

(43) International Publication Date  
17 January 2013 (17.01.2013)(51) International Patent Classification:  
*A61B 1/273* (2006.01) *H04B 7/24* (2006.01)(21) International Application Number:  
PCT/US2012/046120(22) International Filing Date:  
10 July 2012 (10.07.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
13/180,525 11 July 2011 (11.07.2011) US

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

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,

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(54) Title: COMMUNICATION SYSTEM WITH ENHANCED PARTIAL POWER SOURCE AND METHOD OF MANUFACTURING SAME

(57) **Abstract:** The system of the present invention includes a conductive element, an electronic component, and a partial power source in the form of dissimilar materials. Upon contact with a conducting fluid, a voltage potential is created and the power source is completed, which activates the system. The electronic component controls the conductance between the dissimilar materials to produce a unique current signature. The system can also measure the conditions of the environment surrounding the system.

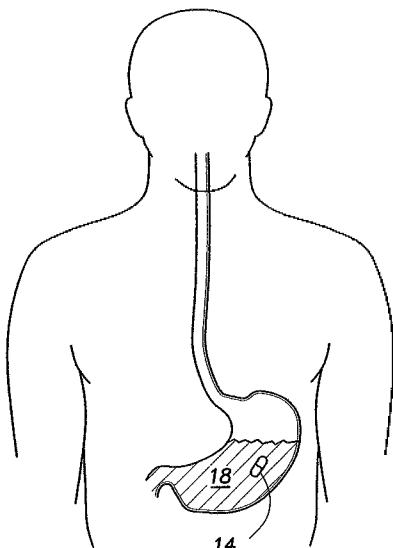


FIG. 1



TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

## COMMUNICATION SYSTEM WITH ENHANCED PARTIAL POWER SOURCE AND METHOD OF MANUFACTURING SAME

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[001]** This application is a continuation-in-part of U.S. Patent Application No. 13/180,525 filed on July 11, 2011 and entitled "Communication System with Enhanced Partial Power Source and Method of Manufacturing the Same," which application is a continuation-in-part of U.S. Patent Application No. 12/564,017, filed on Sept 21, 2009 and entitled "Communication System with Partial Power Source", published on April 1, 2010 as U.S. Publication No. US2010-0081894A1, which is a continuation-in-part application of U.S. Patent Application No. 11/912,475 filed June 23, 2008 and entitled "Pharma-Informatics System", published on November 20, 2008 as U.S. Publication No. 2008-0284599A1 which application is a 371 application of PCT Application No. PCT/US06/16370 filed April 28, 2006 and entitled "Pharma-Informatics System"; published as WO Application No. WO 2006/116718, which application pursuant to 35 U.S.C. § 119 (e), claims priority to the filing dates of: United States Provisional Patent Application Serial No. 60/676,145 filed April 28, 2005 and entitled "Pharma-Informatics System"; United States Provisional Patent Application Serial No. 60/694,078, filed June 24, 2005, and entitled "Pharma-Informatics System"; United States Provisional Patent Application Serial No. 60/713,680 filed September 1, 2005 and entitled "Medical Diagnostic And Treatment Platform Using Near-Field Wireless Communication Of Information Within A Patient's Body"; and United States Provisional Patent Application Serial No. 60/790,335 filed April 7, 2006 and entitled "Pharma-Informatics System"; the disclosures of which are herein incorporated by reference.

**[002]** This application is related to the following US Applications filed on July 11, 2011, the disclosures of which are incorporated herein by reference: US Application Serial No. 13/180,516, filed July 11, 2011 entitled COMMUNICATION SYSTEM WITH REMOTE ACTIVATION; US Application Serial No. 13/180,498, filed July 11, 2011, entitled COMMUNICATION SYSTEM WITH MULTIPLE TYPES OF POWER;

US Application Serial No. 13/180,539, filed July 11, 2011, entitled COMMUNICATION SYSTEM USING AN IMPLANTABLE DEVICE; US Application Serial No. 13/180,538, filed July 11, 2011, entitled COMMUNICATION SYSTEM USING POLYPHARMACY CO-PACKAGED MEDICATION DOSING UNIT; and US Application Serial No. 13/180,507, filed July 11, 2011, entitled COMMUNICATION SYSTEM INCORPORATED IN AN INGESTIBLE PRODUCT.

## FIELD

**[003]** The present invention is related to communication systems for detection of an event. More specifically, the present disclosure includes a system that includes a device with various power sources and communication schemes.

