systems, such as intraventricular catheters, subarachnoid bolts, and catheter tip strain gauges. However, each of these systems has significant drawbacks, including the need for repositioning and balancing, the occurrence of occlusions and blockages, and the risk of infection.

BRIEF SUMMARY OF THE INVENTION

[0007] The present invention provides an anchor for an implantable sensing device, a sensor unit formed by the anchor and sensing device, and a surgical procedure for implanting the sensor unit for monitoring a physiological parameter within a cavity of a living body, such as an intracranial physiological property.

[0008] The anchor includes a shank portion and a head portion. The shank portion defines a distal end of the anchor and has a bore defining an opening at the distal end. The head portion defines a proximal end of the anchor and has a larger cross-sectional dimension than the shank portion. The sensor unit is configured to position a sensing element for monitoring a physiological parameter within a cavity of a living body, and includes the anchor and a sensing device that comprises the sensing element and is configured to be placed and secured within the bore of the anchor.

[0009] The surgical procedure generally entails assembling the sensor unit by placing the sensing device within the bore of the anchor so that the sensing element of the sensing device is exposed at the distal end of the anchor for sensing a physiological parameter. An incision is made in the scalp of a patient to expose a portion of the skull, a hole is made through the skull, and the sensor unit is placed in the hole such that the distal end of the sensor unit (as defined by the sensing device or the distal end of the anchor) is flush with or protrudes into the cranial cavity within the skull, while an oppositely-disposed proximal end of the sensor unit (as defined by the proximal end of the anchor) remains outside the skull. The anchor is secured to the skull so that the hole in the skull is occluded by the sensor unit. A readout device located outside the patient can be used to telemetrically communicate with the sensing device to obtain a reading of the physiological parameter sensed by the sensing element.

[0010] The sensor unit and implantation procedure are intended to be particularly well suited for providing safe, fast, detailed, real-time, and continuous intracranial pressure measurements. Compared to existing systems used for ICP monitoring, particular advantages of the invention include a miniature wireless unit with an uncomplicated anchoring system and implantation/placement procedure that enables accurate placement of a sensing element at various depths in the cranial cavity. The invention also offers reduced infection risk and patient discomfort, increased patient mobility, and improved post-surgical patient care. Preferred embodiments of the sensor unit are very small, allowing the unit to be easily placed under the scalp with minimal discomfort to the patient.

[0011] Other objects and advantages of this invention will be better appreciated from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIGS. 1a and 1b are block diagrams of wireless pressure monitoring systems that utilize resonant and passive sensing schemes, respectively, which can be utilized by the present invention.

[0013] FIGS. 2a and 2b are schematic representations of a wireless sensing device and a readout device suitable for use in wireless monitoring systems of this invention.

[0014] FIG. 3 schematically represents internal components of processing circuitry suitable for use in the sensing device of FIG. 2a.

[0015] FIG. 4 represents a perspective view of a cylindrical self-contained sensing device of the type represented in FIG. 2a.

[0016] FIG. 5 represents the sensing device of FIG. 4 assembled with an anchor in accordance with a preferred embodiment of the invention.

[0017] FIGS. 6 through 8 schematically represent sensor units equipped with alternative anchors implanted through a hole in the skull of a subject.

DETAILED DESCRIPTION OF THE INVENTION

[0018] FIGS. 1a through 4 schematically illustrate monitoring systems and components thereof that implement one or more implantable sensing devices (10,30,60) adapted to be placed through a hole in the skull of a patent for monitoring one or more intracranial physiological parameters, a notable but nonlimiting example of which is intracranial pressure (ICP). Each monitoring system preferably makes use of a readout unit (20,50,80) adapted to wirelessly communicate with the sensing device. The sensing device is placed at a desired location within the skull with an anchor 120, of which several embodiments are shown in FIGS. 5 through 8. Together, the sensing device and its anchor 120 define a sensor unit 150. Because the sensing device communicates wirelessly with a readout unit, the sensor unit 150 lacks a wire, cable, tether, or other physical component that conducts the output of the sensing device to the readout unit or another processing or transmission device outside the body of a patent. As such, the sensor unit 150 defines the only implanted portion of the monitoring system.

[0019] FIGS. 1a and 1b represent two types of wireless pressure sensing schemes disclosed in U.S. Patent Nos. 6,926,670 and 6,968,734 to Rich et al., and capable of use with the present invention. In FIG. 1a, an implant 10 is shown as operating in combination with a non-implanted external reader unit 20, between which a wireless telemetry link is established using a resonant scheme. The implant 10 contains a packaged inductor coil 12 and a pressure sensor in the form of a mechanical capacitor 14. Together, the inductor

coil 12 and capacitor 14 form an LC (inductor-capacitor) tank resonator circuit that has a specific resonant frequency, expressed as $1/(LC)^{1/2}$, which can be detected from the impedance of the circuit. At the resonant frequency, the circuit presents a measurable change in magnetically-coupled impedance load to an external coil 22 associated with the reader unit 20. Because the resonant frequency is a function of the capacitance of the capacitor 14, the resonant frequency of the LC circuit changes in response to pressure changes that alter the capacitance of the capacitor 14. Based on the coil 12 being fixed and therefore having a fixed inductance value, the reader unit 20 is able to determine the pressure sensed by the implant 10 by monitoring the resonant frequency of the circuit.

[0020] FIG. 1b shows another wireless pressure sensor implant 30 operating in combination with a non-implanted external reader unit 50. A wireless telemetry link is established between the implant 30 and reader unit 50 using a passive, magnetically-coupled scheme, in which onboard circuitry of the implant 30 receives power from the reader unit 50. In the absence of the reader unit 50, the implant 30 lays passive and without any internal means to power itself. When a pressure reading is desired, the reader unit 50 must be brought within range of the implant 30. The implant 30 contains a packaged inductor coil 32 and a pressure sensor in the form of a mechanical capacitor 34. The reader unit 50 has a coil 52 by which an alternating electromagnetic field is transmitted to the coil 32 of the implant 30 to induce a voltage in the implant 30. When sufficient voltage has been induced in the implant 30, a rectification circuit 38 converts the alternating voltage on the coil 32 into a direct voltage that can be used by electronics 40 as a power supply for signal conversion and communication. At this point the implant 30 can be considered alert and ready for commands from the reader unit 50. The implant 30 may employ the coil 32 as an antenna for both reception and transmission, or it may utilize the coil 32 solely for receiving power from the reader unit 50 and employ a second coil 42 for transmitting signals to the reader unit 50. Signal transmission circuitry 44 receives an encoded signal generated by signal conditioning circuitry 46 based on the output of the

capacitor 34, and then generates an alternating electromagnetic field that is propagated to the reader unit 50 with the coil 42. The implant 30 is shown in FIG. 1b without a battery, and therefore its operation does not require occasional replacement or charging of a battery. Instead, the energy required to perform the sensing operation is entirely derived from the reader unit 50. However, the implant 30 of FIG. 1b could be modified to use a battery or other power storage device to power the implant 30 when the reader unit 50 is not sufficiently close to induce a voltage in the implant 30.

