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(54) **Title**: ELECTROLYTIC BIOSENSOR

(57) **Abstract**: An electrolytic biosensor for use in intracorporeal leak detection may be incorporated into a surgical drain that is installed post-operatively at the site of a wound. The electrolytic biosensor may be used to monitor drain effluent flowing through the surgical drain by measuring a fluid conductivity of the drain effluent. Certain changes, patterns, or responses of the so measured fluid conductivity values may be indicative of a physiological condition of the wound. For example, when the wound is a gastrointestinal anastomosis, the fluid conductivity values measured with the electrolytic biosensor may be used to characterize a fluid integrity of the gastrointestinal anastomosis. An electrolytic biosensor system may include an application that records conductivity data and provides notifications, such as a patient alarm, when a leak is detected.

ELECTROLYTIC BIOSENSOR

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. Provisional Patent Application No. 61/478,442, filed on April 22, 2011, entitled "ELECTROLYTIC BIOSENSOR", which is incorporated by reference herein in its entirety.

BACKGROUND

Field of the Disclosure

[0002] This disclosure relates to the field of electrolytic biosensors, and more particularly to a measuring unit for electrolytic intracorporeal testing.

Description of the Related Art

[0003] After internal surgery, a surgical drain may be installed to drain effluent from a wound site. The surgical drain may be a medical device that provides a drainage path away from the wound area.

[0004] For example, surgery involving the gastrointestinal tract is commonly performed for a variety of reasons. In many cases, gastrointestinal surgery involves the division of the gastrointestinal tract and removal of a segment of the gastrointestinal tract. When the gastrointestinal tract is divided and/or a segment of the gastrointestinal tract is removed, a subsequent re-connection is performed to restore gastrointestinal continuity using suture material, surgical stapling devices, and/or various reinforcing materials. This re-connection is referred to as a gastrointestinal anastomosis.

[0005] After gastrointestinal anastomosis operations, leakage of material from the gastrointestinal tract into surrounding tissues or body cavities through the gastrointestinal anastomosis may occur. Leakage may result in significant patient morbidity and mortality due to the fact that gastrointestinal contents generally contain bacteria while the body compartments surrounding the gastrointestinal tract are generally sterile and ill equipped to mount an appropriate immunologic defense against bacterial elements. Ultimately, the tissues of the gastrointestinal tract

in the area of an anastomosis undergo regenerative processes that completely seal any areas of potential leakage. In the first few weeks after surgery, while these regenerative processes are occurring, the surgical procedure used to form the anastomosis is expected to establish enough temporary integrity of the gastrointestinal wall to prevent leakage of materials from the gastrointestinal tract into surrounding body compartments. Despite the efforts of surgeons, anastomotic leaks may occur while the tissues undergo regeneration during the first few weeks after surgery. When a surgical drain is in place, leakage of material through the gastrointestinal anastomosis may be evident in the surgical drain.

[0006] In U.S. Patent No. 7,899,508, a monitoring device for intracorporeal leaks is disclosed. The disclosed monitoring device may include sensors and a measurement unit producing an output signal indicative of an impedance near a wound, such as a gastrointestinal anastomosis. A measurement unit producing an output signal indicative of impedance may be difficult to interpret accurately and may be poorly integrated into a modern post-operative instrumentation environment, which may result in an insurmountable barrier to widespread application.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 is a block diagram of selected elements of an embodiment of an electrolytic biosensor system;

[0008] FIG. 2 is a block diagram of selected elements of an embodiment of an electrolytic biosensor system;

[0009] FIG. 3 is a block diagram of selected elements of an embodiment of an electrolytic biosensor system;

[0010] FIG. 4 is a block diagram of selected elements of an embodiment of an electrolytic biosensor system;

[0011] FIG. 5 illustrates an embodiment of a method for performing measurements using an electrolytic biosensor; and

[0012] FIG. 6 illustrates an embodiment of a method for determining wound integrity using an electrolytic biosensor.

DESCRIPTION OF THE EMBODIMENT(S)

[0013] The present disclosure pertains to a novel electrolytic biosensor for use in intracorporeal leak detection. As will be described in detail herein, the disclosed electrolytic biosensor may be incorporated into a surgical drain that is installed post-operatively at the site of a wound. The electrolytic biosensor may be used to monitor drain effluent flowing through the surgical drain by measuring a fluid conductivity of the drain effluent. Certain changes, patterns, or responses of the so measured fluid conductivity values may be indicative of a physiological condition of the wound. For example, when the wound is a gastrointestinal anastomosis, the fluid conductivity values measured with the electrolytic biosensor may be used to characterize a fluid integrity of the gastrointestinal anastomosis, as will be described in further detail below. In this manner, reliable and early warning of dangerous leaks in the gastrointestinal anastomosis may be provided, which may significantly contribute to reduced complications and morbidity.

[0014] In one aspect, an electrolytic biosensor device may include a processor configured to access memory media and a wireless interface. The memory media may store processor instructions executable by the processor. The processor instructions may be executable to balance a bridge circuit that includes a probe installed in a surgical drain at an intracorporeal wound site. The processor instructions may further be executable to acquire conductivity values from the bridge circuit corresponding to conductivity of a drain effluent in contact with the probe when flowing through the surgical drain. The electrolytic biosensor device may then store the conductivity values and/or transmit the conductivity values via the wireless interface.

[0015] In certain embodiments, the electrolytic biosensor device may be incorporated into the surgical drain. The electrolytic biosensor device may include the bridge circuit, a sensor interface coupling the bridge circuit to the probe, and a power source configured to drive the sensor interface. The electrolytic biosensor device may also include a power control module configured to switch connections to the sensor interface. The processor instructions executable to acquire the conductivity values may include processor instructions executable to perform digital signal processing on output signals from the bridge circuit.

[0016] In various embodiments, the electrolytic biosensor device may include processor instructions executable to determine wound integrity based on the conductivity values and transmit an indication of the wound integrity via the wireless interface.

[0017] In another aspect, a method of detecting wound integrity using an electrolytic biosensor may include determining an expected ingestion profile for a patient ingesting a trace fluid, including estimating a conductivity change over time at a gastrointestinal wound site of the patient. Responsive to receiving an indication of the ingesting of the trace fluid, the method may further include collecting ingestion profile conductivity data using an electrolytic probe at the gastrointestinal wound site of the patient. The electrolytic probe may be installed in a surgical drain and may be configured to measure conductivity of an effluent fluid flowing from the gastrointestinal wound site through the surgical drain. The method may still further include analyzing the ingestion profile conductivity data to determine fluid integrity of the gastrointestinal wound site, including comparing the ingestion profile conductivity data with the expected ingestion profile.

[0018] In some embodiments, the trace fluid may have a substantially higher conductivity than a nominal conductivity value of the effluent fluid, while the conductivity change may be a substantial increase in conductivity. The method operation of determining the expected ingestion profile may include using a physiological model describing specific attributes of the patient and estimating a degree of leakage at the gastrointestinal wound site. The method operation of collecting ingestion profile conductivity data may include storing ingestion profile conductivity data, while the method operation of analyzing the ingestion profile conductivity data may include comparing new ingestion profile conductivity data to previously stored ingestion profile conductivity data.

[0019] In particular embodiments, the method may further include wirelessly transmitting an indication of the fluid integrity of the gastrointestinal wound site to a wireless user device. The method may also include transmitting an indication of the fluid integrity of the gastrointestinal wound site to a server via a network. The method operation of analyzing the ingestion profile conductivity data to determine fluid integrity of the gastrointestinal wound site may include determining a degree of leakage at the gastrointestinal wound site. Based on the degree of leakage, the method may include generating an alarm associated with the patient.