## INTRODUCTION

**[004]** Ingestible devices that include electronic circuitry have been proposed for use in a variety of different medical applications, including both diagnostic and therapeutic applications. These devices typically require an internal power supply for operation. Examples of such ingestible devices are ingestible electronic capsules which collect data as they pass through the body, and transmit the data to an external receiver system. An example of this type of electronic capsule is an in-vivo video camera. The swallowable capsule includes a camera system and an optical system for imaging an area of interest onto the camera system. The transmitter transmits the video output of the camera system and the reception system receives the transmitted video output. Other examples include an ingestible imaging device, which has an internal and self-contained power source, which obtains images from within body lumens or cavities. The electronic circuit components of the device are enclosed by an inert indigestible housing (e.g. glass housing) that passes through the body internally. Other examples include an ingestible data recorder capsule medical device. The electronic circuits of the disclosed device (e.g. sensor, recorder, battery etc.) are housed in a capsule made of inert materials.

**[005]** In other examples, fragile radio frequency identification (RFID) tags are used in drug ingestion monitoring applications. In order for the RFID tags to be operational, each requires an internal power supply. The RFID tags are antenna structures that are configured to transmit a radio-frequency signal through the body.

**[006]** The problem these existing devices pose is that the power source is internal to device and such power sources are costly to produce and potentially harmful to the surrounding environment if the power source leaks or is damaged. Additionally, having antennas extending from the device is a concern as related to the antennas getting damaged or causing a problem when the device is used in-vivo. Therefore, what is needed is suitable system with circuitry that eliminates the need for an internal power source and antennas.

## **SUMMARY**

**[007]** The present disclosure includes a system for producing a unique signature that indicates the occurrence of an event. The system includes circuitry and components that can be placed within certain environments that include a conducting fluid. One example of such an environment is inside a container that houses the conducting fluid, such as a sealed bag with a solution, which includes an IV bag. Another example is within the body of a living organism, such as an animal or a human. The systems are ingestible and/or digestible or partially digestible. The system includes dissimilar materials positioned on the framework such that when a conducting fluid comes into contact with the dissimilar materials, a voltage potential difference is created. The voltage potential difference, and hence the voltage, is used to power up control logic that is positioned within the framework. Ions or current flows from the first dissimilar material to the second dissimilar material via the control logic and then through the conducting fluid to complete a circuit. The control logic controls the conductance between the two dissimilar materials and, hence, controls or modulates the conductance.

**[008]** As the ingestible circuitry is made up of ingestible, and even digestible, components, the ingestible circuitry results in little, if any, unwanted side effects, even when employed in chronic situations. Examples of the range of components

that may be included are: logic and/or memory elements; effectors; a signal transmission element; and a passive element, such as a resistor or inductor. The one or more components on the surface of the support may be laid out in any convenient configuration. Where two or more components are present on the surface of the solid support, interconnects may be provided. All of the components and the support of the ingestible circuitry are ingestible, and in certain instances digestible or partially digestible. Furthermore, the circuitry is manufactured according to a process to enhance adhesion of the materials.

## **BRIEF DESCRIPTION OF THE FIGURES**

**[009]** Fig. 1 shows a pharmaceutical product with an event indicator system according to the teaching of the present invention, wherein the product and the event indicator system combination are within the body.

**[010]** Fig. 2A shows the pharmaceutical product of Fig. 1 with the event indicator system on the exterior of the pharmaceutical product.

**[011]** Fig. 2B shows the pharmaceutical product of Fig. 1 with the event indicator system positioned inside the pharmaceutical product.

**[012]** Fig. 3 is a block diagram representation of one aspect of the event indicator system with dissimilar metals positioned on opposite ends.

**[013]** Fig. 4 is a block diagram representation of another aspect of the event indicator system with dissimilar metals positioned on the same end and separated by a non-conducting material.

**[014]** Fig. 5 shows ionic transfer or the current path through a conducting fluid when the event indicator system of Fig. 3 is in contact with conducting liquid and in an active state.

**[015]** Fig. 5A shows an exploded view of the surface of dissimilar materials of Fig. 5.

**[016]** Fig. 5B shows the event indicator system of Fig. 5 with a pH sensor unit.

**[017]** Fig. 5C shows the event indicator system in accordance with another aspect of the present invention.

**[018]** Fig. 6 is a block diagram illustration of one aspect of the control device used in the system of Figs. 3 and 4.