[0021] While the resonant and passive schemes described in reference to FIGS. 1a and 1b are within the scope of the invention, FIG. 2a represents a more preferred sensing device 60 that translates a physiologic parameter into a frequency tone and modulates the impedance of an antenna with the frequency tone to communicate the physiologic parameter to an external readout unit 80 (FIG. 2b). FIG. 2a represents the wireless implantable sensing device 60 as comprising a transducer 62, electronic circuitry 64 (e.g., an application-specific integrated circuit, or ASIC), and an antenna 66. The antenna 66 is shown as comprising windings 68 (e.g., copper wire) wrapped around a core 70 (e.g., ferrite), though other antenna configurations and materials are foreseeable. The transducer 62 is preferably a MEMS device, more particularly a micromachine fabricated by additive and subtractive processes performed on a substrate. The substrate can be rigid, flexible, or a combination of rigid and flexible materials. Notable examples of rigid substrate materials include glass, semiconductors, silicon, ceramics, carbides, metals, hard polymers, and TEFLON. Notable flexible substrate materials include various polymers such as parylene and silicone, or other biocompatible flexible materials. A particular but nonlimiting example of the transducer 62 is a MEMS capacitive pressure sensor for sensing pressure, such as intracranial pressure (ICP) of the cerebrospinal fluid, though other materials and any variety of sensing elements, e.g., capacitive, inductive, resistive, piezoelectric, etc., could be used. For example, the transducer 62 could be configured to sense temperature, flow, acceleration, vibration, pH, conductivity, dielectric constant, and

chemical composition, including the composition and/or contents of cerebrospinal fluid. The sensing device 60 may be powered with a battery or other power storage device, but in preferred embodiments is powered entirely by the readout unit 80 schematically represented in FIG. 2b.

[0022] In addition to powering the sensing device 60, the readout unit 80 is represented as being configured to receive an output signal from the sensing device 60, process the signal, and relay the processed signal as data in a useful form to a user. The readout unit 80 is shown equipped with circuitry 82 that generates a high-frequency (e.g., 13.56 MHz), high-power signal for an antenna 84 to create the magnetic field needed in communicate with the sensing device 60. The readout unit 80 contains additional circuitry 86 to receive and demodulate a backscattered signal from the sensing device 60, which is then processed with a processing unit 88 using calibration coefficients to quantify the physiological parameter of interest. The readout unit 80 is further shown as equipped with a user interface 90, by which the operation of the readout unit 80 can be controlled to allow data logging or other user control and data examination. The readout unit 80 can be further configured for wireless or wired communication with a computer, telephone, or web-based system.

[0023] FIG. 3 represents a block diagram showing particularly suitable components for the electronic circuitry 64 of FIG. 2a. The circuitry 64 includes an oscillator 92, for example a relaxation oscillator, connected to a resistor 93 and a MEMs mechanical capacitor 94 as an example of the transducer 62 of FIG. 2a. A preferred MEMS capacitor 94 comprises a fixed electrode and a moving electrode on a diaphragm that deflects relative to the fixed electrode in response to pressure, such that the capacitor 94 is able to serve as a pressure sensing element for the transducer 62. A nonlimiting example of a preferred MEMS capacitor 94 has a pressure range of about -100 to about +300 mmHg, with an accuracy of about 1 mmHg. Alternatively, a variable resistor transducer could be

used with a fixed capacitance, or an inductor could be substituted for the transducer or fixed circuit element. Based on the RC or other time constant $(1/(LC)^{1/2})$, the oscillator 92 produces a frequency tone that directly relates to the capacitive value of the capacitor 94 and, therefore, the physiologic parameter of interest.

[0024] The circuitry 64 is further shown as including a modulator 96, with which the frequency tone of the oscillator 92 is encoded on a carrier frequency, placed on the antenna 66, and then transmitted to the readout unit 80. This is accomplished simply by opening and closing a switch 98 and adding a capacitance 100 to the antenna matching circuit, resulting in an AM (amplitude modulation) LSK (load shift keying) type modulation. This transmission approach is similar to that used in RFID (radio frequency identification) communications, except RFID does not typically encode analog information but instead encodes a few digital bits either on an AM LSK or FSK (frequency shift keying) modulation.

[0025] Because the preferred embodiment of the sensing device 60 does not utilize wires to transmit data or power to the readout unit 80 (or another remote device), nor contains an internal power source, the circuitry 64 further includes a regulator/rectifier 102 to extract its operating power from electromagnetic (EM) energy generated by the readout unit 80 or another EM power source. The regulator/rectifier 102 rectifies incoming power from the inductive antenna 66 and conditions it for the other circuit components within the circuitry 64. Finally, a matching circuit 104 is shown as comprising a trimmable capacitor bank 106 to resonate the inductor antenna 66, which is energized by the magnetic field and backscatters data as previously described.

[0026] As an alternative to the embodiment of FIG. 3, the modulator 96 could use a 13.56 MHz (or other frequency) magnetic field as a clock reference to create a second carrier frequency, such as one that is one-quarter or another sub-multiple or multiple of the original frequency. The second carrier frequency can then be amplitude modulated (AM)

using the oscillator frequency tone and transmitted to the readout unit 80 via the same antenna 66. In this embodiment, the readout unit 80 may or may not have a second antenna to receive the second carrier frequency-based AM signal.