[0020] In yet another aspect, a non-transitory computer readable memory media may store processor instructions executable by a processor to operate an electrolytic biosensor device. The processor instructions may include instructions executable to balance a bridge circuit that includes an electrolytic probe installed in a surgical drain at an intracorporeal wound site of a patient. The electrolytic probe may include a conductivity cell for measuring conductivity. The processor instructions may be executable to acquire conductivity data from the bridge circuit corresponding to conductivity of a drain effluent flowing through the conductivity cell and determine fluid integrity of the intracorporeal wound site by comparing the conductivity data with previously-stored reference conductivity data. The processor instructions may further be executable to transmit an indication of the fluid integrity of the intracorporeal wound site.

[0021] In certain embodiments, the processor instructions executable to acquire the conductivity data may include processor instructions executable to control a sensor interface to the conductivity cell and process an output signal from the conductivity cell to generate the conductivity data. Based on the indication of the fluid integrity of the intracorporeal wound site, the processor instructions may further be executable to generate an alarm associated with the patient. The processor instructions executable to transmit an indication of the fluid integrity may include processor instructions executable to send a wireless message to a wireless user device. The memory media may further include processor instructions executable to transmit the conductivity data for the patient to a server. The processor instructions executable to compare the conductivity data with previously-stored reference conductivity data may include processor instructions executable to retrieve reference conductivity data for the patient.

[0022] In the following description, details are set forth by way of example to facilitate discussion of the disclosed subject matter. It should be apparent to a person of ordinary skill in the field, however, that the disclosed embodiments are exemplary and not exhaustive of all possible embodiments.

[0023] Throughout this disclosure, a hyphenated form of a reference numeral refers to a specific instance of an element and the un-hyphenated form of the reference numeral refers to the element generically or collectively. Thus, for example, widget 12-1 refers to an instance of a widget

class, which may be referred to collectively as widgets 12 and any one of which may be referred to generically as a widget 12.

[0024] Turning now to the figures, FIG. 1 shows a block diagram of selected elements of an embodiment of electrolytic biosensor system **100**. Electrolytic biosensor system **100** is shown with respect to surgical drain **101** through which a drain effluent (not shown) flows in direction **102**. Surgical drain **101** may represent a portion of any of a variety of devices, such as a Jackson Pratt drain, a fenestrated tube, or similar device. Surgical drain **101** may be subject to pressure or vacuum to assist in flow transport of the drain effluent. In certain embodiments, surgical drain **101** may represent a disposable medical device.

[0025] As shown in FIG. 1, installed within surgical drain **101** is conductivity probe **108**, which may be configured with electrodes (not shown) that are configured to come in physical contact with the drain effluent flowing through surgical drain **101**. The electrodes may form a conductivity cell for measuring conductivity of a material coming in physical contact therewith, such as the drain effluent. Conductivity probe **108** may be coupled to sensor unit **106** via sensor interface **110**. Also shown included with sensor unit **106** is bridge circuit **112**, which may provide signal conditioning and associated power connections to conductivity probe **108** via sensor interface **110** (see also FIG. 4). Bridge circuit **112** may be employed to improve sensitivity and/or accuracy of conductivity measurements performed using electrolytic biosensor system **100**. It is noted that in various embodiments, at least a portion of bridge circuit **112** may be implemented in a separate device, and/or incorporated within conductivity probe **108**, and/or included with sensor interface **110**.

[0026] In the exemplary configuration of electrolytic biosensor system **100**, sensor unit **106** may reside external to surgical drain **101**. In certain embodiments, surgical drain **101** represents a distal portion, while a proximal portion of surgical drain **101** may be installed at an intracorporeal wound site. In other embodiments, surgical drain **101** represents a proximal end near the wound site, while sensor interface **110** may reside within surgical drain **101** for an extended distance. Conductivity probe **108** may be formed in various sizes and configurations and may be affixed or integrated within a portion of surgical drain **101**. Conductivity probe **108** may include exposed portions of electrodes (not shown) in contact with the drain effluent and which have individual

galvanic connections to sensor unit **106** via sensor interface **110**, as will be described in further detail. Thus, certain portions of conductivity probe **108** may be formed with biocompatible electrode materials, including noble metals, metal alloys, conductive polymer over metal, cermets, nanotubes, nanoparticles, nanomaterials, or various combinations thereof. Examples of noble metals and alloys that are considered biocompatible include stainless steel, Co-Cr, Ti, Ta, Ir, and Pt, among others. An example of a biocompatible polymer coated conductor is polypyrrole-coated indium tin oxide. An example of a biocompatible conductive polymer suitable for coating metal is poly(3,4-ethylenedioxythiophene) poly(styrenesulfonate) also referred to as PEDOT. An example of a biocompatible nanotube includes carbon nanotubes.

[0027] In operation of electrolytic biosensor system **100**, as the drain effluent passes over (or through) electrodes of conductivity probe **108**, sensor unit **106** may provide electrical stimulation across a pair of the electrodes, while simultaneously sampling an output signal to generate conductivity values. The electrical stimulation and the output signal may be connected using sensor interface **110**. As shown in FIG. 1, sensor unit **106** includes bridge circuit **112**, of which one branch may be an electrode pair included in conductivity probe **108**. In one embodiment (not shown), bridge circuit **112** may be included in conductivity probe **108** and sensor interface **110** may provide two, three or four wire connection to bridge circuit **112**. In another embodiment (not shown), a voltage or current divider may be used to measure the conductivity of the fluid using connections provided by sensor interface **110**. The electrical stimulation for the electrodes and/or the bridge circuit may be in the form of direct current (DC) or alternating current (AC), in various embodiments. The output signal provided by the bridge circuit configuration may be acquired and digitized by sensor unit **106** (see also FIG. 4). Sensor unit **106** may further be configured to intelligently monitor conductivity values so acquired and perform analysis routines on the conductivity values. Sensor unit **106** may also be configured to communicate externally to transmit the conductivity values and/or the results of the analysis routines, which may include a confirmation of wound integrity, or a notification (e.g., a patient alarm) that a leak through the wound has been detected. In certain embodiments, sensor unit **106** may be removably coupled at sensor interface **110** and may initiate operation when plugged in. Sensor unit **106** may further be equipped with a computer bus interface (not shown in FIG. 1), such as a Universal Serial Bus (USB), to which a

computer processor or a USB device may be coupled to effect measurement, testing, and/or download of conductivity data.

[0028] Turning now to FIG. 2, a block diagram of selected elements of an embodiment of electrolytic biosensor system **200** is shown. It is noted that like numbered elements in FIG. 2 correspond to the same elements in FIG. 1, such as surgical drain **101** and direction **102** of the drain effluent (not shown). In electrolytic biosensor system **200**, conductivity probe **208** may be substantially similar to conductivity probe **108** (see FIG. 1), while sensor unit **206** may provide substantially similar functionality as described above with respect to sensor unit **106**. In electrolytic biosensor system **200**, sensor unit **206** is now integrated within surgical drain **101**. Sensor unit **206** may represent a microdevice, such as a miniaturized circuit board and/or an integrated semiconductor circuit device. Sensor interface **210** may embody substantially similar connectivity as described above with respect to sensor interface **110**, while being integrated into a portion of surgical drain **101**. In certain embodiments, sensor interface **210** may be implemented as an ultra-thin laminate that is attached to an interior surface of surgical drain **101**. In one embodiment, sensor interface **210** may enable conductivity probe **208** to reside at a proximate portion of surgical drain **101**, while sensor unit **206** resides at a distal portion. It is noted that at least some portions of sensor unit **206**, sensor interface **210**, and conductivity probe **208** may be packaged to be thermally, electronically, and/or chemically isolated from an environment within surgical drain **101**.

