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(54) **MULTI-MODAL PHYSIOLOGICAL SENSOR**

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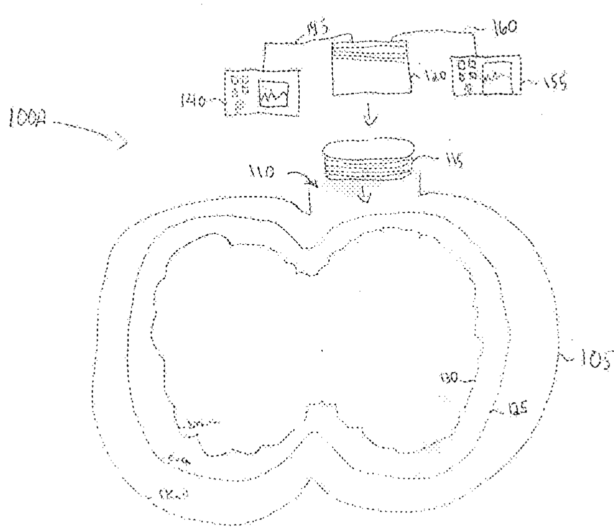
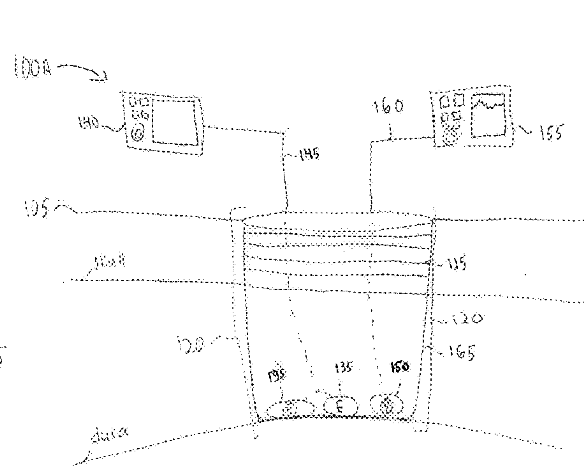
(57) **ABSTRACT**

Apparatus and associated methods relate to a multimodal signal management system (MMSMS) that includes two or more electrodes, and a cerebrospinal fluid pressure (CSF) monitor enclosed within a housing implanted in the brain. In an illustrative example, the MMSMS, may, for example, include a conduit configured to provide fluid communication between the CSF-containing region in the brain and a remote location. Various embodiments may advantageously provide therapeutical CSF draining while monitoring electroencephalogram (EEG) and CSF pressure waveform information.