[0027] The communication scheme described above differs from resonate tank communication systems that use capacitive pressure transducer elements in conjunction with an inductor/antenna. In particular, the circuitry 64 allows the use of any frequency for the high power readout unit 80, which in preferred embodiments utilizes an industrial, scientific, medical (ISM) band frequency. In contrast, the frequencies and potentially large bandwidths required of resonate tank communication systems are subject to FCC emission limitations, likely requiring the use of extra shielding or potentially other measures taken in the facilities where the sensing device 60 and readout unit 80 are to be used. Another feature of the circuitry 64 is the allowance of more combinations of oscillator elements to be used. Because resonator tank systems require an inductive element and a capacitive element in which at least one of the elements serves as a transducer, resonator tank systems do not lend themselves well to resistive-based or other based sensors. Finally, the circuitry 64 also allows for signal conditioning, such as transducer compensation, which allows for such items as removing temperature dependence or other non-idealities that may be inherent to the transducer 62. In the embodiment of FIG. 3, a negative temperature coefficient of the MEMS capacitor 94 can be compensated with simple circuitry relying on the positive temperature coefficient of resistor elements arranged in a trimmable bank of two resistor units with largely different temperature coefficients that can be selectively added in a trimming procedure in production to select the precise level to compensate the transducer variation.

[0028] Restrictive levels of energy available to small implantable medical sensing devices and the desire to maximize data rates to capture more detailed physiological parameter response have typically been met with a robust type of analog communication

that places information on the frequency rather than amplitude of the carrier. In U.S. Patent No. 6,929,970 to Rich et al., a secondary carrier frequency is used for communication with an interrogator unit, resulting in a technique that consumes substantially more power in the implant and requires a second external antenna to receive the signal. The greater power consumption of the implant necessitates a tradeoff between smaller size and longer communication range. In contrast, the communication scheme described above in reference to FIGS. 2a, 2b and 3 draws upon the RFID-type communications, such as those described in U.S. Patent Nos. 7,015,826 and 6,622,567, whose contents are incorporated herein by reference. However instead of communicating digital data using a fixed rate clock, the present invention transmits analog information as the frequency of the clock to lower power consumption and enhance powering and communication range. In this way, much of the readout unit 80 can utilize hardware that is commercially available for RFID, except that a different demodulator is required. An early example of RFID can be found in U.S. Patent No. 4,333,072.

[0029] The transducer 62 (e.g., mechanical capacitor 94), the electronic circuitry 64 (including chips, diodes, capacitors, etc., thereof), the antenna 66 and any additional or optional components (e.g., additional transducers 62) of the sensing device 60 (or any alternative sensing device, such as the devices 10 and 30 of FIGS. 1a and 1b) are preferably contained in a single hermetically-sealed housing. FIG. 4 depicts a preferred example as being a cylindrical housing 110, which is convenient for placing the sensing device 60 within the anchor 120 discussed in reference to FIGS. 5 through 8 below. Other exterior shapes for the housing 110 are also possible to the extent that the exterior shape permits assembly of the sensing device 60 with the anchor 120 as discussed below. The cylindrical-shaped housing 110 of FIG. 4 includes a flat distal face 112, though other shapes are also possible, for example, a torpedo-shape in which the peripheral face 114 of the housing 110 immediately adjacent the distal face 112 is tapered or conical (not shown). The housing 110 can be formed of glass, for example, a borosilicate glass such

as Pyrex Glass Brand No 7740 or another suitable material capable of forming a hermetically-sealed enclosure for the electrical components of the sensing device 60. A biocompatible coating, such as a layer of a hydrogel, titanium, nitride, oxide, carbide, silicide, silicone, parylene and/or other polymers, can be deposited on the housing 110 to provide a non-thrombogenic exterior for the biologic environment in which the sensing device 60 will be placed. As can be seen in FIG. 4, the inductive antenna 66 (for example, comprising the coil 68 surrounding the core 70 as represented in FIG. 2a) occupies most of the internal volume of the housing 110. The size of the antenna 66 is governed by the need to couple to a magnetic field to enable telepowering with the readout unit 80 from outside the body, for example, a transmission distance of about ten centimeters or more. The circuitry 64 is disposed between the antenna 66 and the distal face 112 of the housing 110 that preferably carries the transducer 62. A nonlimiting example of an overall size for the housing 110 is about 3.7 mm in diameter and about 16.5 mm in length.

[0030] A preferred aspect of the invention is to locate the transducer 62 at or near the distal end of the sensing device 60, for example, the flat distal face 112 of the cylindrical housing 110 or on the peripheral face 114 of the housing 110 immediately adjacent the distal face 112. The distal face 112 can be defined by a biocompatible semiconductor material, such as a heavily boron-doped single-crystalline silicon, in whose outer surface the transducer 62 (for example, a pressure-sensitive diaphragm of the capacitor 94) is formed. In this manner, only the distal face 112 of the housing 110 need be in contact with cerebrospinal fluid, whose pressure (or other physiological parameter) is to be monitored. In the case of monitoring intracranial pressures, this aspect of the invention can be used to minimize the protrusion of the sensing device 60 into the cranial cavity. For example, the sensing device 60 can be placed so that the transducer 62 presses against the dura mater (extradural), though it is also within the scope of the invention that the transducer 62 is placed beneath the dura (subdural) in the subarachnoid space or beneath the pia mater and extend into brain tissue.

[0031] FIGS. 5 through 8 represent different embodiments of the anchor 120 assembled with the sensing device 60 to form the sensor unit 150. In FIG. 5, the sensor unit 150 is represented as a coaxial assembly of the sensing device 60 and anchor 120, with the distal face 112 of the sensing device 60 exposed and the oppositely-disposed proximal end of the sensing device 60 concealed within the anchor 120. As represented in FIG. 6, the sensor unit 150 can be anchored to the skull 134, for example, by making an incision in the scalp 142, drilling a hole 136 in the skull 134, and then inserting the sensor unit 150 in the hole 136 so that the anchor 120 secures the sensing device 60 to the skull 134. The protrusion of the sensor unit 150 and its sensing device 60 relative to the skull 134 can be determined by the anchor 120. For example, the distal end of the unit 150 (for example, as defined by the distal face 112 of the housing 110 or the distal end 128 of the anchor 120) may be slightly recessed or flush with the interior surface of the skull 134 so that the transducer 62 presses against the dura mater 138, or may be placed beneath the dura mater 138 into the subarachnoid space or into brain tissue. As such, the length of the shank portion 122 can be varied depending on the desired location of the transducer 92. Furthermore, the shank portion 122 could be configured as a catheter through which pressure is conducted to the sensing device 60, which can then be located within the shank portion 122 nearer the head portion 124 than the distal end 128 of the anchor 120.