**[019]** Fig. 7 shows a cross sectional side view of the event indicator system in accordance with the present invention.

**[020]** Fig. 8 is an exploded view of two components of the event indicator system of Fig. 7 in accordance with the present invention.

**[021]** Fig. 9 is an assembly process of a portion of the event indicator system of Fig. 7 in accordance with the present invention.

**[022]** Fig. 10 shows a wafer with multiple event indicator systems in accordance with the present invention.

**[023]** Fig. 11 shows a non-conducting membrane sheet with holes for receiving a device forming part of the event indicator system of Fig. 7 in accordance with the present invention.

**[024]** FIG. 12 is a functional block diagram of a demodulation circuit that performs coherent demodulation that may be present in a receiver, according to one aspect.

**[025]** FIG. 13 illustrates a functional block diagram for a beacon module within a receiver, according to one aspect.

**[026]** FIG. 14 is a block diagram of the different functional modules that may be present in a receiver, according to one aspect.

**[027]** FIG. 15 is a block diagram of a receiver, according to one aspect.

**[028]** FIG. 16 provides a block diagram of a high frequency signal chain in a receiver, according to one aspect.

**[029]** FIG. 17 provides a diagram of how a system that includes a signal receiver and an ingestible event marker may be employed, according to one aspect..

#### **DETAILED DESCRIPTION**

**[030]** The present disclosure includes multiple aspects for indicating the occurrence of an event. As described in more detail below, a system of the present invention is used with a conducting fluid to indicate the event marked by contact between the conducting fluid and the system. For example, the system of the present disclosure may be used with pharmaceutical product and the event that is indicated is when the

product is taken or ingested. The term “ingested” or “ingest” or “ingesting” is understood to mean any introduction of the system internal to the body. For example, ingesting includes simply placing the system in the mouth all the way to the descending colon. Thus, the term ingesting refers to any instant in time when the system is introduced to an environment that contains a conducting fluid. Another example would be a situation when a non-conducting fluid is mixed with a conducting fluid. In such a situation the system would be present in the non-conduction fluid and when the two fluids are mixed, the system comes into contact with the conducting fluid and the system is activated. Yet another example would be the situation when the presence of certain conducting fluids needed to be detected. In such instances, the presence of the system, which would be activated, within the conducting fluid could be detected and, hence, the presence of the respective fluid would be detected.

**[031]** Referring again to the instance where the system is used with the product that is ingested by the living organism, when the product that includes the system is taken or ingested, the device comes into contact with the conducting liquid of the body. When the system of the present invention comes into contact with the body fluid, a voltage potential is created and the system is activated. A portion of the power source is provided by the device, while another portion of the power source is provided by the conducting fluid, which is discussed in detail below.

**[032]** Referring now to Fig. 1, an ingestible product 14 that includes a system of the present invention is shown inside the body. The product 14 is configured as an orally ingestible pharmaceutical formulation in the form of a pill or capsule. Upon ingestion, the pill moves to the stomach. Upon reaching the stomach, the product 14 is in contact with stomach fluid 18 and undergoes a chemical reaction with the various materials in the stomach fluid 18, such as hydrochloric acid and other digestive agents. The system of the present invention is discussed in reference to a pharmaceutical environment. However, the scope of the present invention is not limited thereby. The present invention can be used in any environment where a conducting fluid is present or becomes present through mixing of two or more components that result in a conducting liquid.

**[033]** Referring now to Fig. 2A, a pharmaceutical product 10, similar to the product 14 of Fig. 1, is shown with a system 12, such as an ingestible event marker or an ionic emission module. The scope of the present invention is not limited by the shape or type of the product 10. For example, it will be clear to one skilled in the art that the product 10 can be a capsule, a time-release oral dosage, a tablet, a gel cap, a sub-lingual tablet, or any oral dosage product that can be combined with the system 12. In the referenced aspect, the product 10 has the system 12 secured to the exterior using known methods of securing micro-devices to the exterior of pharmaceutical products. Example of methods for securing the micro-device to the product is disclosed in US Provisional Application No. 61/142,849 filed on Jan 1, 2009 and entitled "HIGH-THROUGHPUT PRODUCTION OF INGESTIBLE EVENT MARKERS" as well as US Provisional Application No. 61/177,611 filed on May 12, 2009 and entitled "INGESTIBLE EVENT MARKERS COMPRISING AN IDENTIFIER AND AN INGESTIBLE COMPONENT", the entire disclosure of each is incorporated herein by reference. Once ingested, the system 12 comes into contact with body liquids and the system 12 is activated. The system 12 uses the voltage potential difference to power up and thereafter modulates conductance to create a unique and identifiable current signature. Upon activation, the system 12 controls the conductance and, hence, current flow to produce the current signature.