[0029] Turning now to FIG. 3, a block diagram of selected elements of an embodiment of electrolytic biosensor system **300** is shown. It is noted that like numbered elements in FIG. 3 correspond to the same elements in FIGS. 1 and 2, such as surgical drain **101** and direction **102** of the drain effluent (not shown). In electrolytic biosensor system **200**, conductivity probe **308** may be substantially similar to conductivity probe **108** (see FIG. 1), while sensor unit **306** may include substantially similar functionality as described above with respect to sensor unit **106**. In electrolytic biosensor system **300**, conductivity probe **308** is now integrated within sensor unit **306** inside surgical drain **101** as a single device that incorporates sensor interfaces (not explicitly shown in FIG. 3). Sensor unit **306** may represent a microdevice, such as a miniaturized circuit board and/or an integrated semiconductor circuit device. Sensor unit **306** may be placed at any desired location within surgical drain **101**. In certain embodiments, sensor unit **306** may be implemented as a microdevice that is attached to, or integrated within, a portion of surgical drain **101**. It is noted that

at least some portions of sensor unit **306** and conductivity probe **308** may be packaged to be thermally, electronically, and/or chemically isolated from an environment within surgical drain **101**. It is further noted that surgical drain **101** may include or incorporate additional connections (not shown), such as a power connection, between sensor unit **306** and an external system (not shown).

[0030] Referring now to FIG. 4, a block diagram of selected elements of an embodiment of an electrolytic biosensor system **400** is depicted. In electrolytic biosensor system **400**, sensor unit **406** may represent various embodiments, including sensor units **106**, **206**, and **306**, and is shown without a conductivity probe for descriptive clarity. Also omitted from FIG. 4 is surgical drain **101** (see FIGS. 1-3).

[0031] As shown in FIG. 4, sensor unit **406**, which may be a microdevice or a miniaturized device, includes numerous elements, and may include additional elements (not shown in FIG. 4) in various embodiments. Sensor unit **406** is shown including processor **402**, wireless transceiver **404**, memory **430**, power source **408**, power control **410**, signal conditioning **412**, and digital data acquisition **414**. Memory **430** is depicted in FIG. 4 including conductivity monitoring application **432**, wound integrity application **434**, conductivity data **436**, digital signal processing **438**, and sensor interface control **440**. Accordingly, sensor unit **406** may comprise elements configured to function as an embodiment of an electronic device capable of executing program instructions. Sensor unit **406** may further include at least one shared bus (not shown in FIG. 4) for interconnectivity among internal elements, such as those depicted in FIG. 4, as well as connectivity to sensor interfaces, such as sensor interface **110**, **210**, and **310** (not shown in FIG. 4, see FIGS. 1-3).

[0032] Processor **402** may represent at least one processing unit and may further include internal memory, such as a cache for storing processor executable instructions. In certain embodiments, processor **402** serves as a main controller for sensor unit **406**. In various embodiments, processor **402** is operable to perform operations associated with electrolytic biosensor systems, as described herein. Processor **402** may access memory **430** to receive executable instructions and/or to store data in memory **430**.

[0033] In FIG. 4, wireless transceiver **404** may represent a communications transceiver providing an interface for any of a number of communication links. In certain embodiments,

wireless transceiver **404** supports wireless communication links, such as infrared (IR), radio frequency (RF), and audio, among others. Examples of RF wireless links include the IEEE 802.xx family, such as WiFi® (IEEE 802.11) and Bluetooth® (IEEE 802.15.1). In addition to wireless transceiver **404**, sensor unit **406** may further support mechanically connected communication links, such as galvanically wired connections, sensor interface connections, connections to external antennas, network connections (i.e., Ethernet), etc., and may accordingly include a physical adapter or receptacle (not shown in FIG. 4) for receiving such connections. Wireless transceiver **404** may transform an instruction received from processor **402** into a signal sent via wireless communication link **422**. It is noted that wireless transceiver **404** may be a bidirectional interface, such that responses, such as commands, information, or acknowledgements, may be received via wireless communication link **422**.

[0034] In FIG. 4, wireless user device **420** may represent a smart phone or other mobile communication device with application processing capacity. Wireless user device **420** may be in possession of a physician or other medical staff charged with the care of a patient whose post-operative wound is being monitored by electrolytic biosensor system **400**. It is noted that an application executing on wireless user device **420** may specifically be configured to operate with one or more instances of sensor unit **406**. In one embodiment, a message may be sent to wireless user device **420** via wireless communication link **422-1** and an acknowledgement of the message may be received from wireless user device **420** via wireless communication link **422-1**, such that the message is sent and the acknowledgment is received via wireless transceiver **404**. Wireless transceiver **404** may further represent a client device in wireless network **424** that is accessible via wireless communication link **422-2**. Wireless network **424** may be a wide-area wireless network, such as a cellular telephony network, for example. Wireless network **424** may enable sensor unit **406** to communicate with application server **426** to exchange application data, commands, and measurement data, as desired.

[0035] In FIG. 4, memory **430** encompasses persistent and volatile media, fixed and removable media, magnetic and semiconductor media, or a combination thereof. Memory **430** is operable to store instructions, data, or both. Memory **430** as shown includes data, which may be in the form of sets or sequences of executable instructions, namely, conductivity monitoring application **432**, wound integrity application **434**, digital signal processing **438**, and sensor interface control **440**.

Conductivity monitoring application **432** may include processor executable instructions to measure conductivity values from a conductivity probe coupled to (or integrated with) sensor unit **406** (see also FIG. 5). Wound integrity application **434** may include processor executable instructions to determine whether or not a wound for which conductivity values are measured is leaking (see also FIG. 6). Digital signal processing **438** may include processor executable instructions to process output signals from a conductivity probe (not shown in FIG. 4, see FIGS. 1-3), including operations such as digital filtering, normalization, scaling, numerical calculations, differential calculations, etc. In certain instances, digital signal processing **438** may perform operations in substantially real-time or immediately upon measurement. Sensor interface control **440** may include processor executable instructions to control a sensor interface (not shown in FIG. 4, see FIGS. 1-2), including switching or power and output signals, as well as other logical operations. During operation of sensor unit **406**, sensor interface control **440** may accordingly operate in conjunction with power source **408**, power control **410**, signal conditioning **412**, and digital data acquisition **414**. Memory **430** is further shown including conductivity data **436**, representing conductivity values that have been acquired, such as conductivity data reference values and/or ingestion profile conductivity data, for example.