[0032] The anchor 120 can be fabricated as a unitary component or as an assembly, and can be formed of various biocompatible materials, nonlimiting examples of which include NITINOL, TEFLON, polymers such as parylene, silicone and PEEK, metals, glass, and ceramics. The anchor 120 is represented in FIGS. 5 through 8 as having a shank portion 122 and a head portion 124 that define, respectively, the distal end 128 and an oppositely-disposed proximal end of the anchor 120. The head portion 124 is represented as having a larger cross-sectional dimension than the shank portion 122 to prevent the entire anchor 120 from being placed within the skull hole 136. The shank and head portions 122 and 124 are represented as having coaxial tubular and disk shapes,

respectively, though a round outer periphery is not a requirement for either portion 122 and 124. The shank portion 122 is further represented as having an internal bore 126 that defines an opening at the distal end 128 of the anchor 120. The sensing device 60 is axially disposed within the anchor bore 126 such that the distal face 112 carrying the transducer 62 is exposed outside the anchor 120. The distal face 112 of the sensing device 60 is shown as protruding from the shank portion 122, though it is also within the scope of the invention that the distal face 112 could be recessed within the anchor bore 126. The anchor bore 126 and sensing device housing 110 are represented as having complementary shapes, providing a close fit that prevents biological material (for example, cerebrospinal fluid) from infiltrating the bore 126. The sensing device 60 can be temporarily or permanently secured within the bore 126, for example, with an interference fit or another mechanical securement device, or a biocompatible adhesive such as a cement, glue, epoxy, etc. While the antenna 66 of the sensing device 60 is shown enclosed with the housing 110 in FIG. 5, the antenna 66 could be placed within the head portion 124 of the anchor 120, or within a separate subassembly (not shown) placed remotely on the patient and electrically coupled to the remaining components of the sensing device 60 via the anchor 120.

[0033] In FIG. 6, the sensor unit 150 is represented as anchored to the skull 134, with the shank portion 122 of the anchor 120 received in the skull hole 136, and the distal end of the unit 150 (as defined by the distal face 112 of the housing 110) placed by the anchor 120 beneath the dura mater 138 in the subarachnoid space 140. The head portion 124 of the anchor 120 abuts the exterior surface of the skull 134, and may be exposed through the scalp 142 (as shown) or covered by the scalp 142. The anchor 120 can be secured to the skull 134 with an interference fit between the shank portion 122 and the skull hole 136, and/or with threads formed on the exterior of the shank portion 122, or with a biocompatible cement, glue or epoxy, spring, etc., placed between the skull 134 and the shank portion 122.

[0034] In FIG. 7, the shank portion 122 is shown to have a smaller cross-section than the skull hole 136, for example, as a result of the hole 136 being formed for another medical procedure. The anchor 120 is secured to the skull 134 with the head portion 124 assisted by an attachment element 144, for example, a biocompatible cement, glue or epoxy, screws, nails, etc.

[0035] In FIG. 8, the sensor unit 150 is shown as further including an insert 146 between the shank portion 122 and the skull 134. The insert 146 can have a tubular shape, can be secured to the anchor 120 by an interference fit, and can provide for an interference fit with the skull hole 136. Alternatively or in addition, the insert 146 can be or comprise a spring or threads capable of securing the shank portion 122 to the skull 134, optionally assisted by a biocompatible cement, glue or epoxy, nails, etc. A preferred aspect of the embodiment of FIG. 8 is that the anchor 120 is not permanently joined to the insert 146, which permits the insert 146 to remain secured to the skull 134 while allowing the sensor unit 150 and/or its sensing device 60 and/or anchor 120 to be replaced.

[0036] In addition to the above-noted features, the anchor 120 can be modified to provide other functional features useful to the sensing device 60 or sensor unit 150, for example, a device similar to an RFID tag can be added to the anchor 120 to wirelessly transmit ID information concerning the sensing device 60. The ID information may include an ID number, ID name, patient name/ID, calibration coefficients/information, range of operation, date of implantation, valid life of the device (operation life), etc. The anchor 120 may further include additional capabilities such as features for connection to a catheter, shunt, or other device (not shown) that may be useful when monitoring ICP or treating intracranial hypertension (ICH) and severe head injuries.

[0037] In addition to the sensing device 60, sensor unit 150 and reader unit 80 described above, the monitoring systems of this invention can be combined with other

technologies to achieve additional functionalities. For example, the reader unit 80 can be implemented to have a remote transmission capability, such as home monitoring that may employ telephone, wireless communication, or web-based delivery of information received from the sensor units 150 by the reader unit 80 to a physician or caregiver. In this manner, the reader unit 80 can be adapted for remote monitoring of the patient, closed-loop drug delivery of medications to treat the patient, warning of changes in the physiological parameter (pressure), portable or ambulatory monitoring or diagnosis, monitoring of battery operation, data storage, reporting global positioning coordinates for emergency applications, and communication with other medical devices such as deep brain stimulation (DBS) devices, drug delivery systems, non-drug delivery systems, and wireless medical management systems. Furthermore, the placement of the sensor unit 150 can be utilized as part of a variety of different medical procedures, including diagnosis, treatment intervention, tailoring of medications, disease management, identification of complications, and chronic disease management.

[0038] While the invention has been described in terms of specific embodiments, it is apparent that other forms could be adopted by one skilled in the art. Therefore, the scope of the invention is to be limited only by the following claims.

CLAIMS:

1. An sensor unit configured to position a sensing element for monitoring a physiological parameter within a cavity of a living body, the sensor unit having an anchor comprising:

a shank portion defining a distal end of the anchor and having a bore defining an opening at the distal end; and

a head portion defining a proximal end of the anchor and having a larger cross-sectional dimension than the shank portion.

2. The sensor unit according to claim 1, wherein the shank portion comprises means for securing the anchor within a hole.

3. The sensor unit according to claim 2, wherein the securing means is at least one biocompatible attachment device chosen from the group consisting of inserts, threads, nails, screws, springs, and adhesives.

4. The sensor unit according to claim 2, wherein the anchor consists of the shank portion, the head portion, the bore, and the securing means.

5. The sensor unit according to claim 1, further comprising a sensing device within the bore of the anchor, the sensing device comprising a sensing element exposed and adapted to sense the physiological parameter within the cavity.

6. The sensor unit according to claim 5, wherein the sensing device is operable to telemetrically communicate a reading of the physiological parameter to a readout device that is not adapted to be implanted in the living body.

7. The sensor unit according to claim 5, wherein the sensing device has a distal end and the sensing element is disposed at the distal end of the sensing device.