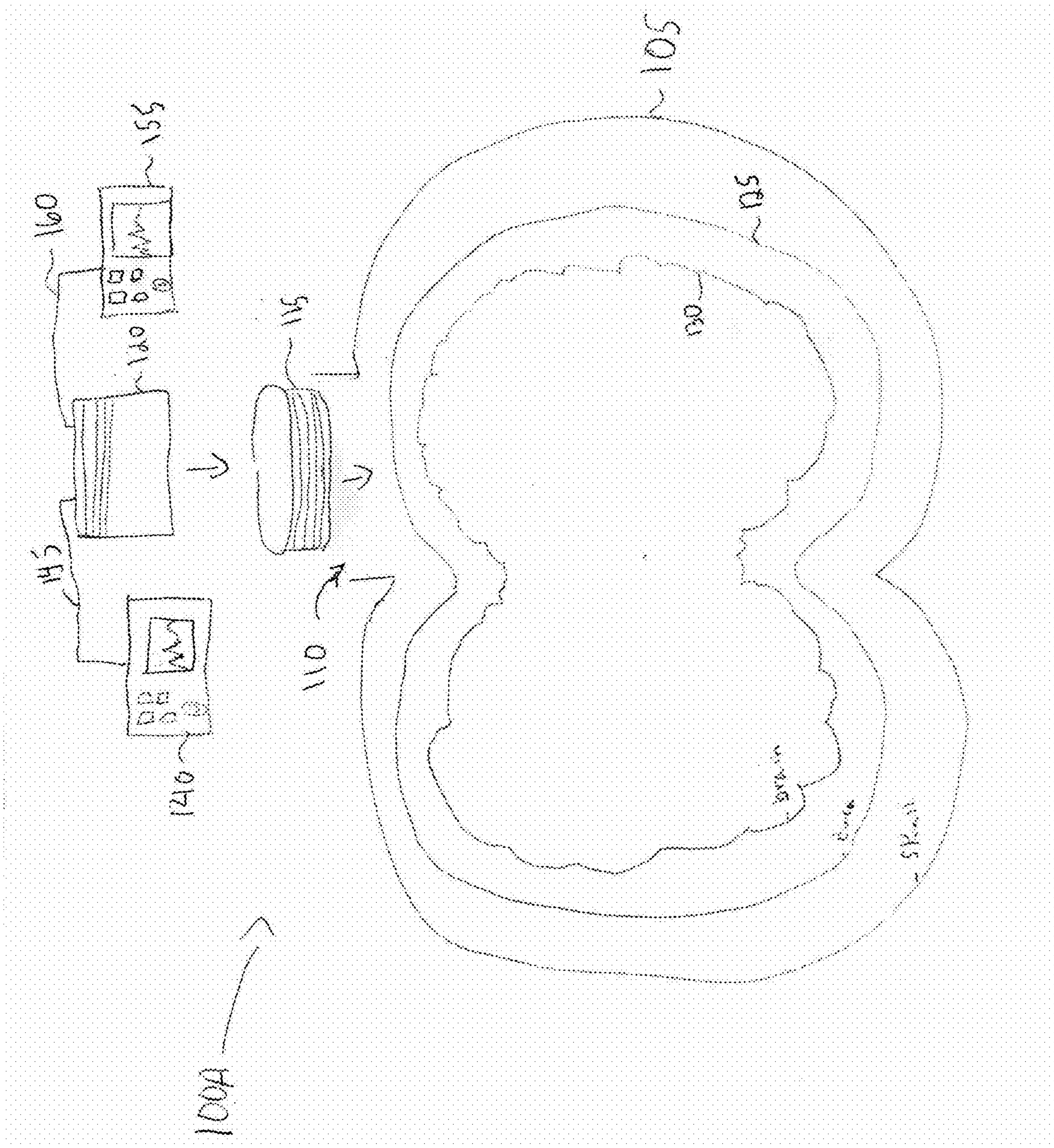


FIG. 1A

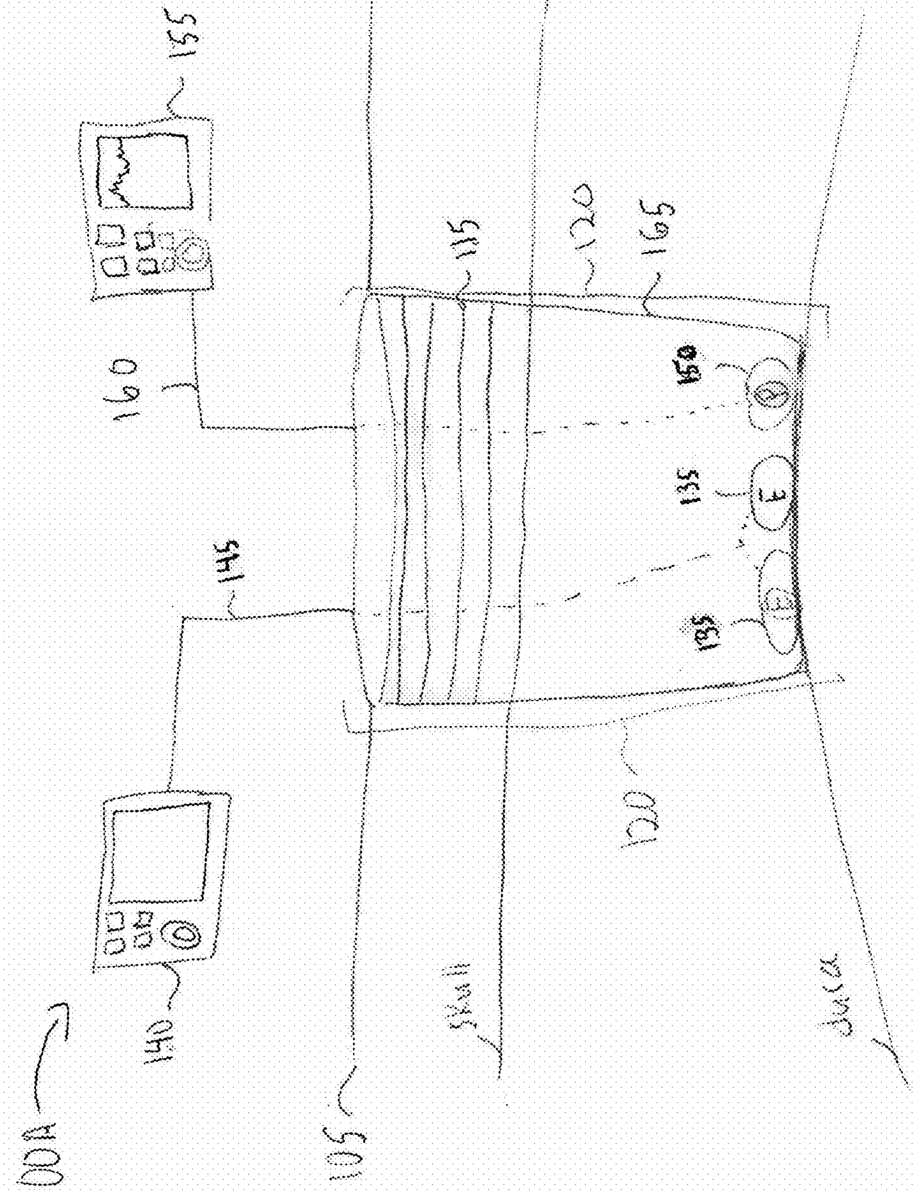


FIG. 1B

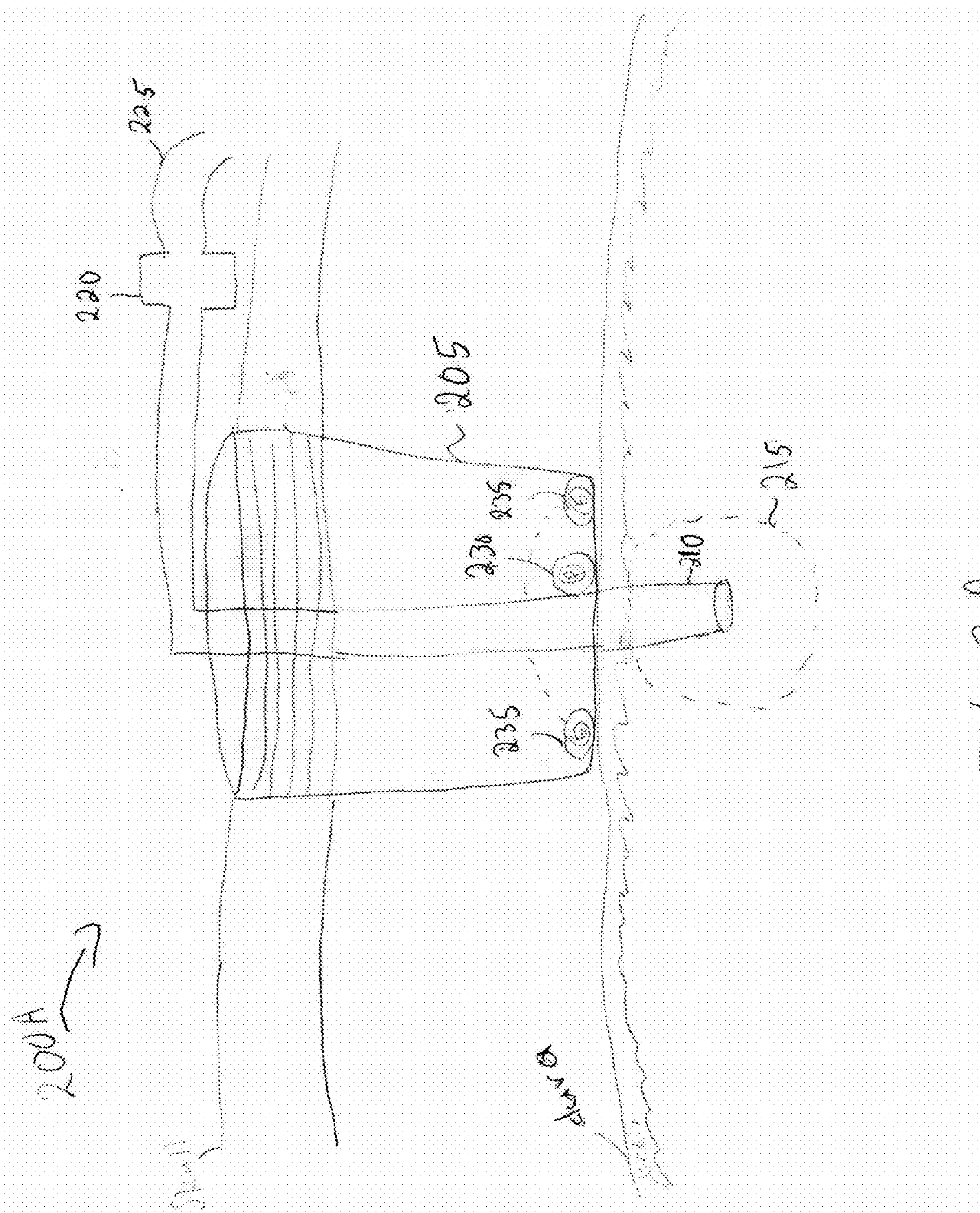


FIG. 2A

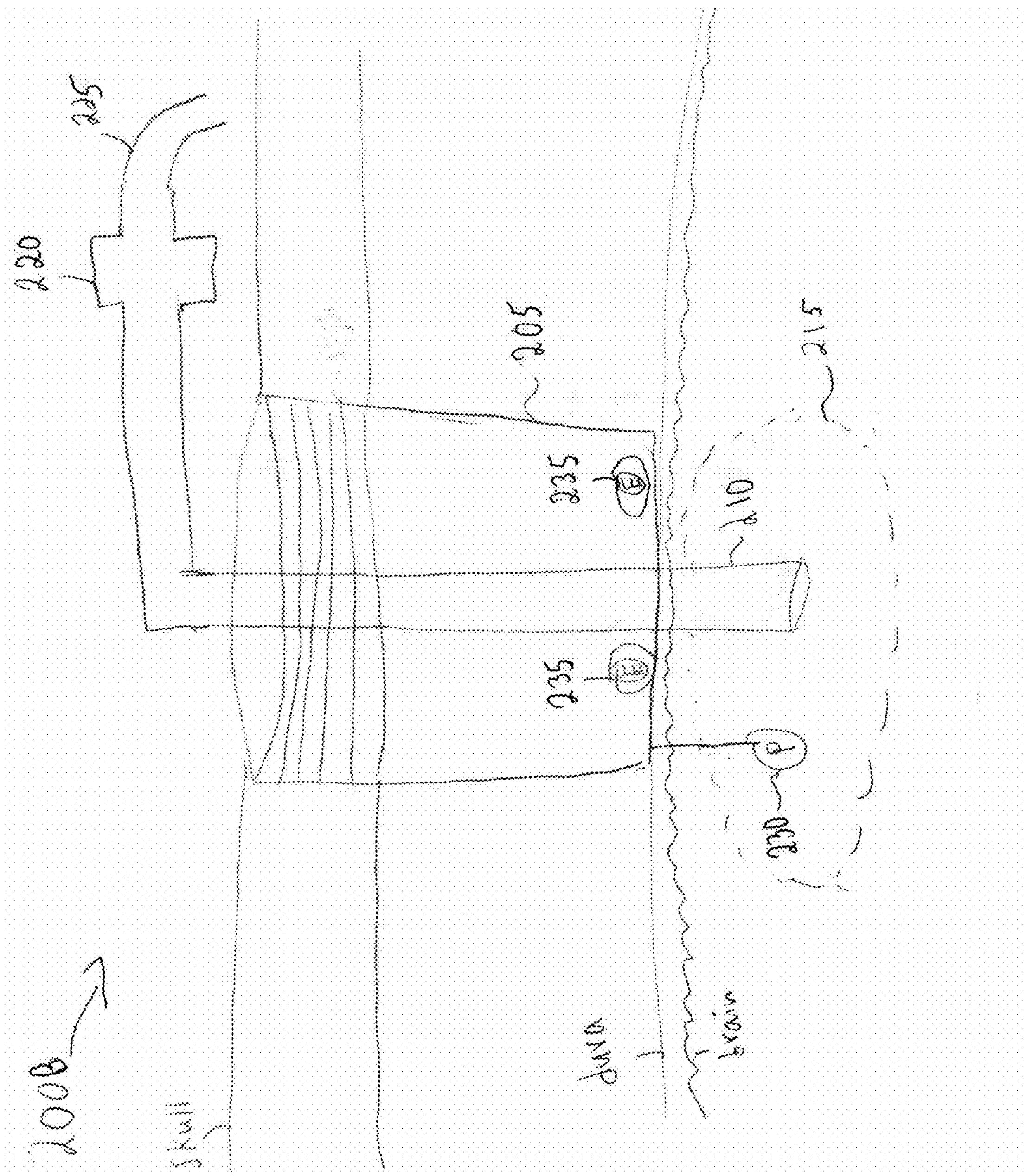


FIG. 2B

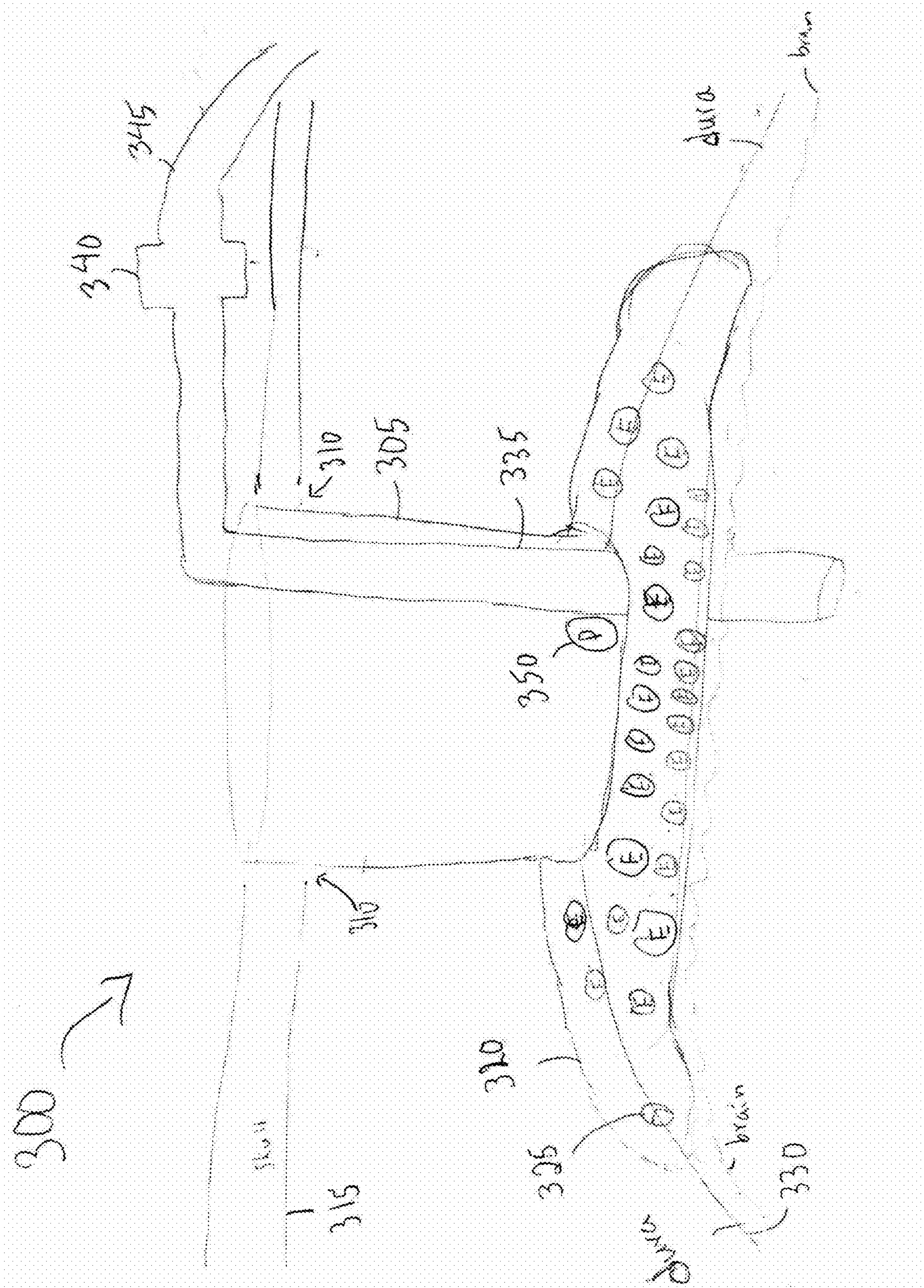


FIG. 3

FIG. 4A

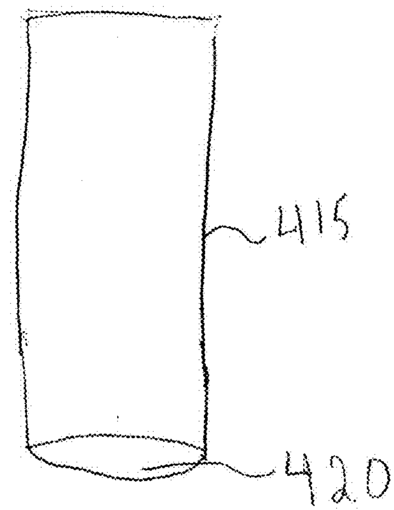


FIG. 4B

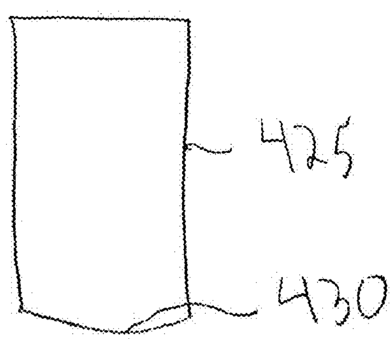


FIG. 4C

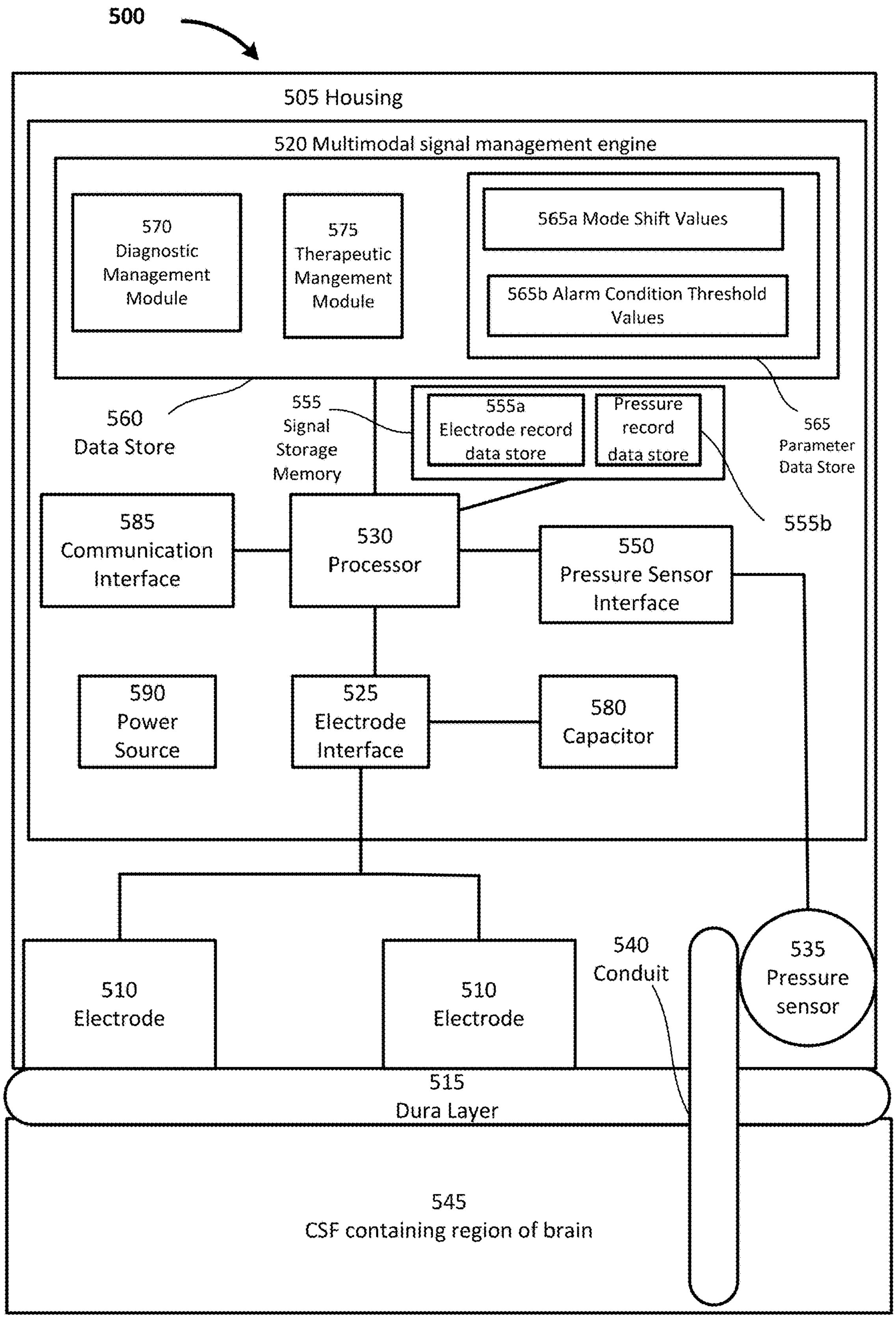

500
505 Housing
520 Multimodal signal management engine
570 Diagnostic Management Module
575 Therapeutic Mangement Module
565a Mode Shift Values
565b Alarm Condition Threshold Values
565 Parameter Data Store
560 Data Store
555 Signal Storage Memory
555a Electrode record data store
Pressure record data store
555b
585 Communication Interface
530 Processor
550 Pressure Sensor Interface
590 Power Source
525 Electrode Interface
580 Capacitor
510 Electrode
510 Electrode
540 Conduit
535 Pressure sensor
515 Dura Layer
545 CSF containing region of brain