[0036] Also shown included with sensor unit **406** in FIG. 4 is power source **408**, which may represent a local power source, such as a battery and/or an interface to an external power supply. Power source **408** may be configured for DC, AC or both, and may be configured to convert between various levels of AC and/or DC power. Power source **408** may be configured to regulate an output voltage or an output current, as desired. Power control **410** may represent a switching system for routing power to desired interfaces, such as via sensor interfaces (not shown in FIG. 4, see FIGS. 1-3). Power control **410** may be configured to route and switch power connections on command or in a pre-programmed manner, such as under control of processor **402** and/or sensor interface control **440**. Signal conditioning **412** may represent hardware components for isolating and/or amplifying output measurement signals, such as from conductivity probes via sensor interfaces. It is noted that signal conditioning **412** may include filtering capability, in particular, for selectively isolating a desired bandwidth of conductivity signals. It is further noted that certain signal conditioning operations may be performed by signal conditioning **412** and/or by digital signal processing **438**, as desired. In certain embodiments, a bridge circuit (see also bridge circuit **112** in FIG. 1) and/or a voltage divider may be implemented using signal conditioning **412**. Digital data acquisition **414**

may represent any of a number of different types of analog-to-digital converters (ADC), such as, but not limited to, successive approximation ADCs, flash ADCs, Sigma-Delta ADCs, integrating ADCs, ramp ADCs, and digital multimeters (DMM), among others.

[0037] Turning now to FIG. 5, an embodiment of novel method **500** for performing measurements using an electrolytic biosensor is illustrated in flow chart form. In one embodiment, method **500** is performed by conductivity monitoring application **432** (see FIG. 4). It is noted that certain operations described in method **500** may be optional or may be rearranged in different embodiments. Although method **500** is described with respect to a bridge circuit, in some embodiments, another type of signal conditioning arrangement for conductivity measurements may be implemented.

[0038] Method **500** may begin by connecting (operation **502**) an electrolytic probe in contact with an effluent to a bridge circuit. In various embodiments, the electrolytic probe is included in conductivity probe **108**, **208**, **308** (see FIGS. 1-3). The electrolytic probe may be a conductivity cell with electrodes configured to probe conductivity (or resistance or impedance) from a drain effluent flowing through a surgical drain installed at an intracorporeal wound site. The connection in operation **502** may be performed by power control **410** and/or sensor interface control **440** (see FIG. 4). The bridge circuit may also be included in conductivity probe **108**, **208**, **308** (see FIGS. 1-3). The bridge circuit may be balanced (operation **504**) to a nominal conductivity value for the effluent. The balancing of the bridge circuit may correspond with a background, or baseline, level of conductivity in the electrolytic probe. The balancing may be performed digitally by processor **402** in conjunction with digital data acquisition **414** and/or sensor interface control **440** (see FIG. 4). The balancing may be performed using AC and/or DC excitation of the bridge circuit. Conductivity values may be acquired (operation **506**) from the bridge circuit. The acquisition in operation **506** may be performed with digital data acquisition **414** (see FIG. 4). Operation **506** may continue with acquisition of conductivity values at a given interval over a desired period of time. The acquired conductivity values may be processed, such as by averaging or digital filtering using digital signal processing **438**, to improve a signal to noise ratio of the conductivity values. The conductivity values may be calibrated against a standard sample and acquired in normalized form. In certain embodiments, high frequency conductivity values may be acquired in operation **506**. The conductivity values may be stored (operation **508**). The conductivity values may be stored on sensor

unit **406** or on application server **426** (see FIG. 4). The conductivity values may be transmitted (operation **510**). The conductivity values may be transmitted to wireless user device **420** and/or application server **426**. It is noted that application server **426** may be configured to store and receive conductivity values from a plurality of sensor units. Application server **426** may be configured to store conductivity values in a database (not shown). It is noted that operations **508** and **510** may also be implemented using a local interface, such as with a removable USB storage device on which the conductivity values are stored.

[0039] Turning now to FIG. 6, an embodiment of novel method **600** for determining wound integrity using an electrolytic biosensor is illustrated in flow chart form. In one embodiment, method **600** is performed by wound integrity application **434** executing on sensor unit **406** (see FIG. 4) for testing the integrity of a gastrointestinal anastomosis. In other embodiments, wound integrity application **434** may be configured to perform method **600** by execution on application server **426**, in conjunction with conductivity monitoring application **432**, for example, by transmitting conductivity data to application server **426**. It is noted that certain operations described in method **600** may be optional or may be rearranged in different embodiments. Method **600** may be performed using any combination of electrolytic biosensor systems **100**, **200**, **300** to determine the integrity of a post-operative intracorporeal wound, such as a gastrointestinal anastomosis. It is noted that method **600** may be performed intermittently or continuously for wound condition monitoring and tracking. It is further noted that method **600** may be used to monitor wound integrity in substantially real time and to generate notifications of wound integrity in real time, such as a patient alarm.

[0040] Method **600** may begin by receiving (operation **602**) an indication of ingestion of a trace fluid. The indication may be received by wireless user device **420** (see FIG. 4) or application server **426**. The indication may include a time of ingestion, an amount of ingested trace fluid, an identity of a patient ingesting the trace fluid, and/or an identifier for the trace fluid. In certain embodiments, the identifier for the trace fluid is a conductivity of the trace fluid. Then, an expected ingestion profile may be determined (operation **603**). The expected ingestion profile may reflect an expected conductivity change over time at a point in the gastrointestinal tract where a wound, whose integrity is being determined by method **600**, is located. The expected ingestion profile may be determined using reference ingestion profile conductivity data stored in operation **612**. In certain embodiments, the expected ingestion profile may be determined using physiological models with

input parameters describing the patient, such as gender, age, height, weight, metabolism values, etc. The expected ingestion profile may also be generated using an estimate for a degree of leakage at a particular wound site, such as a gastrointestinal anastomosis. An electrolytic biosensor, as described herein, may be placed at the point in the gastrointestinal tract for which the expected ingestion profile is determined, for example, in a surgical drain at a wound site. Different expected ingestion profiles may be determined (or estimated) for various degrees of wound leakage in operation **603**. The expected ingestion profile may comprise threshold values for conductivity that indicate whether or not the anastomosis is leaking. Then, ingestion profile conductivity data may be collected (operation **604**). The collection in operation **604** may involve digital data acquisition and data storage of individual conductivity data points that are correlated in time. The collection in operation **604** may also involve acquiring signal traces comprising a plurality of individual clocked data points. It is noted that in particular embodiments, operations **602-604** may be performed in a different order. For example, when an immediate response to ingestion of a trace fluid is expected, such as with anastomosis sites at the esophagus or the stomach, operation **604** may be initiated prior to ingestion of the trace fluid and may collect baseline conductivity data.

[0041] Next in method **600**, a decision may be made whether the ingestion profile is complete (operation **606**). The completion of the ingestion profile may represent a time period corresponding to the passing of the trace fluid through a location of the gastrointestinal tract where the wound is located. In certain instances, the determination in operation **606** is made based on a time period associated with an expected ingestion profile. When the result of operation **606** is NO, method **600** may loop back to operation **604**. When the result of operation **606** is YES, the data collection in operation **604** may stop and the ingestion profile conductivity data may be analyzed (operation **608**). The analysis may determine whether the integrity of the wound for which method **600** was performed is intact. The analysis may also determine whether a leak in the wound exists, and optionally, a degree or an extent of the leak. The analysis may involve comparing the ingestion profile conductivity data with reference conductivity data, such as the expected ingestion profile. Other reference conductivity data, such as previously stored ingestion profile conductivity data, may also be used. In some embodiments, reference conductivity data, either for a particular patient or in generalized form, may be retrieved from application server **426** (see FIG. 4). A leak may be detected by an increase in conductivity of the drain effluent that is correlated with expected

expulsion of the trace fluid at the wound location. The integrity of the wound may be determined by an absence of the increase in conductivity in the drain effluent associated with the trace fluid. An increase in the conductivity may be determined by comparison with threshold values, which may be pre-determined or may be adaptively or relatively determined. Then, notification of the analysis results may be sent (operation **610**). The notification in operation **610** may be sent to wireless user device **420** and/or application server **426** (see FIG. 4). In certain embodiments, application server **426** may be configured to generate an alarm or other message to health care staff in response to analysis results indicating wound leakage and/or in response to a degree of wound leakage. Finally in method **600**, ingestion profile conductivity data may be stored (operation **612**) for reference.