**[034]** There are various reasons for delaying the activation of the system 12. In order to delay the activation of the system 12, the system 12 may be coated with a shielding material or protective layer. The layer is dissolved over a period of time, thereby allowing the system 12 to be activated when the product 10 has reached a target location.

**[035]** Referring now to Fig. 2B, a pharmaceutical product 20, similar to the product 14 of Fig. 1, is shown with a system 22, such as an ingestible event marker or an identifiable emission module. The scope of the present invention is not limited by the environment to which the system 22 is introduced. For example, the system 22 can be enclosed in a capsule that is taken in addition to/independently from the pharmaceutical product. The capsule may be simply a carrier for the system 22 and may not contain any product. Furthermore, the scope of the present invention is not

limited by the shape or type of product 20. For example, it will be clear to one skilled in the art that the product 20 can be a capsule, a time-release oral dosage, a tablet, a gel capsule, a sub-lingual tablet, or any oral dosage product. In the referenced aspect, the product 20 has the system 22 positioned inside or secured to the interior of the product 20. In one aspect, the system 22 is secured to the interior wall of the product 20. When the system 22 is positioned inside a gel capsule, then the content of the gel capsule is a non-conducting gel-liquid. On the other hand, if the content of the gel capsule is a conducting gel-liquid, then in an alternative aspect, the system 22 is coated with a protective cover to prevent unwanted activation by the gel capsule content. If the content of the capsule is a dry powder or microspheres, then the system 22 is positioned or placed within the capsule. If the product 20 is a tablet or hard pill, then the system 22 is held in place inside the tablet. Once ingested, the product 20 containing the system 22 is dissolved. The system 22 comes into contact with body liquids and the system 22 is activated. Depending on the product 20, the system 22 may be positioned in either a near-central or near-perimeter position depending on the desired activation delay between the time of initial ingestion and activation of the system 22. For example, a central position for the system 22 means that it will take longer for the system 22 to be in contact with the conducting liquid and, hence, it will take longer for the system 22 to be activated. Therefore, it will take longer for the occurrence of the event to be detected.

**[036]** Referring now to Fig. 3, in one aspect, the systems 12 and 22 of Figs. 2A and 2B, respectively, are shown in more detail as system 30. The system 30 can be used in association with any pharmaceutical product, as mentioned above, to determine when a patient takes the pharmaceutical product. As indicated above, the scope of the present invention is not limited by the environment and the product that is used with the system 30. For example, the system 30 may be placed within a capsule and the capsule is placed within the conducting liquid. The capsule would then dissolve over a period of time and release the system 30 into the conducting liquid. Thus, in one aspect, the capsule would contain the system 30 and no product. Such a capsule may then be used in any environment where a conducting liquid is present and with any product. For example, the capsule may be dropped

into a container filled with jet fuel, salt water, tomato sauce, motor oil, or any similar product. Additionally, the capsule containing the system 30 may be ingested at the same time that any pharmaceutical product is ingested in order to record the occurrence of the event, such as when the product was taken.

**[037]** In the specific example of the system 30 combined with the pharmaceutical product, as the product or pill is ingested, the system 30 is activated. The system 30 controls conductance to produce a unique current signature that is detected, thereby signifying that the pharmaceutical product has been taken. The system 30 includes a framework 32. The framework 32 is a chassis for the system 30 and multiple components are attached to, deposited upon, or secured to the framework 32. In this aspect of the system 30, a digestible material 34 is physically associated with the framework 32. The material 34 may be chemically deposited on, evaporated onto, secured to, or built-up on the framework all of which may be referred to herein as “deposit” with respect to the framework 32. The material 34 is deposited on one side of the framework 32. The materials of interest that can be used as material 34 include, but are not limited to: Cu or Cul. The material 34 is deposited by physical vapor deposition, electrodeposition, or plasma deposition, among other protocols. The material 34 may be from about 0.05 to about 500  $\mu\text{m}$  thick, such as from about 5 to about 100  $\mu\text{m}$  thick. The shape is controlled by shadow mask deposition, or photolithography and etching. Additionally, even though only one region is shown for depositing the material, each system 30 may contain two or more electrically unique regions where the material 34 may be deposited, as desired. The various methods for depositing the materials onto the framework 32 are discussed in greater detail with respect to Figs. 7-9 below.