FIG. 5

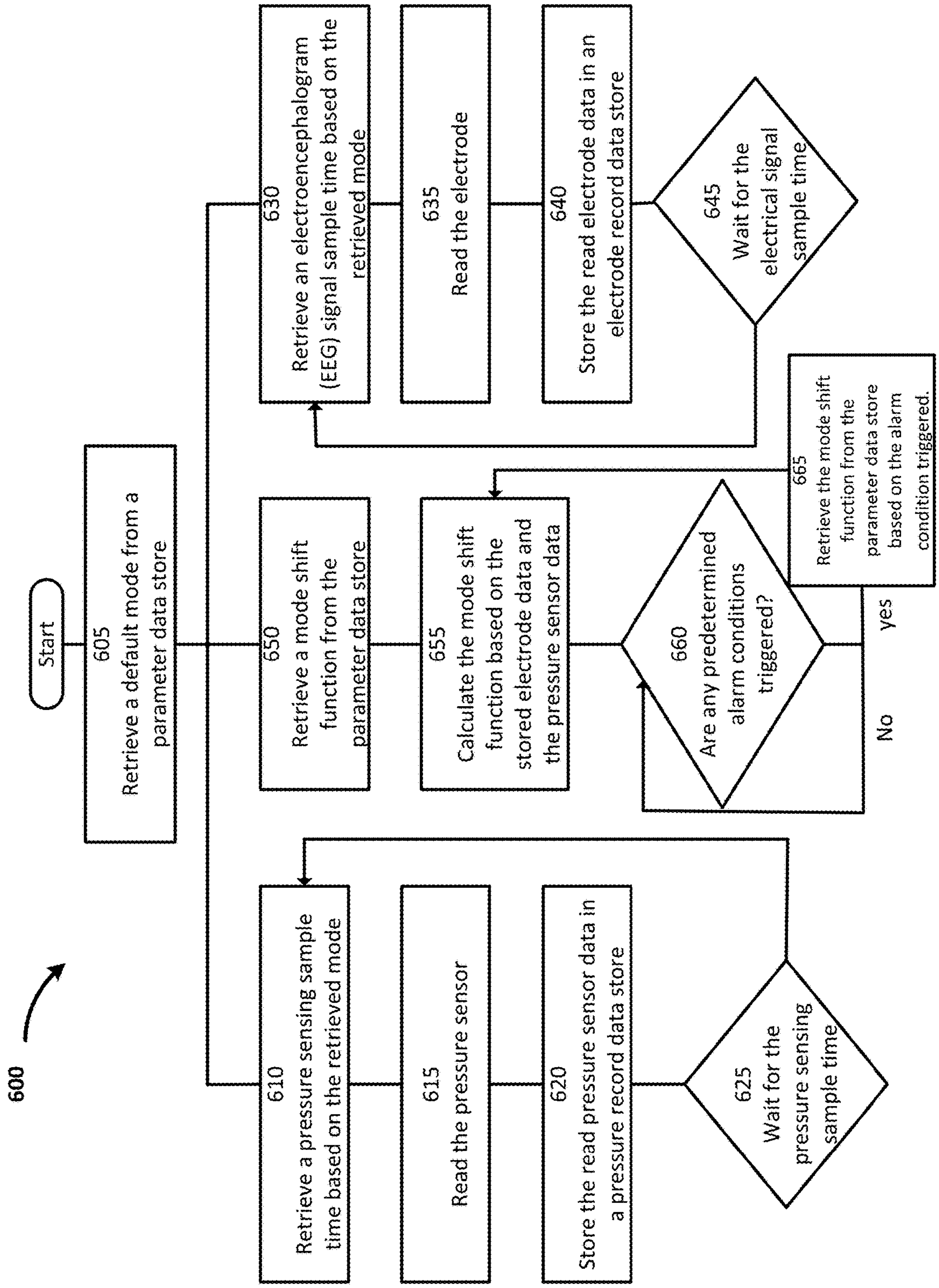

600
Start
605
Retrieve a default mode from a parameter data store
610
Retrieve a pressure sensing sample time based on the retrieved mode
615
Read the pressure sensor
620
Store the read pressure sensor data in a pressure record data store
625
Wait for the pressure sensing sample time
630
Retrieve an electroencephalogram (EEG) signal sample time based on the retrieved mode
635
Read the electrode
640
Store the read electrode data in an electrode record data store
645
Wait for the electrical signal sample time
650
Retrieve a mode shift function from the parameter data store
655
Calculate the mode shift function based on the stored electrode data and the pressure sensor data
660
Are any predetermined alarm conditions triggered?
No
yes
665
Retrieve the mode shift function from the parameter data store based on the alarm condition triggered.

FIG. 6

MULTI-MODAL PHYSIOLOGICAL SENSOR

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a nonprovisional application and claims the benefit of U.S. Provisional Application Ser. No. 63/552,563, titled "MULTI-MODAL PHYSIOLOGICAL SENSOR," filed by Samuel Robert Browd on Feb. 12, 2024.

[0002] This application also claims the benefit of U.S. Provisional Application Ser. No. 63/552,894, titled "CONTINUOUS NEUROCARE," filed by Samuel Robert Browd and Ryan J. Douglas on Feb. 13, 2024.

[0003] This application incorporates the entire contents of the foregoing application(s) herein by reference.

[0004] The subject matter of this application may have common inventorship with and/or may be related to the subject matter of the following:

[0005] U.S. Provisional application Ser. No. 63/364,253, titled "SHUNT TECHNOLOGY AND THE POTENTIAL FOR A SMART SHUNT," filed by Samuel Robert Browd on May 5, 2022.

[0006] U.S. Provisional application Ser. No. 63/447,158, titled "SHUNT TECHNOLOGY AND THE POTENTIAL FOR A SMART SHUNT," filed by Samuel Robert Browd and Ryan J. Douglas on Dec. 23, 2022.

[0007] U.S. Provisional application Ser. No. 63/447,162, titled "Cerebrospinal Fluid Polarization," filed by Samuel Robert Browd and Ryan J. Douglas on Dec. 23, 2022.

[0008] U.S. Provisional application Ser. No. 63/488,412, titled "Dynamic Shunt Systems," filed by Samuel Robert Browd, et al., on Mar. 3, 2023.

[0009] U.S. application Ser. No. 18/313,249, titled "Dynamically Controlled Cerebrospinal Fluid Shunt," filed by Samuel Robert Browd, et al., on May 5, 2023

[0010] U.S. Application Ser. No. 63/365,407, titled "Distributed Sensing and Control of Cerebrospinal Fluid," filed by Samuel Robert Browd, et al., on May 26, 2022

[0011] U.S. Application Ser. No. 63/477,158, titled "Central Nervous System Monitoring and Intervention," filed by Samuel Robert Browd, et al., on Dec. 23, 2022

[0012] U.S. Application Ser. No. 63/590,313, titled "Neurosurgical Devices and Methods," and filed by Samuel Robert Browd, et al., on Oct. 13, 2023

[0013] U.S. Application Ser. No. 63/590,191, titled "Dynamic Guided Physician-Patient Interaction Engine," and filed by Samuel Robert Browd, et al., on Oct. 13, 2023

[0014] This application incorporates the entire contents of the foregoing application(s) herein by reference.

TECHNICAL FIELD

[0015] Various embodiments relate generally to methods and apparatus for an implantable physiological sensor, particularly for monitoring cerebrospinal fluid (CSF) pressure and electroencephalogram (EEG) signals within the brain.

SUMMARY

[0016] Apparatus and associated methods relate to a multimodal signal management system (MMSMS) that includes two or more electrodes, and a cerebrospinal fluid pressure (CSF) monitor enclosed within a housing implanted in the brain. In an illustrative example, the MMSMS, may, for example, include a conduit configured to provide fluid communication between the CSF-containing region in the brain and a remote location. Various embodiments may advantageously provide optional therapeutical CSF draining while monitoring electroencephalogram (EEG) and CSF pressure waveform information.