8. The sensor unit according to claim 7, wherein the distal end of the sensing device protrudes from the bore of the anchor such that the sensing device defines a distal end of the sensor unit.

9. The sensor unit according to claim 7, wherein the sensing device has an oppositely-disposed proximal end concealed within the anchor.

10. The sensor unit according to claim 5, wherein the physiological parameter is pressure.

11. The sensor unit according to claim 10, wherein the sensing element comprises a diaphragm responsive to pressure.

12. The sensor unit according to claim 11, wherein the diaphragm is at a distal surface of the sensing device.

13. The sensor unit according to claim 5, wherein the sensing element comprises a micromachined structure.

14. The sensor unit according to claim 5, further comprising a telemetry antenna adapted for telemetrically communicating a reading of the physiological parameter sensed by the sensing element and optionally electromagnetically receiving power for the sensing device.

15. The sensor unit according to claim 14, wherein the telemetry antenna is

within the sensing device.

16. The sensor unit according to claim 14, wherein the sensor unit is wirelessly coupled with the telemetry antenna to a readout device that is not adapted to be implanted in the living body.

17. The sensor unit according to claim 16, wherein the sensor unit is wirelessly coupled to the readout device for telemetric communication therewith using a resonant scheme in which the sensing device telemetrically receives power from the readout device.

18. The sensor unit according to claim 16, wherein the sensor unit is wirelessly coupled to the readout device for telemetric communication therewith using a passive scheme in which the sensing device telemetrically receives electromagnetic power from the readout device.

19. The sensor unit according to claim 16, wherein the sensing device further comprises processing circuitry for processing electrical communications between the sensing element and the telemetry antenna.

20. The sensor unit according to claim 19, wherein the processing circuitry causes the telemetry antenna to transmit an amplitude modulation transmission.

21. The sensor unit according to claim 5, wherein the sensor unit consists of the sensing device, the anchor, and means for telemetrically communicating a reading of the physiological parameter to a readout device.

22. A surgical procedure comprising:

assembling a sensor unit by placing a sensing device within a bore of an anchor so that a sensing element of the sensing device is exposed at a distal end of the anchor, the sensing element being adapted to sense a physiological parameter;

making an incision in the scalp of a patient to expose a portion of the skull;

making a hole through the skull;

placing the sensor unit in the hole such that the distal end of the sensor unit is flush with or protrudes into the cranial cavity within the skull and an oppositely-disposed proximal end of the sensor unit is outside the skull;

securing the anchor to the skull such that the sensing device is secured to the skull by the anchor and the hole is occluded by the sensor unit; and then

telemetrically communicating with the sensing device to obtain a reading of the physiological parameter using a readout device located outside the patient.

23. The surgical procedure according to claim 22, wherein the sensing device has a distal end, the sensing element is disposed at the distal end of the sensing device, and the distal end of the sensing device protrudes from the anchor such that the sensing device defines the distal end of the sensor unit.

24. The surgical procedure according to claim 22, wherein the anchor comprises a shank portion at the distal end of the sensor unit and a head portion that defines the proximal end of the sensor unit, the shank portion is inserted into the hole during the placing step and occludes the hole as a result of the placing step, and the head portion is not inserted into the hole during the placing step but instead is external to the skull following the placing step.

25. The surgical procedure according to claim 24, wherein the securing step comprises securing the shank portion of the anchor to the skull.

26. The surgical procedure according to claim 25, wherein the shank portion of the anchor is secured within the hole in the skull by an interference fit therebetween.

27. The surgical procedure according to claim 25, wherein the shank portion of the anchor is secured within the hole in the skull by an element chosen from the group consisting of inserts, threads, nails, screws, springs, and adhesives.

28. The surgical procedure according to claim 24, wherein an interference fit does not exist between the shank portion of the anchor and the hole in the skull.

29. The surgical procedure according to claim 24, wherein the securing step comprises securing the head portion of the anchor to the skull.

30. The surgical procedure according to claim 29, wherein the head portion of the anchor is secured to the skull by an element chosen from the group consisting of nails, screws, springs, and adhesives.

31. The surgical procedure according to claim 24, wherein the bore of the anchor is located within the shank portion of the anchor.

32. The surgical procedure according to claim 22, wherein the physiological parameter is pressure.

33. The surgical procedure according to claim 22, wherein the telemetric communicating step between the sensing device and the readout device is established using a resonant scheme in which the sensing device telemetrically receives power from the readout device.

34. The surgical procedure according to claim 22, wherein the telemetric communicating step between the sensing device and the readout device is established using a passive scheme in which the sensing device telemetrically receives electromagnetic power from the readout device.

35. The surgical procedure according to claim 22, further comprising processing electrical communications between the sensing element and a telemetry antenna of the sensor unit.

36. The surgical procedure according to claim 35, wherein the telemetry antenna of the sensor unit transmits an amplitude modulation transmission to the readout device.

37. The surgical procedure according to claim 22, wherein the surgical procedure is part of at least one of the following medical procedures: diagnosis, treatment intervention, tailoring of medications, disease management, identification of complications, and chronic disease management.

38. The surgical procedure according to claim 22, wherein the readout device is used to perform at least one of the following: remote monitoring of the patient, closed-loop drug delivery of medications to treat the patient, warning of changes in the physiological parameter, portable or ambulatory monitoring or diagnosis, monitoring of battery operation, data storage, reporting global positioning coordinates for emergency applications, and communication with other medical devices.

39. The surgical procedure according to claim 22, wherein the sensor unit consists of the sensing device, the anchor, and means for telemetrically communicating the reading of the physiological parameter to the readout device.