**[038]** At a different side, which is the opposite side as shown in Fig. 3, another digestible material 36 is deposited, such that materials 34 and 36 are dissimilar. Although not shown, the different side selected may be the side next to the side selected for the material 34. The scope of the present invention is not limited by the side selected and the term “different side” can mean any of the multiple sides that are different from the first selected side. Furthermore, even though the shape of the system is shown as a square, the shape maybe any geometrically suitable shape.

Material 34 and 36 are selected such that they produce a voltage potential difference when the system 30 is in contact with conducting liquid, such as body fluids. The materials of interest for material 36 include, but are not limited to: Mg, Zn, or other electronegative metals. As indicated above with respect to the material 34, the material 36 may be chemically deposited on, evaporated onto, secured to, or built-up on the framework. Also, an adhesion layer may be necessary to help the material 36 (as well as material 34 when needed) to adhere to the framework 32. Typical adhesion layers for the material 36 are Ti, TiW, Cr or similar material. Anode material and the adhesion layer may be deposited by physical vapor deposition, electrodeposition or plasma deposition. The material 36 may be from about 0.05 to about 500  $\mu\text{m}$  thick, such as from about 5 to about 100  $\mu\text{m}$  thick. However, the scope of the present invention is not limited by the thickness of any of the materials nor by the type of process used to deposit or secure the materials to the framework 32.

**[039]** According to the disclosure set forth, the materials 34 and 36 can be any pair of materials with different electrochemical potentials. Additionally, in the aspects wherein the system 30 is used in-vivo, the materials 34 and 36 may be vitamins that can be absorbed. More specifically, the materials 34 and 36 can be made of any two materials appropriate for the environment in which the system 30 will be operating. For example, when used with an ingestible product, the materials 34 and 36 are any pair of materials with different electrochemical potentials that are ingestible. An illustrative example includes the instance when the system 30 is in contact with an ionic solution, such as stomach acids. Suitable materials are not restricted to metals, and in certain aspects the paired materials are chosen from metals and non-metals, e.g., a pair made up of a metal (such as Mg) and a salt (such as CuCl or Cul). With respect to the active electrode materials, any pairing of substances – metals, salts, or intercalation compounds - with suitably different electrochemical potentials (voltage) and low interfacial resistance are suitable.

**[040]** Materials and pairings of interest include, but are not limited to, those reported in Table 1 below. In one aspect, one or both of the metals may be doped with a non-metal, e.g., to enhance the voltage potential created between the

materials as they come into contact with a conducting liquid. Non-metals that may be used as doping agents in certain aspects include, but are not limited to: sulfur, iodine and the like. In another aspect, the materials are copper iodine (CuI) as the anode and magnesium (Mg) as the cathode. Aspects of the present invention use electrode materials that are not harmful to the human body.

TABLE 1

	Anode	Cathode
Metals	Magnesium, Zinc Sodium, Lithium Iron	
Salts		Copper salts: iodide, chloride, bromide, sulfate, formate, (other anions possible)  $Fe^{3+}$ salts: e.g. orthophosphate, pyrophosphate, (other anions possible)  Oxygen or Hydrogen ion (H <sup>+</sup> ) on platinum, gold or other catalytic surfaces
Intercalation compounds	Graphite with Li, K, Ca, Na, Mg	Vanadium oxide Manganese oxide

**[041]** Thus, when the system 30 is in contact with the conducting liquid, a current path, an example is shown in Fig. 5, is formed through the conducting liquid between material 34 and 36. A control device 38 is secured to the framework 32 and electrically coupled to the materials 34 and 36. The control device 38 includes electronic circuitry, for example control logic that is capable of controlling and altering the conductance between the materials 34 and 36.