[0017] In various embodiments, a multimodal signal management system may include at least two electrodes and a cerebrospinal fluid (CSF) pressure monitor enclosed within a housing that is implanted in the brain. The system enables simultaneous EEG monitoring, CSF pressure measurement, and therapeutic CSF drainage through a conduit that provides fluid communication between the CSF-containing region in the brain and a designated drainage location.

[0018] Various embodiments may advantageously regulate CSF drainage relative to EEG signals, which may advantageously enhance researchers and healthcare providers ability to explore relationships between CSF pressure dynamics and neurological activity. The MMSMS may also provide automated diagnostic support and therapeutic interventions, enhancing patient treatment in trauma and neurosurgical applications.

[0019] Various embodiments may achieve one or more advantages. For example, some embodiments may advantageously modulate CSF drainage relative to EEG signals. In some implementations the MMSMS may enable the ability to research connections between CSF pressure and EEG signals. In some embodiments, the MMSMS may provide data that health care providers may use to diagnose or treat the patient.

[0020] The details of various embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. **1**A depicts an exemplary multimodal signal management system (MMSMS) architecture employed in an illustrative use-case scenario.

[0022] FIG. **1**B depicts a close-up schematic of the illustrative use-case scenario in FIG. **1**A surgically implanted in a patient. FIG. **2**A depicts a schematic of an exemplary embodiment of an MMSMS.

[0023] FIG. **2**B depicts a schematic of another exemplary embodiment of an MMSMS.

[0024] FIG. **3** depicts a schematic of another exemplary embodiment of an MMSMS.

[0025] FIGS. **4**A-**4**C depict partial views of exemplary embodiments of a catheter capable of use with various embodiments of the MMSMS.

[0026] FIG. **5** is a block diagram depicting an exemplary MMSMS in operative contact with a dura of a patient's brain.

[0027] FIG. **6** is a flowchart illustrating exemplary operations that may be performed by a multimodal signal management engine (MMSME) in the MMSMS of FIG. **5**.

[0028] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0029] To aid understanding, this document is organized as follows. First, to help introduce discussion of various embodiments, a multimodal signal management system

(MMSMS) is introduced with reference to FIGS. **1**-**3**. Second, exemplary embodiments of a catheter are described with reference to FIGS. **4**A-**4**C. Third, with reference to FIG. **5**, a block diagram of an exemplary MMSMS deployed in vivo is presented. Lastly, with reference to FIG. **6**, the discussion turns to a flowchart of an exemplary method of operations that may be performed by a multimodal signal management engine (MMSME), such as the embodiment introduced with reference to FIG. **5**. Finally, the document discusses further embodiments, exemplary applications and aspects relating to a MMSMS.

[0030] FIG. **1**A depicts an exemplary multimodal signal management system (MMSMS) architecture employed in an illustrative use-case scenario. As shown in FIG. **1**A, an illustrative surgical scenario **100**A may occur, for example, when a surgeon acts to provide a patient skull **105** with an implantable sensor system, for example, based on trauma to the patient. In the exemplary scenario **100**A, the surgeon may create in the patient's skull **105** an aperture **110**. The aperture **110** is configured to receive a ferrule **115**. In this example, the depicted ferrule **115** has outer threads for engaging a burr hole in the skull **105**, and inner threads for positioning a MMSMS **120**. The MMSMS **120** includes outer threads for engaging the corresponding inner threads on the ferrule **115**. In various implementations, the inner threads of the ferrule **115** may be configured to precisely control the linear position of the MMSMS **120**, for example, which may advantageously permit the surgeon to accurately control the amount of engagement (e.g., contact pressure and/or interference) between a proximal end of the MMSMS **120** and a dura **125** that substantially surrounds a brain **130** in the skull **105**.

[0031] This illustrative use-case scenario **100**A may represent, for example, a trauma surgical environment in which a surgeon (not shown) may be preparing to install the MMSMS **120** via threaded engagement with the ferrule **115**. As will be described in further detail with reference, for example, to at least FIGS. **5**-**6**, the MMSMS **120** includes pressure sensing and electroencephalogram (EEG) monitoring capabilities. In various implementations, the installed MMSMS **120** may record both EEG waveform information and cerebrospinal fluid (CSF) pulsatile pressure waveform information and may store the captured waveform information over a predetermined period of time.

[0032] In some embodiments, the MMSMS **120** may simultaneously provide EEG/CSF pressure monitoring while also providing fluid communication between the CSF-containing region in the brain **130** and a remote location. In some examples, the remote location may be external to the patient, such as in a trauma scenario (e.g., scenario **100**A of FIG. **1**A). In some implementations, the remote location may be another drainage location in the patient's body, such as in an ambulatory application (examples of which are described with reference to FIGS. **2**A **2**B and **3**).

[0033] Various advantages may be achieved from the MMSMS **120** providing EEG and CSF pressure monitoring at the same time as providing fluid communication for aspirating CSF fluid, for example. In some embodiments, the MMSMS **120** may provide data that health care providers may use to diagnose or treat the patient. For example, brain health may be indicated by the monitored CSF pulsatile waveform information in association with EEG activity. Various embodiments may further provide continuous passive and/or regulated drainage of excess CSF, which may advantageously protect the patient's brain **130**. In some embodiments, the MMSMS **120** may be configured to be fully implanted with internal drainage at a remote location, wherein the CSF fluid flow passes through the MMSMS **120**. In some embodiments, pressure may be regulated by a valve or other flow restriction device. In some implementations the MMSMS **120** may provide control of one or more pressure regulating actuators, where the MMSMS **120** generates control signals as a function of monitored CSF pressure waveform data and/or EEG waveform information.

[0034] FIG. **1**B depicts a close-up schematic of the illustrative use-case scenario in FIG. **1**A surgically implanted in a patient. As depicted, the MMSMS **120** is implanted in the skull **105** via threaded engagement with the ferrule **115**. The MMSMS **120** includes two or more electrodes **135** positioned at the proximal end of the MMSMS **120**. The two or more electrodes **135** are in electrical contact with the dura **125** such that the two or more electrodes **135** may detect EEG activity generated within the brain **130**. The two or more electrodes **135** transmit the detected EEG activity to an EEG monitoring device **140** via leads **145**. The EEG monitoring device **140** may, for example, amplify, filter, digitize, store, perform signal processing and/or display the detected EEG activity into a digitized waveform. The two or more electrodes **135** may, for example, wirelessly transmit the detected EEG activity to an EEG monitoring device **140**.

[0035] In this illustrative surgical scenario **100**A, the MMSMS **120** includes at least one pressure sensor **150**. The at least one pressure sensor **150** is positioned at a proximal end of the MMSMS **120**. The at least one pressure sensor **150** is in mechanical communication with the dura such that it may detect pressure exerted on its sensing surface due to intracranial pressure variations. The intracranial pressure variations may, for example, include changes in CSF pressure. The intracranial pressure variations may, for example, include changes in brain swelling. As depicted, the at least one pressure sensor **150** transmits the detected changes in intracranial pressure to a pressure sensor monitor **155** via leads **160**. The pressure sensor monitor **155** may, for example, amplify, filter, digitize, store, perform signal processing and/or display the detected changes in intracranial pressure into a digitized waveform. The at least one pressure sensor **150** may, for example, wirelessly transmit the detected changes in intracranial pressure to a pressure sensor monitor **155**.

[0036] In this illustrative surgical scenario **100**A, the MMSMS **120** encloses the at least one pressure sensor **150** and the two or more electrodes **135** into a housing **165**. The housing **165** may, for example, fit within a burr hole. By way of example, and not limitation, the housing **165** may have a diameter of about 1.5 millimeters. The housing **165** enclosing the at least one pressure sensor **150** and the two or more electrodes **135** in one unit may advantageously enable the MMSMS to monitor the brain's EEG activity and intracranial pressure during a brain trauma event in a minimally invasive manner.

[0037] FIG. **2**A depicts a schematic of an exemplary embodiment of an MMSMS **200**A. In the depicted embodiment, the MMSMS **200**A is a fully implanted implementation in which the MMSMS **200**A and any attached drainage conduit are located subcutaneously such that the patient may, for example, be untethered to leads or tubing. This may be advantageous for ambulatory long-term applications.