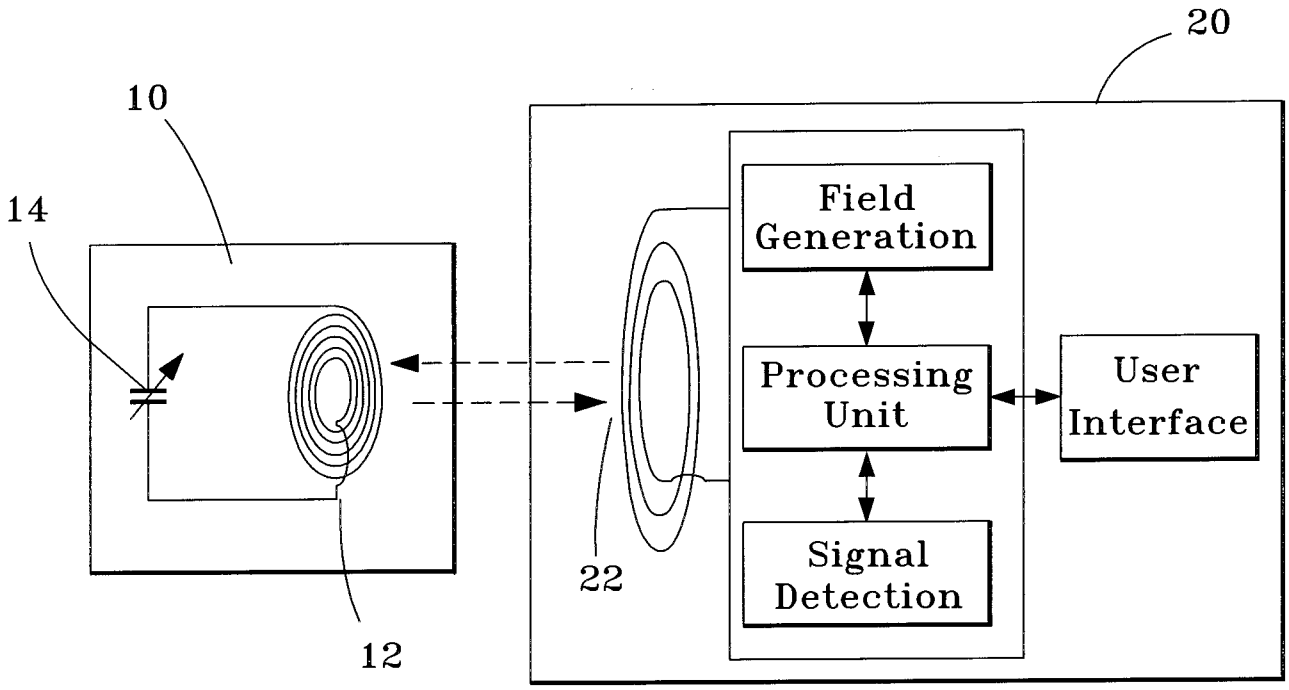

20
10
14
Field Generation
Processing Unit
User Interface
Signal Detection
22
12

FIG. 1a

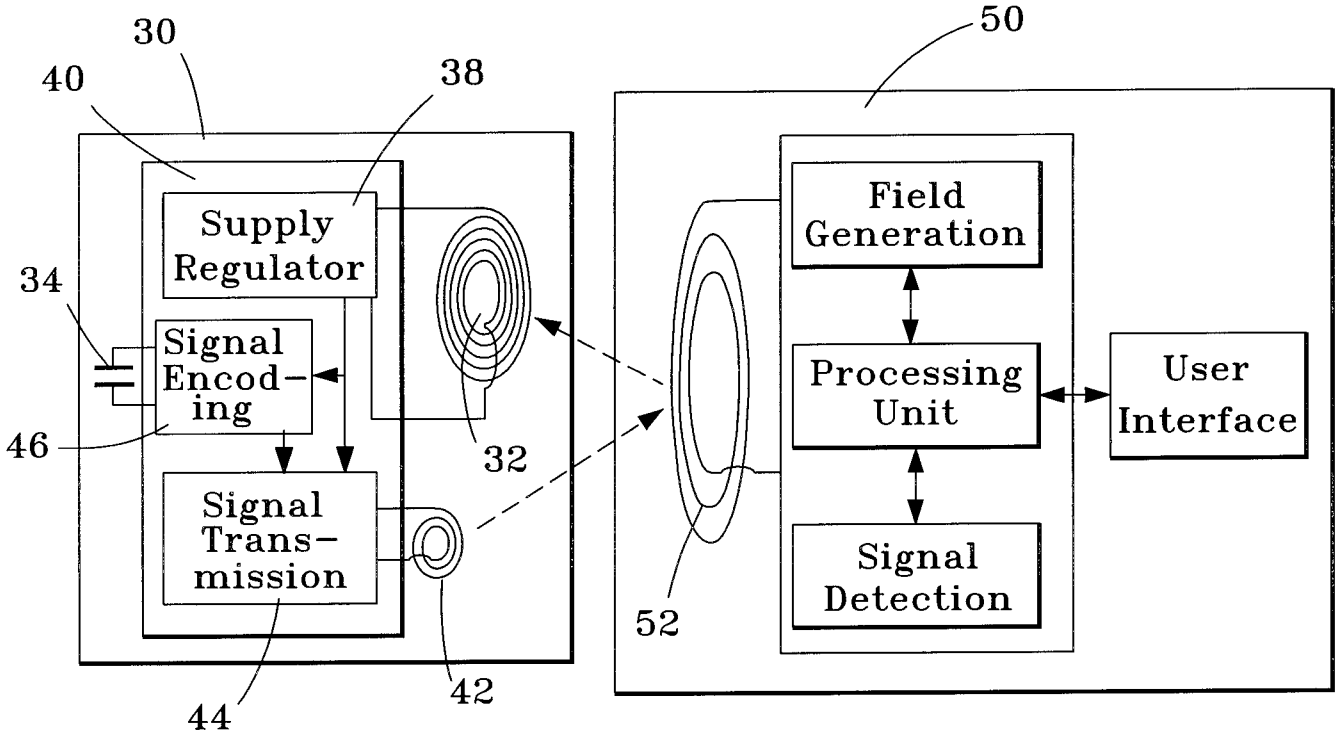

50
30
40
38
Supply Regulator
34
Signal Encod-ing
46
Signal Trans-mission
32
44
42
Field Generation
Processing Unit
User Interface
Signal Detection
52