**[042]** The voltage potential created between the materials 34 and 36 provides the power for operating the system as well as produces the current flow through the conducting fluid and the system. In one aspect, the system operates in direct current mode. In an alternative aspect, the system controls the direction of the current so that the direction of current is reversed in a cyclic manner, similar to alternating current. As the system reaches the conducting fluid or the electrolyte,

where the fluid or electrolyte component is provided by a physiological fluid, e.g., stomach acid, the path for current flow between the materials 34 and 36 is completed external to the system 30; the current path through the system 30 is controlled by the control device 38. Completion of the current path allows for the current to flow and in turn a receiver, not shown, can detect the presence of the current and recognize that the system 30 has been activate and the desired event is occurring or has occurred. Illustrative examples of receivers are shown in Figs. 12 to 17, as described hereinafter.

**[043]** In one aspect, the two materials 34 and 36 are similar in function to the two electrodes needed for a direct current power source, such as a battery. The conducting liquid acts as the electrolyte needed to complete the power source. The completed power source described is defined by the electrochemical reaction between the materials 34 and 36 of the system 30 and enabled by the fluids of the body. The completed power source may be viewed as a power source that exploits electrochemical conduction in an ionic or a conducting solution such as gastric fluid, blood, or other bodily fluids and some tissues. Additionally, the environment may be something other than a body and the liquid may be any conducting liquid. For example, the conducting fluid may be salt water or a metallic based paint.

**[044]** In certain aspects, these two materials are shielded from the surrounding environment by an additional layer of material. Accordingly, when the shield is dissolved and the two dissimilar materials are exposed to the target site, a voltage potential is generated.

**[045]** In certain aspects, the complete power source or supply is one that is made up of active electrode materials, electrolytes, and inactive materials, such as current collectors, packaging, etc. The active materials are any pair of materials with different electrochemical potentials. Suitable materials are not restricted to metals, and in certain aspects the paired materials are chosen from metals and non-metals, e.g., a pair made up of a metal (such as Mg) and a salt (such as CuI). With respect to the active electrode materials, any pairing of substances – metals, salts, or intercalation compounds - with suitably different electrochemical potentials (voltage) and low interfacial resistance are suitable.

**[046]** A variety of different materials may be employed as the materials that form the electrodes. In certain aspects, electrode materials are chosen to provide for a voltage upon contact with the target physiological site, e.g., the stomach, sufficient to drive the system of the identifier. In certain aspects, the voltage provided by the electrode materials upon contact of the metals of the power source with the target physiological site is 0.001 V or higher, including 0.01 V or higher, such as 0.1 V or higher, e.g., 0.3 V or higher, including 0.5 volts or higher, and including 1.0 volts or higher, where in certain aspects, the voltage ranges from about 0.001 to about 10 volts, such as from about 0.01 to about 10 V.

**[047]** Referring again to Fig. 3, the materials 34 and 36 provide the voltage potential to activate the control device 38. Once the control device 38 is activated or powered up, the control device 38 can alter conductance between the materials 34 and 36 in a unique manner. By altering the conductance between materials 34 and 36, the control device 38 is capable of controlling the magnitude of the current through the conducting liquid that surrounds the system 30. This produces a unique current signature that can be detected and measured by a receiver (not shown), which can be positioned internal or external to the body. Illustrative examples of receivers are shown in Figs. 12 to 17, as described hereinafter. In addition to controlling the magnitude of the current path between the materials, non-conducting materials, membrane, or “skirt” are used to increase the “length” of the current path and, hence, act to boost the conductance path, as disclosed in the U.S. Patent Application Serial No. 12/238,345 entitled, “In-Body Device with Virtual Dipole Signal Amplification” filed September 25, 2008, the entire content of which is incorporated herein by reference. Alternatively, throughout the disclosure herein, the terms “non-conducting material”, “membrane”, and “skirt” are used interchangeably with the term “current path extender” without impacting the scope or the present aspects and the claims herein. The skirt, shown in portion at 35 and 37, respectively, may be associated with, e.g., secured to, the framework 32. Various shapes and configurations for the skirt are contemplated as within the scope of the present invention. For example, the system 30 may be surrounded entirely or partially by the skirt and the skirt maybe positioned along a central axis of the system 30 or off-

center relative to a central axis. Thus, the scope of the present invention as claimed herein is not limited by the shape or size of the skirt. Furthermore, in other aspects, the materials 34 and 36 may be separated by one skirt that is positioned in any defined region between the materials 34 and 36.