[0038] The MMSMS **200**A includes a housing **205**. The housing **205** is implanted in a skull via threaded engagement with the skull. The housing **205** includes a conduit **210**. The conduit **210** may, for example, provide a catheter. The conduit **210** may, for example, provide an external ventricular drain (EVD). The conduit **210** is disposed in a CSF-containing region of the brain **215**. The conduit **210** is configured to be in fluid communication with the CSF-containing region of the brain **215**. The conduit **210** is operatively coupled to a valve **220**. The conduit **210** extends radially from the housing **205** to the valve **220**. The conduit may, for example, extend subcutaneously. The valve **220** is configured to control the rate of CSF flow into the conduit **210**. The valve operatively couples tubing **225** to the conduit **210**. CSF may, for example, flow up through the conduit **210** and the tubing **225** to a remote location. The remote location may, for example, include another drainage location in the patient's body. The remote location may, for example, include a location external to the patient.

[0039] The conduit **210** is operably coupled to an at least one pressure sensor **230**. The valve **220** may, for example, halt the drainage of CSF out of the conduit such that the pulsatile CSF pressure within the conduit **210** may represent the pulsatile CSF pressure within the CSF-containing region of the brain **215**. The at least one pressure sensor **230** may, for example, measure the pulsatile CSF pressure within the brain by measuring the pulsatile CSF pressure in the conduit **210**. This exemplary MMSMS **200**A may advantageously enable the MMSMS to measure intracranial pressure while therapeutically draining CSF.

[0040] FIG. **2**B depicts a schematic of another exemplary embodiment of an MMSMS **200**B. The MMSMS **200**B includes an at least one pressure sensor **230** operatively coupled to a proximal end of the housing **205**. The at least one pressure sensor **230** is positioned within the CSF-containing region **215**. The at least one pressure sensor **230** positioned within the CSF-containing region **215** may, for example, advantageously enable continuous measurement of pressure within the CSF-containing region **215** of the brain without halting the drainage of CSF out of the conduit **210**, which may enable its use in an ambulatory setting.

[0041] In the exemplary MMSMS **200**A and **200**B, the two or more electrodes **235** are configured in a substantially similar arrangement to the two or more electrodes **135** as described above with reference to FIGS. **1**A and **1**B.

[0042] FIG. **3** depicts a schematic of another exemplary embodiment of an MMSMS **300**. The MMSMS **300** includes a housing **305**. The housing **305** is implanted within an aperture **310** in a skull **315**. The housing includes an annular flex circuit **320**. The annular flex circuit **320** operatively couples an array of electrodes **325**. The array of electrodes **325** are in electrical contact with a dura **330**. The annular flex circuit **320** may, for example, be flexible. The flexibility of the annular flex circuit **320** may permit the annular flex circuit **320** to conform substantially to a non-planar surface region of the dura **330**. The annular flex circuit **320** may advantageously enable the array of electrodes **325** to cover a large surface area of the dura **330**. The annular flex circuit **320** may advantageously enable the array of electrodes **325** to multidimensionally monitor EEG signals from the brain. The array of electrodes **325** may, for example, include individual electrodes angled in different directions to monitor EEG signals according to a preferred direction such as by beam steering techniques. This MMSMS **300** may, for example, be advantageously employed within an ambulatory setting.

[0043] In this exemplary MMSMS **300**, the conduit **335**, valve **340**, tubing **345**, and pressure sensor **350** may be substantially similar to the respective conduit **210**, valve **220**, tubing **225**, and pressure sensor **230** as described above with reference to FIGS. **2**A and **2**B.

[0044] In some implementations of the MMSMS **300**, a system may include multiple MMSMSs **300** implanted in the brain. The multiple MMSMSs **300** may, for example, be communicably coupled via wired or wireless techniques.

[0045] FIGS. **4**A-**4**C depict partial views of exemplary embodiments of a catheter capable of use with various embodiments of the MMSMS. FIG. **4**A includes a catheter **405** with a pointed open tip **410**. The pointed open tip **410** may advantageously enable the catheter to puncture the dura and to be positioned within a CSF-containing region of the brain. FIG. B includes a catheter **415** with a rounded open tip **420**. The rounded open tip **420** may advantageously enable the catheter **415** to fill with CSF quickly. FIG. **4**C includes a catheter **425** with a flexible membrane pressure sensing tip **430**. The flexible membrane pressure sensing tip **430** may advantageously enable pressure measurement, for example, without an additional pressure sensor.

[0046] FIG. **5** is a block diagram depicting an exemplary MMSMS **500** in operative contact with a dura of a patient's brain. The MMSMS includes a housing **505**. The housing **505** encloses two or more electrodes **510**. The two or more electrodes **510** are in electrical contact with a dura layer **515**. The two or more electrodes **510** measure the EEG activity of the brain while in electrical contact with the dura layer **515**. The two or more electrodes **510** transmit a signal representing the EEG activity of the brain to a multimodal signal management engine (MMSME) **520** via an electrode interface **525** within the MMSME **520**. The electrode interface **525** communicably couples the two or more electrodes **510** such that the two or more electrodes **510** transmit the signal to the electrode interface **525**. The electrode interface **525** transmits the signal to the processor **530** of the MMSME **520**.

[0047] The housing encloses at least one pressure sensor **535**. The at least one pressure sensor **535** operably couples a conduit **540**. The conduit **540** is positioned in a CSF containing region of the brain **545** via an aperture in the dura layer **515**. The conduit **540** draws in CSF from the CSF containing region of the brain **545**. The conduit **540** may, for example, provide fluid communication between the CSF-containing field in the brain and a remote location. The remote location may include, for example, a location external to the patient's body for CSF to drain. The remote location may include, for example, an internal body system within the patient for CSF to drain. The at least one pressure sensor **535** measures the pressure within the conduit **540**. The pressure measurement within the conduit **540** represents the CSF pressure within the brain. The at least one pressure sensor **535** transmits a signal representing the CSF pressure within the brain to the MMSME **520** via a pressure sensor interface **550** within the MMSME **520**. The pressure sensor interface **550** communicably couples at least one pressure sensor **535** such that at least one pressure sensor **535** transmits the signal to the pressure sensor interface **550**. The pressure sensor interface **550** transmits the signal to a processor **530**.

[0048] The processor **530** is coupled to a signal storage memory **555**. The processor **530** may, for example, transmit the signal representing the EEG activity of the brain and the signal representing the CSF pressure within the brain to a signal storage memory **555**. The signal storage memory **555** includes an electrode record data store **555***a*. The processor **530** may transmit the signal representing the EEG activity of the brain **545** to the electrode record data store **555***a*. The electrode record data store **555***a* may accumulate a time series of data from the EEG activity measurements such that the processor can store individual values of measurements of EEG activity within the electrode record data store **555***a*. The signal storage memory includes a pressure record data store **555***b*. The processor may transmit the signal representing the CSF pressure within the CSF containing region of the brain to the pressure record data store **555***b*. The pressure record data store **555***b* may accumulate a time series of data from the CSF pressure measurements such that the processor can store individual values of measurements of CSF pressure within the pressure record data store **555***b*.

[0049] The processor **530** is coupled to a data store **560**. The processor **530** may, for example, transmit the signal representing the EEG activity of the brain and the signal representing the CSF pressure within the brain to the data store **560**. The data store **560** includes a parameter data store **565**. The parameter data store **565** includes mode shift values **565***a*. The mode shift values **565***a* may, for example, include signal collection times that determine how often the two or more electrodes **520** and the at least one pressure sensor **535** measure a signal. The mode shift values **565***a* may, for example, include a default mode. The default mode may, for example, include a signal collection time that is present when the MMSMS **500** is not in a mode function based on an alarm condition. The parameter data store **565** includes one or more alarm condition threshold values **565***b*. The alarm condition threshold values **565***b* may include pressure threshold values and EEG activity threshold values that when reached, cause the processor **530** to generate an alarm condition. By way of example, and not limitation, an exemplary pressure threshold value may, for example, include a CSF pressure in the brain above 20 millimeters of mercury. By way of example, and not limitation, an exemplary EEG activity threshold value may, for example, include delta power of 100 $\mu V^2/Hz$ in frontal regions during wakefulness. By way of example, and not limitation, an exemplary EEG activity threshold value may, for example, include spike-wave discharges at 3 Hz in the frontal lobe. The parameter data store **565** may, for example, transmit a signal to the processor **530** to alert the processor an alarm condition is triggered. In some embodiments, the processor **530** may retrieve a mode shift function from the parameter data store **565** based on the triggered alarm condition.