[0042] While the subject of this specification has been described in connection with one or more exemplary embodiments, it is not intended to limit the claims to the particular forms set forth. On the contrary, the appended claims are intended to cover such alternatives, modifications and equivalents as may be included within their spirit and scope.

WHAT IS CLAIMED IS:

1. An electrolytic biosensor device, comprising:

a processor configured to access memory media; and

a wireless interface,

wherein the memory media store processor instructions executable by the processor to:

balance a bridge circuit that includes a probe installed in a surgical drain at an intracorporeal wound site;

acquire conductivity values from the bridge circuit corresponding to conductivity of a drain effluent in contact with the probe when flowing through the surgical drain;

store the conductivity values; and

transmit the conductivity values via the wireless interface.

2. The electrolytic biosensor device of claim 1, wherein the electrolytic biosensor device is incorporated into the surgical drain.

3. The electrolytic biosensor device of claim 1, further comprising:

the bridge circuit;

a sensor interface coupling the bridge circuit to the probe; and

a power source configured to drive the sensor interface.

4. The electrolytic biosensor device of claim 3, further comprising:

a power control module configured to switch connections to the sensor interface.

5. The electrolytic biosensor device of claim 1, wherein the processor instructions executable to acquire the conductivity values include processor instructions executable to:

perform digital signal processing on output signals from the bridge circuit.

6. The electrolytic biosensor device of claim 1, including processor instructions executable to:

based on the conductivity values, determine wound integrity; and

transmit an indication of the wound integrity via the wireless interface.

7. A method of detecting wound integrity using an electrolytic biosensor, comprising:

determining an expected ingestion profile for a patient ingesting a trace fluid, including estimating a conductivity change over time at a gastrointestinal wound site of the patient;

responsive to receiving an indication of the ingesting of the trace fluid, collecting ingestion profile conductivity data using an electrolytic probe at the gastrointestinal wound site of the patient, wherein the electrolytic probe is installed in a surgical drain and is configured to measure conductivity of an effluent fluid flowing from the gastrointestinal wound site through the surgical drain; and

analyzing the ingestion profile conductivity data to determine fluid integrity of the gastrointestinal wound site, including comparing the ingestion profile conductivity data with the expected ingestion profile.

8. The method of claim 7, wherein the trace fluid has a substantially higher conductivity than a nominal conductivity value of the effluent fluid, and wherein the conductivity change is a substantial increase in conductivity.

9. The method of claim 7, wherein the determining the expected ingestion profile includes:

using a physiological model describing specific attributes of the patient; and

estimating a degree of leakage at the gastrointestinal wound site.

10. The method of claim 7, wherein collecting ingestion profile conductivity data includes storing ingestion profile conductivity data, and wherein analyzing the ingestion profile conductivity data includes comparing new ingestion profile conductivity data to previously stored ingestion profile conductivity data.

11. The method of claim 7, further comprising:

wirelessly transmitting an indication of the fluid integrity of the gastrointestinal wound site to a wireless user device.

12. The method of claim 7, further comprising:

transmitting an indication of the fluid integrity of the gastrointestinal wound site to a server via a network.

13. The method of claim 7, wherein analyzing the ingestion profile conductivity data to determine fluid integrity of the gastrointestinal wound site includes:

determining a degree of leakage at the gastrointestinal wound site.

14. The method of claim 13, further comprising:

based on the degree of leakage, generating an alarm associated with the patient.

15. A non-transitory computer readable memory media storing processor instructions executable by a processor to operate an electrolytic biosensor device, the processor instructions including instructions executable to:

balance a bridge circuit that includes an electrolytic probe installed in a surgical drain at an intracorporeal wound site of a patient, wherein the electrolytic probe includes a conductivity cell for measuring conductivity;

acquire conductivity data from the bridge circuit corresponding to conductivity of a drain effluent flowing through the conductivity cell;

determine fluid integrity of the intracorporeal wound site by comparing the conductivity data with previously-stored reference conductivity data; and

transmit an indication of the fluid integrity of the intracorporeal wound site.

16. The memory media of claim 15, wherein the processor instructions executable to acquire the conductivity data include processor instructions executable to:

control a sensor interface to the conductivity cell; and

process an output signal from the conductivity cell to generate the conductivity data.

17. The memory media of claim 15, including processor instructions executable to:

based on the indication of the fluid integrity of the intracorporeal wound site, generate an alarm associated with the patient.

18. The memory media of claim 15, wherein the processor instructions executable to transmit an indication of the fluid integrity include processor instructions executable to:

send a wireless message to a wireless user device.

19. The memory media of claim 15, including processor instructions executable to:

transmit the conductivity data for the patient to a server.

20. The memory media of claim 15, wherein the processor instructions executable to compare the conductivity data with previously-stored reference conductivity data include processor instructions executable to:

retrieve reference conductivity data for the patient.