**[048]** Referring now to Fig. 4, in another aspect, the systems 12 and 22 of Figs. 2A and 2B, respectively, are shown in more detail as system 40. The system 40 includes a framework 42. The framework 42 is similar to the framework 32 of Fig. 3. In this aspect of the system 40, a digestible or dissolvable material 44 is deposited on a portion of one side of the framework 42. At a different portion of the same side of the framework 42, another digestible material 46 is deposited, such that materials 44 and 46 are dissimilar. More specifically, material 44 and 46 are selected such that they form a voltage potential difference when in contact with a conducting liquid, such as body fluids. Thus, when the system 40 is in contact with and/or partially in contact with the conducting liquid, then a current path, an example is shown in Fig. 5, is formed through the conducting liquid between material 44 and 46. A control device 48 is secured to the framework 42 and electrically coupled to the materials 44 and 46. The control device 48 includes electronic circuitry that is capable of controlling part of the conductance path between the materials 44 and 46. The materials 44 and 46 are separated by a non-conducting skirt 49. Various examples of the skirt 49 are disclosed in US Provisional Application No. 61/173,511 filed on April 28, 2009 and entitled "HIGHLY RELIABLE INGESTIBLE EVENT MARKERS AND METHODS OF USING SAME" and US Provisional Application No. 61/173,564 filed on April 28, 2009 and entitled "INGESTIBLE EVENT MARKERS HAVING SIGNAL AMPLIFIERS THAT COMPRISE AN ACTIVE AGENT"; as well as U.S. Application No. 12/238,345 filed September 25, 2008 and entitled "IN-BODY DEVICE WITH VIRTUAL DIPOLE SIGNAL AMPLIFICATION"; the entire disclosure of each is incorporated herein by reference.

**[049]** Once the control device 48 is activated or powered up, the control device 48 can alter conductance between the materials 44 and 46. Thus, the control device 48 is capable of controlling the magnitude of the current through the conducting liquid that surrounds the system 40. As indicated above with respect to system 30, a

unique current signature that is associated with the system 40 can be detected by a receiver (not shown) to mark the activation of the system 40. Illustrative examples of receivers are shown in Figs. 12 to 17, as described hereinafter.

**[050]** In order to increase the “length” of the current path the size of the skirt 49 is altered. The longer the current path, the easier it may be for the receiver to detect the current.

**[051]** Referring now to Fig. 5, the system 30 of Fig. 3 is shown in an activated state and in contact with conducting liquid. The system 30 is grounded through ground contact 52. For example, when the system 30 is in contact with a conducting fluid, the conducting fluid provides the ground. The system 30 also includes a sensor module 74, which is described in greater detail with respect to Fig. 6. Ion or current paths 50 extend between material 34 to material 36 and flow through the conducting fluid in contact with the system 30. The voltage potential created between the material 34 and 36 is created through chemical reactions between materials 34/36 and the conducting fluid.

**[052]** If the conditions of the environment change to become favorable to communication, as determined by the measurements of the environment, then the unit 75 sends a signal to the control device 38 to alter the conductance between the materials 34 and 36 to allow for communication using the current signature of the system 30. Thus, if the system 30 has been deactivated and the impedance of the environment is suitable for communication, then the system 30 can be activated again.

**[053]** Referring now to Fig. 5A, this shows an exploded view of the surface of the material 34. In one aspect, the surface of the material 34 is not planar, but rather an irregular surface. The irregular surface increases the surface area of the material and, hence, the area that comes in contact with the conducting fluid. In one aspect, at the surface of the material 34, there is an electrochemical reaction between the material 34 and the surrounding conducting fluid such that mass is exchanged with the conducting fluid. The term “mass” as used here includes any ionic or non-ionic species that may be added or removed from the conductive fluid as part of the electrochemical reactions occurring on material 34. One example includes the

instant where the material is CuCl and when in contact with the conducting fluid, CuCl is converted to Cu metal (solid) and Cl<sup>-</sup> is released into the solution. The flow of positive ions into the conducting fluid is depicted by the current path 50. Negative ions flow in the opposite direction. In a similar manner, there is an electrochemical reaction involving the material 36 that results in ions released or removed from the conducting fluid. In this example, the release of negative ions at the material 34 and release of positive ions by the material 36 are related to each other through the current flow that is controlled by the control device 38. The rate of reaction and hence the ionic emission rate or current, is controlled by the control device 38. The control device 38 can increase or decrease the rate of ion flow by altering its internal conductance, which alters the impedance, and therefore the current flow and reaction rates at the materials 34 and 36. Through controlling the reaction rates, the system 30 can encode information in the ionic flow. Thus, the system 30 encodes information using ionic emission or flow.