[0050] The processor **530** may, for example, retrieve a mode shift function from the parameter data store **565**. The parameter data store may, for example, include electrode sample times. The parameter data store may, for example, include pressure sensing sample times. The processor **530** may, for example, retrieve a mode shift function from a diagnostic management module **570** within the data store **560**. The diagnostic management module **570** may, for example, include diagnostic information about a patient based on the recorded signal representing the EEG activity of the brain and the recorded signal representing the CSF pressure of the brain. The processor **530** may, for example, retrieve a mode shift function from a therapeutic management module **575** within the data store **560**. The therapeutic management module **575** may, for example, include instructions about treating a patient based on the recorded signal representing the EEG activity of the brain and the recorded signal representing the CSF pressure of the brain. For example, the therapeutic management module **575** may include instructions, that when executed by the processor **530**, may perform operations to cause a capacitor **580** to discharge through the two or more electrodes **510** an electrical charge for a predetermined therapeutic purpose.

[0051] The processor **530** may, for example, transmit a signal to a communication interface **585**. The communication interface **585** may, for example, be in operative communication (e.g., over a wired, wireless, or optical communication link) to an external data processing device that may be configured to log data received from the MMSMS. The external data processing device may, for example, include a display device to display the electrode data and the pressure data, for example, relative to a common time axis. The external device may, for example, include an external medical device configured to provide treatment to a patient based on the readings of the MMSMS **500**.

[0052] FIG. **6** is a flowchart illustrating exemplary operations that may be performed by a multimodal signal management engine (MMSME) in the MMSMS of FIG. **5**. In the depicted Figure, an exemplary set of operations **600** for monitoring the MMSMS multi-modal sensors is disclosed. By way of example and not limitation, and with reference to FIG. **5**, the set of operations may be included in a program of instructions stored in, for example, the diagnostic management module **570**. In operation, the MMSMSE **520** may perform operations to monitor EEG and CSF waveform signals in response to the processor **530** executing the instructions stored in the diagnostic management module **570**.

[0053] The set of operations **600** begins at step **605**, in which a processor of an MMSME retrieves a default mode from a parameter data store. The default mode may, for example, include a predetermined signal collection time that is present when a MMSMS is not in a mode function based on an alarm condition.

[0054] At step **610**, the processor retrieves a pressure sensing sample time based on the retrieved mode in step **605**. At step **615**, the processor reads a pressure sensor and retrieves pressure sensor data. At step **620**, the processor sends the read pressure sensor data to a pressure record data store for the pressure sensor data to be stored. At step **625**, the processor waits for the pressure sensing sample time, and then reverts to step **610**.

[0055] Concurrently, at step **630**, the processor **530** retrieves an EEG signal sample time based on the retrieved mode from step **105**. At step **635**, the processor reads an electrode and retrieves electrode data. At step **640**, the processor sends the read electrode data to an electrode data store for the electrode data to be stored. At step **645**, the processor waits for the EEG signal sample time, and then reverts to step **630**.

[0056] Concurrently, at step **650**, the processor **530** retrieves a mode shift function from the parameter data store. At step **655**, the processor **530** calculates the mode shift function based on the stored electrode data and the stored pressure sensor data. At step **660**, the processor determines if any predetermined alarm conditions have been triggered based on the electrode data and the pressure sensor data. If no, the processor remains at step **660**. If yes, then at step **665**, the processor retrieves the mode shift function from the parameter data store based on the alarm condition triggered.

[0057] Although various embodiments have been described with reference to the figures, other embodiments are possible.

[0058] In some implementations, the MMSMS of, for example, the embodiments described with reference to FIG. **1**B or **2**B, may further be adapted to drain the CSF fluid to an external location while monitoring the CSF pressure and EEG activity.

[0059] In some implementations, the MMSMS may, for example, externally transmit recorded EEG and CSF pressure data in its raw form, providing direct electrode readings and pressure sensor measurements for real-time monitoring or further analysis. The MMSMS may process the recorded EEG and CSF pressure data via a processor that applies a predetermined algorithm stored in data store. The processed data may, for example, be transmitted externally to indicate specific health conditions, such as an alarm condition triggered by abnormal EEG patterns or CSF pressure levels. The MMSMS may, for example, externally transmit the processed data to assess the overall health status of a patient. Additionally, the MMSMS may be configured to minimize power consumption to extend the useful charge of the battery.

[0060] In some implementations the MMSMS may, for example, be configured for minimally invasive implantation. The MMSMS may be securely housed within a ferrule-threaded enclosure such that the MMSMS interfaces a patient's skull. The MMSMS may, for example, provide real-time multimodal data acquisition through electrodes for EEG monitoring, CSF pressure sensors to detect intracranial pressure variations, and a drainage conduit for passive regulated CSF removal. In some embodiments, the system's processor may, for example, synchronize EEG and CSF pressure data, enabling correlation between brain activity and fluid dynamics. In some implementations, machine-learning algorithms may, for example, analyze data trends to predict abnormal conditions, triggering preemptive alerts or therapeutic responses.

[0061] Various embodiments may provide various advantages. For example, the MMSMS may, uniquely integrate EEG and CSF pressure sensing within a single implantable unit. Some embodiments may provide for concurrent draining of excess CSF, alone or combination with injection with prescribed materials (e.g., pharmaceuticals, nutrients, diagnostic contrast materials, etc.) Some embodiments may include therapeutic capabilities such as actuated control of CSF drainage based on detected EEG anomalies or pressure thresholds. In some implementations, the MMSMS advantageously enables real-time patient monitoring through a remote interface. The MMSMS may include configurations such as annular flex circuits, for example, that enable broad-area EEG signal collection, enhancing diagnostic accuracy. In some embodiments, the processor may, for example, dynamically adjust sampling frequency in response to predefined alarm conditions (e.g., pressure spikes, abnormal EEG patterns).

[0062] In some implementations, the MMSMS may be employed in an exemplary method for monitoring and regulating intracranial pressure and EEG activity. The method may, for example include: collecting real-time CSF pressure waveforms via at least one implantable pressure sensor; detecting EEG activity via at least two dura-contact electrodes; storing and analyzing sensor data to detect abnormalities; automatically adjusting CSF drainage rate in response to detected conditions; and/or transmitting EEG and CSF pressure data wirelessly to a remote medical interface.

[0063] In some embodiments the MMSMS may, for example, include a processor-controlled CSF drainage system that dynamically modulates fluid flow in response to EEG signal fluctuations. In some implementations, the MMSMS includes, for example, an implantable multimodal sensor with configurable electrode orientations to enhance EEG signal detection from multiple brain regions. In some implementations, the MMSMS includes, for example, a wireless communication module configured to interface with external medical systems, enabling real-time data access.

[0064] Although exemplary methods and apparatus have been described with reference to FIGS. **1-6**, other implementations may be deployed in other industrial, scientific, medical, commercial, and/or residential applications. For example, the MMSMS may be deployed in animal studies to research a connection between CSF pressure within the brain and EEG activity. For example, the MMSMS may be deployed to modulate sleep. In some embodiments, the EEG activity can be compared to CSF pulsatility via pressure waves to manage sleep and CSF movement.

[0065] In various embodiments, some bypass circuits implementations may be controlled in response to signals from analog or digital components, which may be discrete, integrated, or a combination of each. Some embodiments may include programmed, programmable devices, or some combination thereof (e.g., PLAs, PLDs, ASICs, microcontroller, microprocessor), and may include one or more data stores (e.g., cell, register, block, page) that provide single or multi-level digital data storage capability, and which may be volatile, non-volatile, or some combination thereof. Some control functions may be implemented in hardware, software, firmware, or a combination of any of them.

[0066] Computer program products may contain a set of instructions that, when executed by a processor device, cause the processor to perform prescribed functions. These functions may be performed in conjunction with controlled devices in operable communication with the processor. Computer program products, which may include software, may be stored in a data store tangibly embedded on a storage medium, such as an electronic, magnetic, or rotating storage device, and may be fixed or removable (e.g., hard disk, floppy disk, thumb drive, CD, DVD).

[0067] Although an example of a system, which may be portable, has been described with reference to the above figures, other implementations may be deployed in other processing applications, such as desktop and networked environments.

[0068] Temporary auxiliary energy inputs may be received, for example, from chargeable or single-use batteries, which may enable use in portable or remote applications. Some embodiments may operate with other DC voltage sources, such as a 9V (nominal) batteries, for example. Alternating current (AC) inputs, which may be provided, for example from a 50/60 Hz power port, or from a portable electric generator, may be received via a rectifier and appropriate scaling. Provision for AC (e.g., sine wave, square wave, triangular wave) inputs may include a line frequency transformer to provide voltage step-up, voltage step-down, and/or isolation.

[0069] Although particular features of an architecture have been described, other features may be incorporated to improve performance. For example, caching (e.g., L1, L2, . . .) techniques may be used. Random access memory may be included, for example, to provide scratch pad memory and or to load executable code or parameter information stored for use during runtime operations. Other hardware and software may be provided to perform operations, such as network or other communications using one or more protocols, wireless (e.g., infrared) communications, stored operational energy and power supplies (e.g., batteries), switching and/or linear power supply circuits, software maintenance (e.g., self-test, upgrades), and the like. One or more communication interfaces may be provided in support of data storage and related operations.