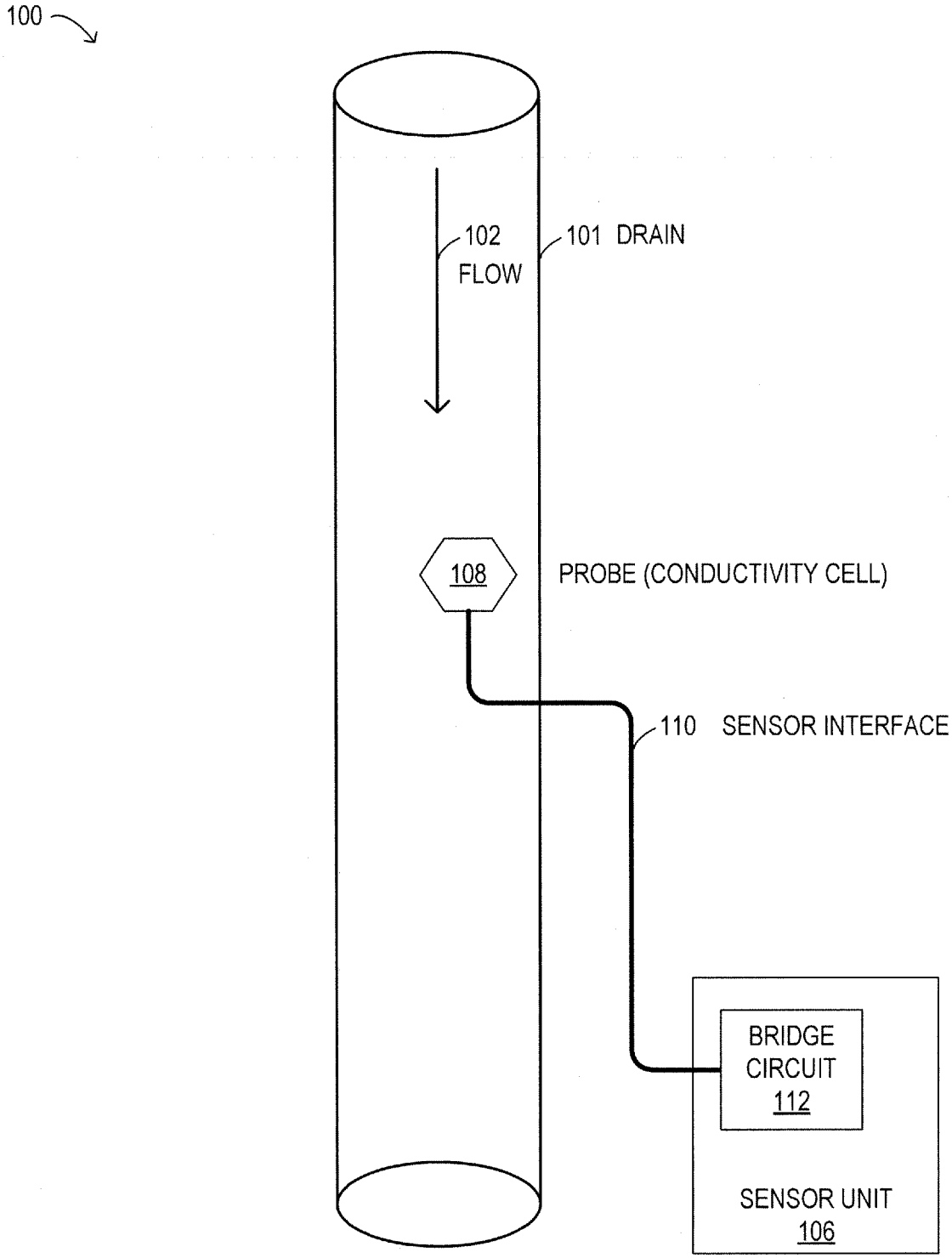
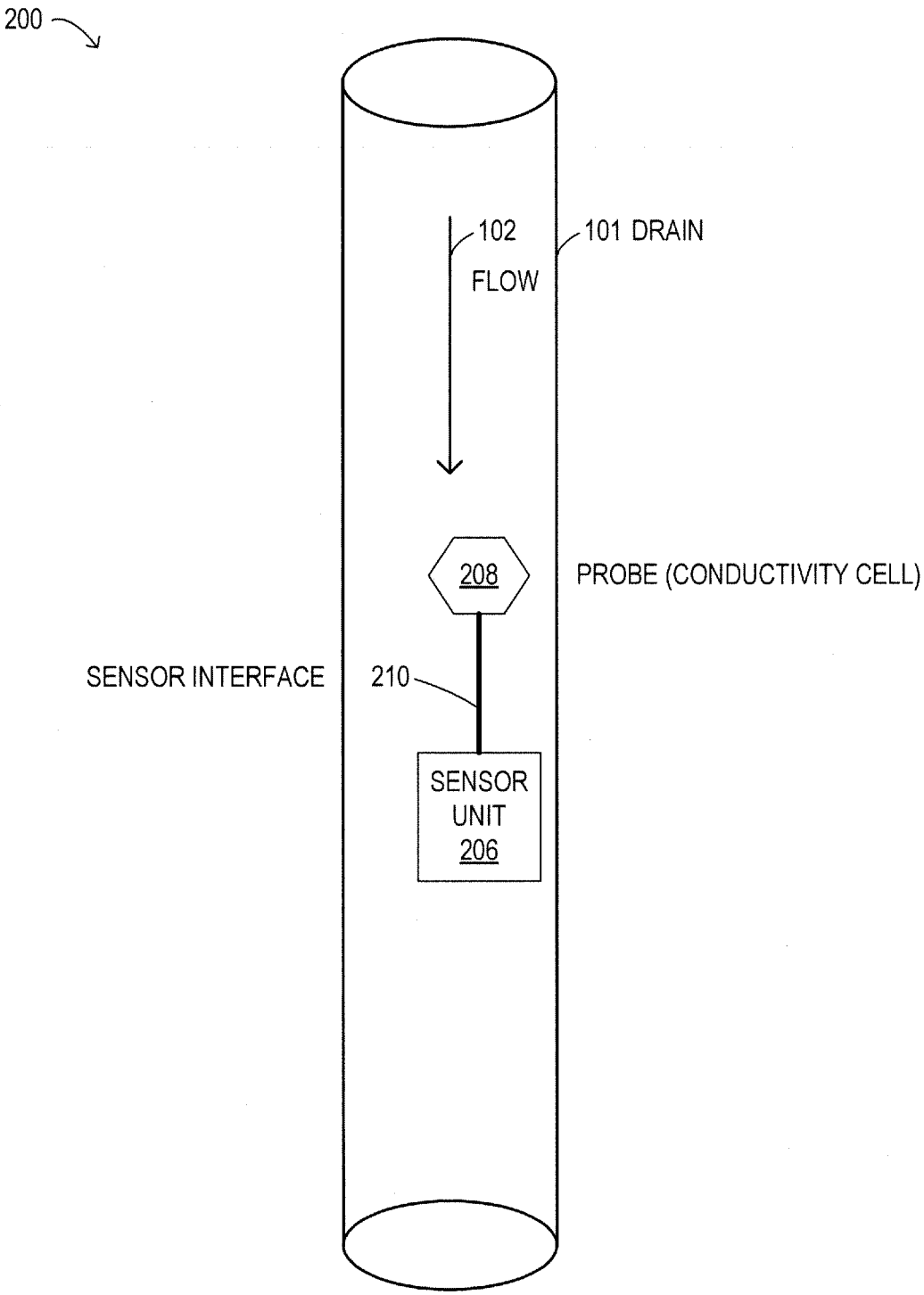

100
102
FLOW
101 DRAIN
108
PROBE (CONDUCTIVITY CELL)
110 SENSOR INTERFACE
BRIDGE
CIRCUIT
112
SENSOR UNIT
106

FIG. 1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FLOW
101 DRAIN
208
PROBE (CONDUCTIVITY CELL)
SENSOR INTERFACE
210
SENSOR
UNIT
206