FIG. 1b

FIG.2a

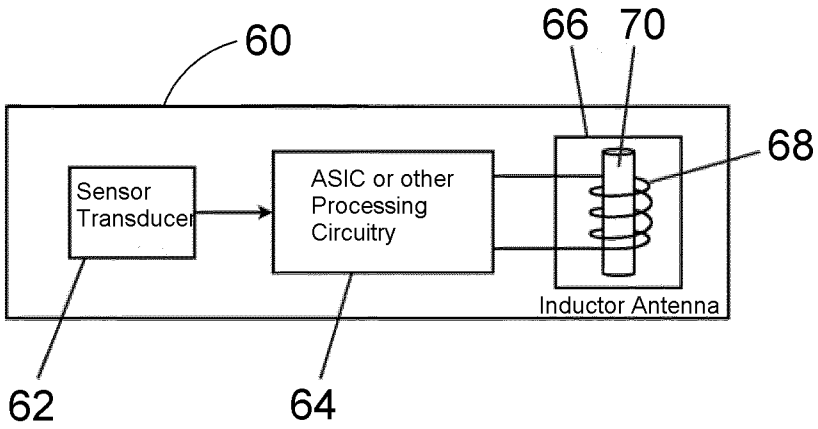


FIG.2b

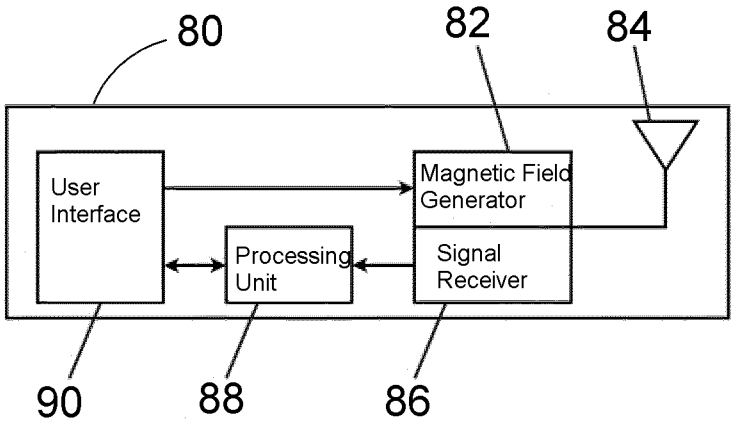
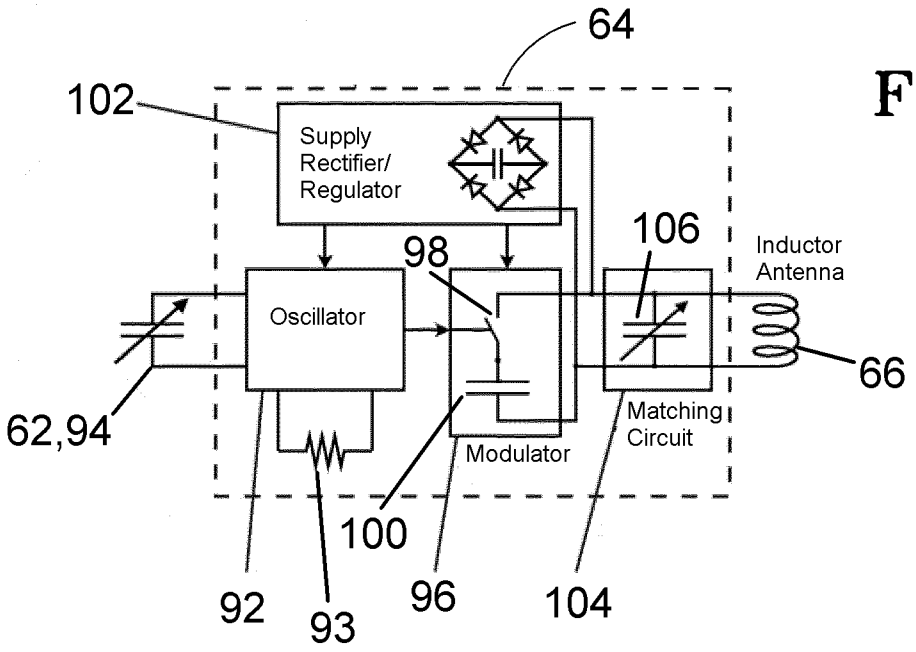