[0070] Some systems may be implemented as a computer system that can be used with various implementations. For example, various implementations may include digital circuitry, analog circuitry, computer hardware, firmware, software, or combinations thereof. Apparatus can be implemented in a computer program product tangibly embodied in an information carrier, e.g., in a machine-readable storage device, for execution by a programmable processor; and methods can be performed by a programmable processor executing a program of instructions to perform functions of various embodiments by operating on input data and generating an output. Various embodiments can be implemented advantageously in one or more computer programs that are executable on a programmable system including at least one programmable processor coupled to receive data and instructions from, and to transmit data and instructions to, a data storage system, at least one input device, and/or at least one output device. A computer program is a set of instructions that can be used, directly or indirectly, in a computer to perform a certain activity or bring about a certain result. A computer program can be written in any form of programming language, including compiled or interpreted languages, and it can be deployed in any form, including as a stand-alone program or as a module, component, subroutine, or other unit suitable for use in a computing environment.

[0071] Suitable processors for the execution of a program of instructions include, by way of example, both general and special purpose microprocessors, which may include a single processor or one of multiple processors of any kind of computer. Generally, a processor will receive instructions and data from a read-only memory or a random-access memory or both. The essential elements of a computer are a processor for executing instructions and one or more memories for storing instructions and data. Generally, a computer will also include, or be operatively coupled to communicate with, one or more mass storage devices for storing data files; such devices include magnetic disks, such as internal hard disks and removable disks; magneto-optical disks; and optical disks. Storage devices suitable for tangibly embodying computer program instructions and data include all forms of non-volatile memory, including, by way of example, semiconductor memory devices, such as EPROM, EEPROM, and flash memory devices; magnetic disks, such as internal hard disks and removable disks; magneto-optical disks; and CD-ROM and DVD-ROM disks. The processor and the memory can be supplemented by, or incorporated in, ASICs (application-specific integrated circuits).

[0072] In some implementations, each system may be programmed with the same or similar information and/or initialized with substantially identical information stored in volatile and/or non-volatile memory. For example, one data interface may be configured to perform auto configuration, auto download, and/or auto update functions when coupled to an appropriate host device, such as a desktop computer or a server.

[0073] In some implementations, one or more user-interface features may be custom configured to perform specific functions. Various embodiments may be implemented in a computer system that includes a graphical user interface and/or an Internet browser. To provide for interaction with a user, some implementations may be implemented on a computer having a display device. The display device may, for example, include an LED (light-emitting diode) display. In some implementations, a display device may, for example, include a CRT (cathode ray tube). In some implementations, a display device may include, for example, an LCD (liquid crystal display). A display device (e.g., monitor) may, for example, be used for displaying information to the user. Some implementations may, for example, include a keyboard and/or pointing device (e.g., mouse, trackpad, trackball, joystick), such as by which the user can provide input to the computer.

[0074] In various implementations, the system may communicate using suitable communication methods, equipment, and techniques. For example, the system may communicate with compatible devices (e.g., devices capable of transferring data to and/or from the system) using point-to-point communication in which a message is transported directly from the source to the receiver over a dedicated physical link (e.g., fiber optic link, point-to-point wiring, daisy-chain). The components of the system may exchange information by any form or medium of analog or digital data communication, including packet-based messages on a communication network. Examples of communication networks include, e.g., a LAN (local area network), a WAN (wide area network), MAN (metropolitan area network), wireless and/or optical networks, the computers and networks forming the Internet, or some combination thereof. Other implementations may transport messages by broadcasting to all or substantially all devices that are coupled together by a communication network, for example, by using omni-directional radio frequency (RF) signals. Still other implementations may transport messages characterized by high directivity, such as RF signals transmitted using directional (i.e., narrow beam) antennas or infrared signals that may optionally be used with focusing optics. Still other implementations are possible using appropriate interfaces and protocols such as, by way of example and not intended to be limiting, USB 2.0, Firewire, ATA/IDE, RS-232, RS-422, RS-485, 802.11 a/b/g, Wi-Fi, Ethernet, IrDA, FDDI (fiber distributed data interface), token-ring networks, multiplexing techniques based on frequency, time, or code division, or some combination thereof. Some implementations may optionally incorporate features such as error checking and correction (ECC) for data integrity, or security measures, such as encryption (e.g., WEP) and password protection.

[0075] In various embodiments, the computer system may include Internet of Things (IoT) devices. IoT devices may include objects embedded with electronics, software, sensors, actuators, and network connectivity which enable these objects to collect and exchange data. IoT devices may be in-use with wired or wireless devices by sending data through an interface to another device. IoT devices may collect useful data and then autonomously flow the data between other devices.

[0076] Various examples of modules may be implemented using circuitry, including various electronic hardware. By way of example and not limitation, the hardware may include transistors, resistors, capacitors, switches, integrated circuits, other modules, or some combination thereof. In various examples, the modules may include analog logic, digital logic, discrete components, traces, and/or memory circuits fabricated on a silicon substrate including various integrated circuits (e.g., FPGAs, ASICs), or some combination thereof. In some embodiments, the module(s) may involve execution of preprogrammed instructions, software executed by a processor, or some combination thereof. For example, various modules may involve both hardware and software.

[0077] A number of implementations have been described. Nevertheless, it will be understood that various modifications may be made. For example, advantageous results may be achieved if the steps of the disclosed techniques were performed in a different sequence, or if components of the disclosed systems were combined in a different manner, or if the components were supplemented with other components. Accordingly, other implementations are contemplated within the scope of the following claims.

What is claimed is:

1. A system comprising:

a housing, the housing configured to operably contact a dura while implanted through an aperture in a patient's skull, the housing providing an enclosure for a multimodal signal management engine (MMSME), the MMSME comprising:

at least one pressure sensor configurable to monitor a cerebrospinal fluid (CSF) pulsatile pressure in a CSF-filled region of a brain;

two or more electrodes configured to be in electrical contact with the dura and monitor an electroencephalogram (EEG) signal in the patient's brain;

a processor operatively coupled to the at least one pressure sensor and the two or more electrodes; and

a datastore containing instructions that, when operated by the processor, cause operations to be performed to collect a CSF pressure signal waveform and an EEG signal waveform over a predetermined period.

2. The system of claim **1**, wherein the operations further comprise retrieving pressure sensor data representing the patient's CSF waveform signal.

3. The system of claim **1**, wherein the operations further comprise retrieving electrode data representing the patient's EEG waveform signal.

4. The system of claim **1**, wherein the operations further comprise retrieving a mode shift function from a parameter data store.

5. The system of claim **4**, wherein the mode shift function is calculated based on stored pressure sensor data and stored electrode data.

6. The system of claim **4**, wherein the mode shift function is retrieved based on a triggered predetermined alarm condition.

7. The system of claim **1**, further comprising a ferrule having outer threads configured for fixedly engaging the ferrule in a burr hole of a skull, and inner threads configured to threadedly engage the housing, wherein the housing is axially positionable with respect to the dura by selective rotation of the housing while engaged in the ferrule.

8. The system of claim **1**, wherein the two or more electrodes are communicably coupled to an electrode interface, wherein the electrode interface is positioned within the MMSME and electrically coupled to a capacitor, such that the electrode interface is configured to provide an electrical charge to the two or more electrodes via the capacitor.

9. The system of claim **1**, wherein the housing further comprises an annular flex circuit, wherein the two or more two electrodes are operatively coupled to the annular flex circuit.

10. The system of claim **1**, wherein the housing further comprises a catheter positioned at the base of the housing, wherein the catheter is configured to provide fluid communication from a CSF-filled region in the brain into the housing via an aperture in the dura.

11. The system of claim **10**, wherein the catheter extends the fluid communication path distally to an external reservoir for drainage.

12. The system of claim **10**, wherein the catheter provides a fluid communication path that extends through the housing and radially from the housing into a subcutaneous path to a location within the body for drainage.

13. The system of claim **10**, further comprising a valve, the valve positioned radially outside from the MMSME housing, such that the valve is operably coupled to the catheter, wherein the valve is configured to control the rate of CSF drainage from the catheter.

14. The system of claim **10**, wherein the at least one pressure sensor is positioned in the housing such that the at least one pressure sensor is operably coupled to the catheter, wherein the at least one pressure sensor is configured to monitor the pulsatile pressure of CSF within the catheter.

15. The system of claim **1**, wherein the at least one pressure sensor is positioned in a subdural space such that the at least one pressure sensor is configured to provide fluid communication from a CSF-filled region in the brain into the housing via an aperture in the dura.

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