FIG. 2

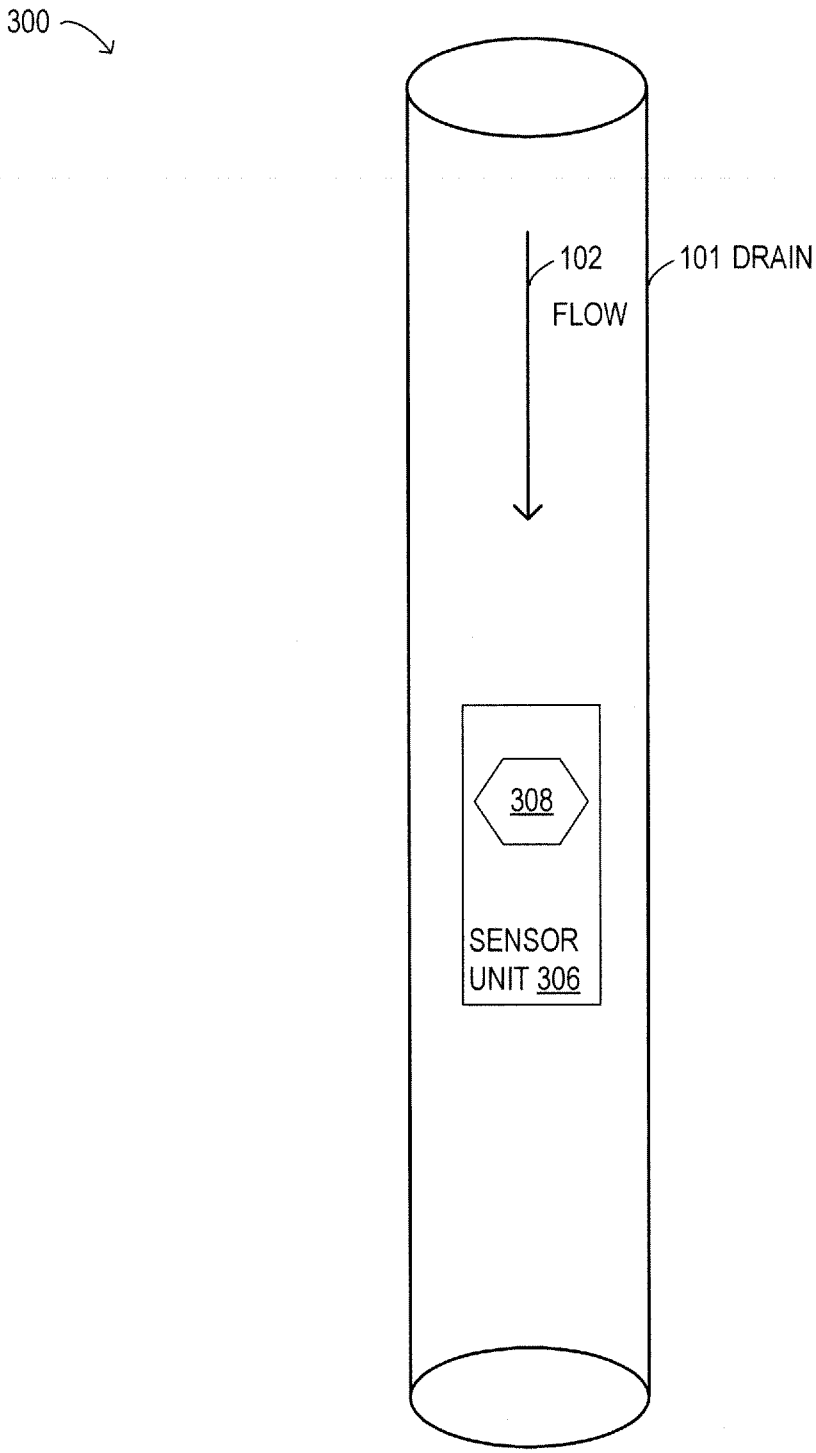
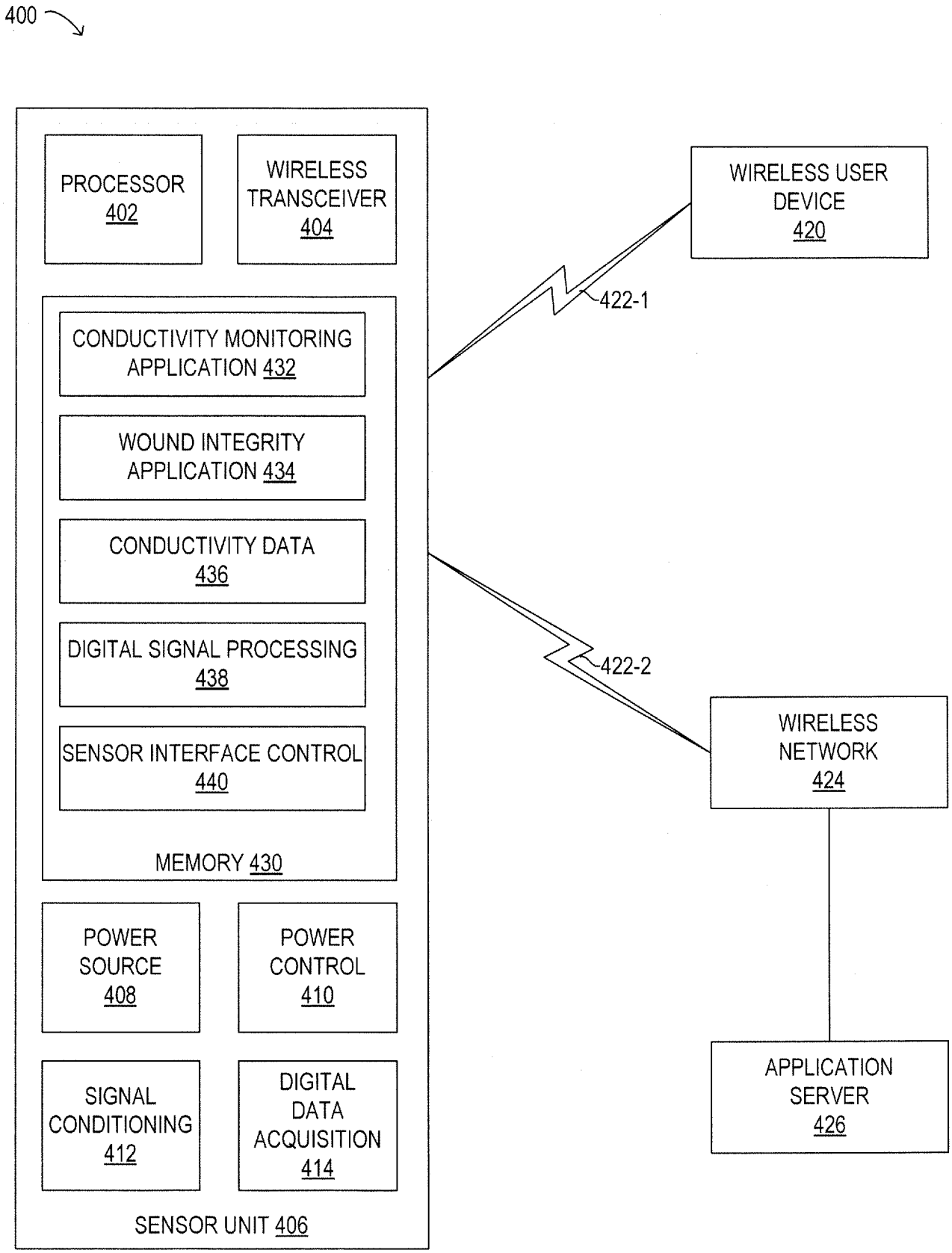


FIG. 3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PROCESSOR 402
WIRELESS TRANSCEIVER 404
CONDUCTIVITY MONITORING APPLICATION 432
WOUND INTEGRITY APPLICATION 434
CONDUCTIVITY DATA 436
DIGITAL SIGNAL PROCESSING 438
SENSOR INTERFACE CONTROL 440
MEMORY 430
POWER SOURCE 408
POWER CONTROL 410
SIGNAL CONDITIONING 412
DIGITAL DATA ACQUISITION 414
SENSOR UNIT 406
WIRELESS USER DEVICE 420
422-1
422-2
WIRELESS NETWORK 424
APPLICATION SERVER 426