FIG.3



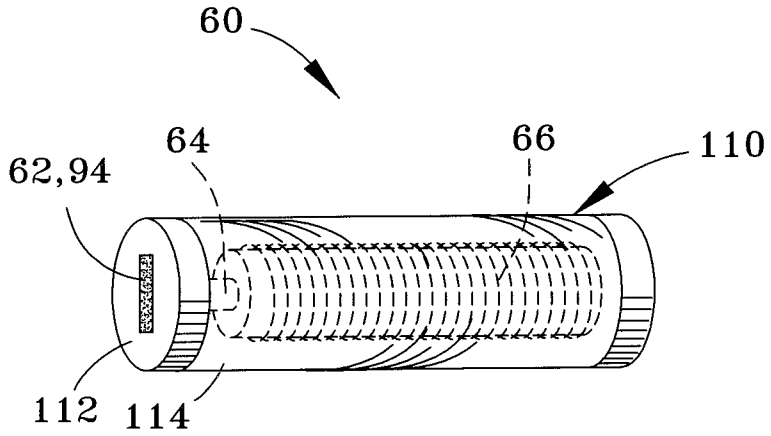


FIG.4

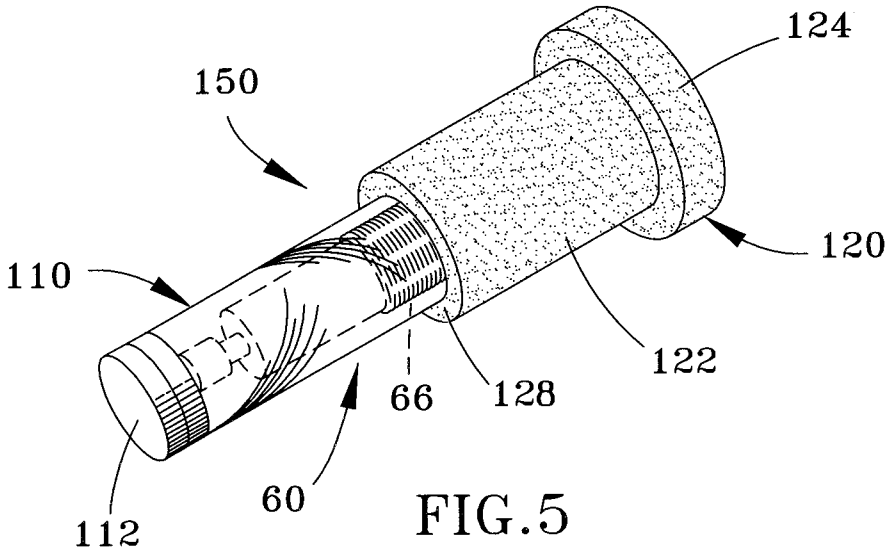


FIG.5

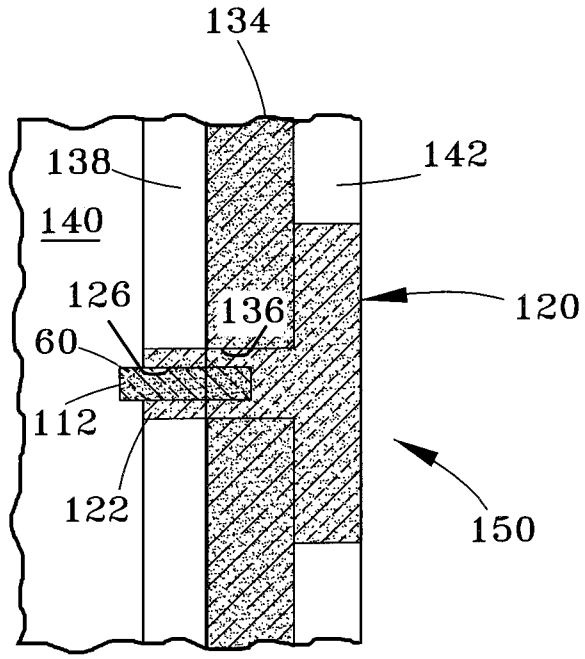


FIG.6

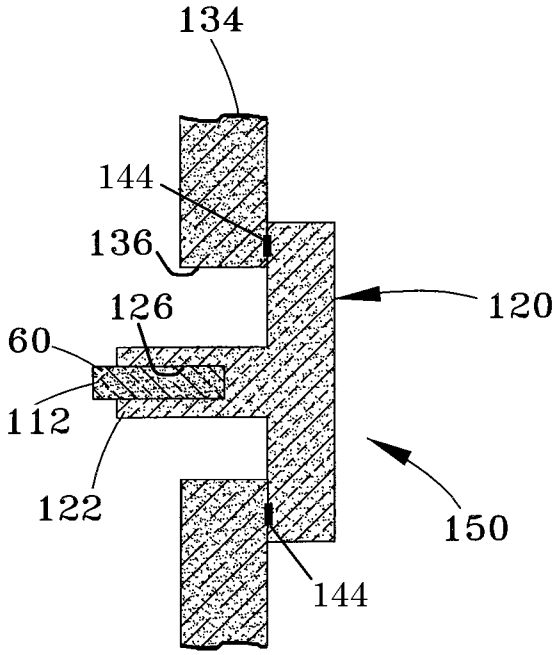


FIG. 7

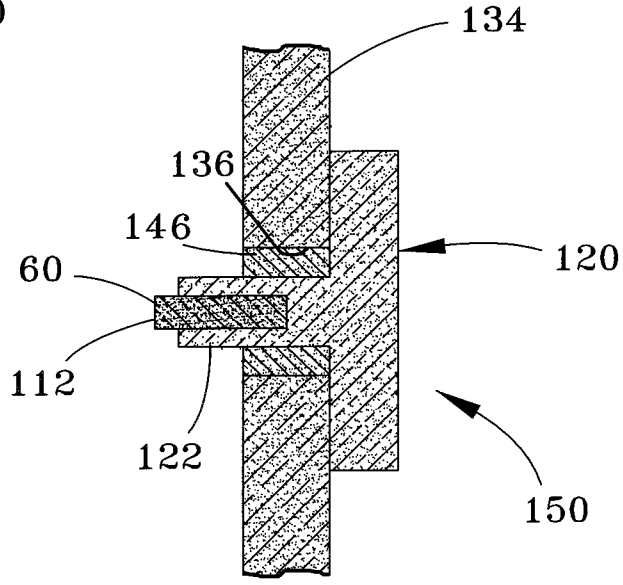


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/085155

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/0215(2006.01)i, H01B 5/00(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC8: A61B

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

Korean Utility models and applications for Utility models since 1975

Japanese Utility models and applications for Utility models since 1975

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

eKIPASS(KIPO internal) "sensing element, anchor, shank, hear portion, interface"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006-0173263 A1 (JIPING HE et al.) 3 August 2006 see abstract, paragraphs 44-61, and fig.4a	1-39
A	US 2006-0173259 A1 (J. CHRISTOPHER FLAHERTY et al.) 3 August 2006 see abstract, paragraphs 9-17, and fig.1	1-39
A	US 2005-0096648 A1 (ARI MOSKOWITZ et al.) 5 May 2005 see abstract, paragraphs 13-18, and fig.1	1-39
A	US 2006-0293578 A1 (ROBERT L. RENNAKER II) 28 December 2006 see abstract, paragraphs 42-64, and fig.2	1-39

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 MARCH 2009 (24.03.2009)	**27 MARCH 2009 (27.03.2009)**

Name and mailing address of the ISA/KR

Korean Intellectual Property Office
Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

Kim, Sae Byul

Telephone No. 82-42-481-8543

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/085155

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006-0173263 A1	03.08.2006	None	
US 2006-0173259 A1	03.08.2006	None	
US 2005-0096648 A1	05.05.2005	US 7300434 B2	27.11.2007
US 2006-0293578 A1	28.12.2006	None	

专利名称(译)	用于监测颅内生理特性的传感器单元和程序		
公开(公告)号	EP2217138A4	公开(公告)日	2013-05-01
申请号	EP2008857348	申请日	2008-12-01
申请(专利权)人(译)	集成传感系统，INC.		
当前申请(专利权)人(译)	集成传感系统，INC.		
[标]发明人	NAJAFI NADER HOOK MORGAN CATHERINE GOETZINGER DAVID JOSEPH MASSOUD ANSARI SONBOL		
发明人	NAJAFI, NADER HOOK-MORGAN, CATHERINE GOETZINGER, DAVID JOSEPH MASSOUD-ANSARI, SONBOL		
IPC分类号	A61B5/0215 H01B5/00 A61B5/00 A61B5/03 A61B5/07		
CPC分类号	A61B5/031 A61B5/0031 A61B5/076 A61B5/6849 A61B5/6864 A61B2560/0219		
优先权	61/008202 2007-12-19 US 61/004508 2007-11-29 US		
其他公开文献	EP2217138A1		
外部链接	Espacenet		

摘要(译)

用于可植入感测装置的锚，由锚和感测装置形成的传感器单元，以及用于植入传感器单元的外科手术，用于监测活体腔内的生理参数，例如颅内生理特性。锚包括柄部和头部。柄部限定锚的远端并且具有在远端限定开口的孔。头部限定锚的近端并且具有比柄部更大的横截面尺寸。传感器单元包括锚和传感装置，传感装置放置并固定在锚的孔内，使得传感装置的传感元件被暴露以感测腔内的生理参数。