FIG. 4

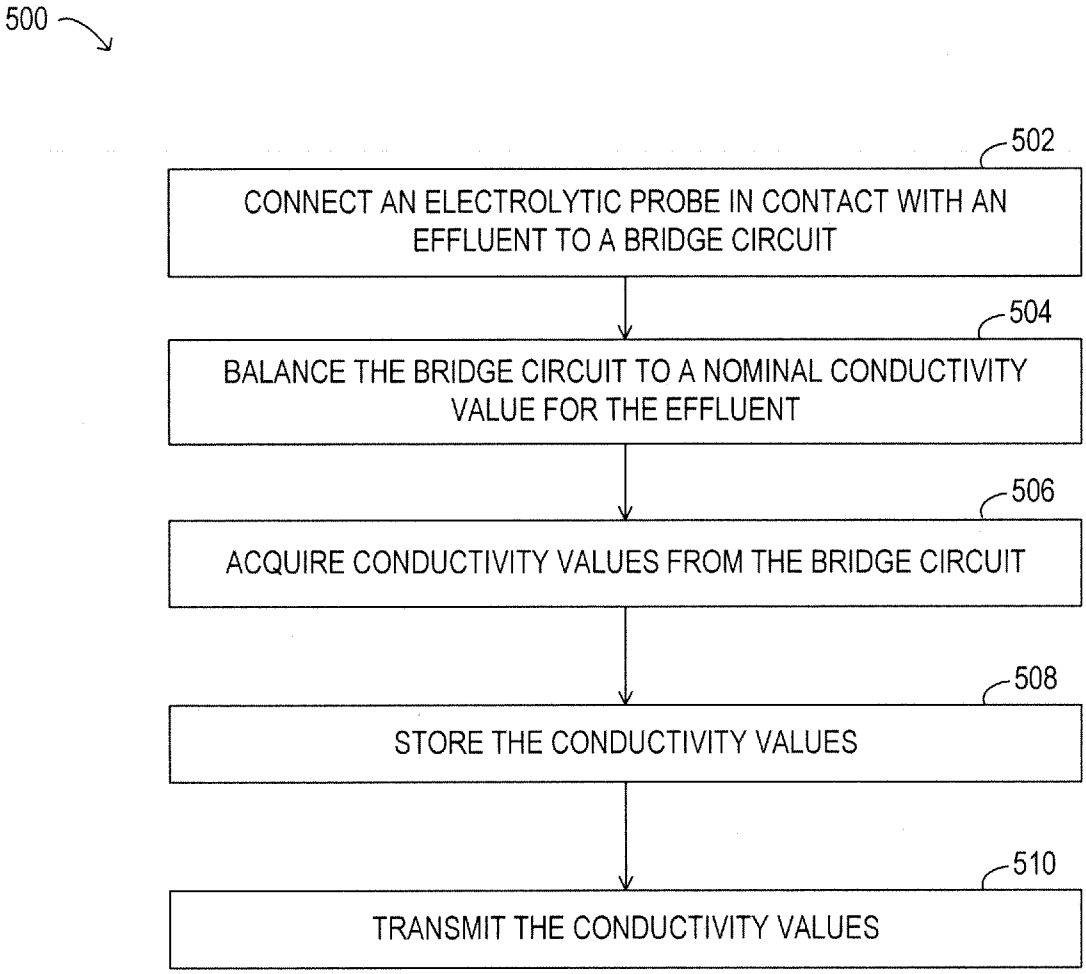
500
502
CONNECT AN ELECTROLYTIC PROBE IN CONTACT WITH AN EFFLUENT TO A BRIDGE CIRCUIT
504
BALANCE THE BRIDGE CIRCUIT TO A NOMINAL CONDUCTIVITY VALUE FOR THE EFFLUENT
506
ACQUIRE CONDUCTIVITY VALUES FROM THE BRIDGE CIRCUIT
508
STORE THE CONDUCTIVITY VALUES
510
TRANSMIT THE CONDUCTIVITY VALUES

FIG. 5

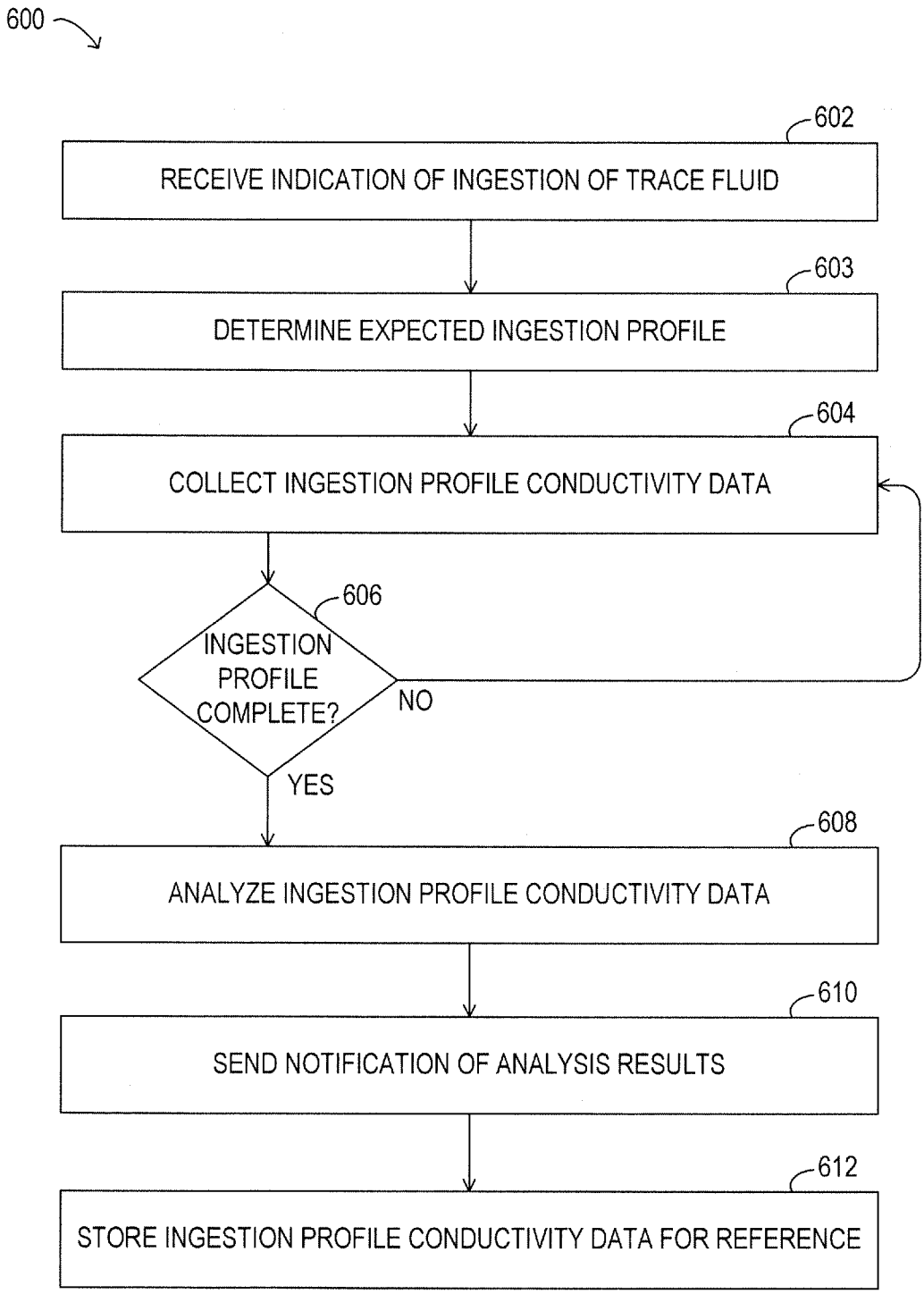
600
602
RECEIVE INDICATION OF INGESTION OF TRACE FLUID
603
DETERMINE EXPECTED INGESTION PROFILE
604
COLLECT INGESTION PROFILE CONDUCTIVITY DATA
606
INGESTION PROFILE COMPLETE?
NO
YES
608
ANALYZE INGESTION PROFILE CONDUCTIVITY DATA
610
SEND NOTIFICATION OF ANALYSIS RESULTS
612
STORE INGESTION PROFILE CONDUCTIVITY DATA FOR REFERENCE

FIG. 6