**[054]** The control device 38 can vary the duration of ionic flow or current while keeping the current or ionic flow magnitude near constant, similar to when the frequency is modulated and the amplitude is constant. Also, the control device 38 can vary the level of the ionic flow rate or the magnitude of the current flow while keeping the duration near constant. Thus, using various combinations of changes in duration and altering the rate or magnitude, the control device 38 encodes information in the current or the ionic flow. For example, the control device 38 may use, but is not limited to any of the following techniques, including Binary Phase-Shift Keying (PSK), Frequency modulation, Amplitude modulation, on-off keying, and PSK with on-off keying.

**[055]** As indicated above, the various aspects disclosed herein, such as systems 30 and 40 of Figs. 3 and 4, respectively, include electronic components as part of the control device 38 or the control device 48. Components that may be present include but are not limited to: logic and/or memory elements, an integrated circuit, an inductor, a resistor, and sensors for measuring various parameters. Each component may be secured to the framework and/or to another component. The components on the surface of the support may be laid out in any convenient

configuration. Where two or more components are present on the surface of the solid support, interconnects may be provided.

**[056]** As indicated above, the system, such as control devices 30 and 40, control the conductance between the dissimilar materials and, hence, the rate of ionic flow or current. Through altering the conductance in a specific manner the system is capable of encoding information in the ionic flow and the current signature. The ionic flow or the current signature is used to uniquely identify the specific system. Additionally, the systems 30 and 40 are capable of producing various different unique patterns or signatures and, thus, provide additional information. For example, a second current signature based on a second conductance alteration pattern may be used to provide additional information, which information may be related to the physical environment. To further illustrate, a first current signature may be a very low current state that maintains an oscillator on the chip and a second current signature may be a current state at least a factor of ten higher than the current state associated with the first current signature.

**[057]** Referring now to Fig. 6, a block diagram representation of the control device 38 is shown. The device 30 includes a control module 62, a counter or clock 64, and a memory 66. Additionally, the control device 38 is shown to include a sensor module 72 as well as the sensor module 74, which was referenced in Fig. 5. The control module 62 has an input 68 electrically coupled to the material 34 and an output 70 electrically coupled to the material 36. The control module 62, the clock 64, the memory 66, and the sensor modules 72/74 also have power inputs (some not shown). The power for each of these components is supplied by the voltage potential produced by the chemical reaction between materials 34 and 36 and the conducting fluid, when the system 30 is in contact with the conducting fluid. The control module 62 controls the conductance through logic that alters the overall impedance of the system 30. The control module 62 is electrically coupled to the clock 64. The clock 64 provides a clock cycle to the control module 62. Based upon the programmed characteristics of the control module 62, when a set number of clock cycles have passed, the control module 62 alters the conductance characteristics between materials 34 and 36. This cycle is repeated and thereby the

control device 38 produces a unique current signature characteristic. The control module 62 is also electrically coupled to the memory 66. Both the clock 64 and the memory 66 are powered by the voltage potential created between the materials 34 and 36.

**[058]** The control module 62 is also electrically coupled to and in communication with the sensor modules 72 and 74. In the aspect shown, the sensor module 72 is part of the control device 38 and the sensor module 74 is a separate component. In alternative aspects, either one of the sensor modules 72 and 74 can be used without the other and the scope of the present invention is not limited by the structural or functional location of the sensor modules 72 or 74. Additionally, any component of the system 30 may be functionally or structurally moved, combined, or repositioned without limiting the scope of the present invention as claimed. Thus, it is possible to have one single structure, for example a processor, which is designed to perform the functions of all of the following modules: the control module 62, the clock 64, the memory 66, and the sensor module 72 or 74. On the other hand, it is also within the scope of the present invention to have each of these functional components located in independent structures that are linked electrically and able to communicate.

**[059]** Referring again to Fig. 6, the sensor modules 72 or 74 can include any of the following sensors: temperature, pressure, pH level, and conductivity. In one aspect, the sensor modules 72 or 74 gather information from the environment and communicate the analog information to the control module 62. The control module then converts the analog information to digital information and the digital information is encoded in the current flow or the rate of the transfer of mass that produces the ionic flow. In another aspect, the sensor modules 72 or 74 gather information from the environment and convert the analog information to digital information and then communicate the digital information to control module 62. In the aspect shown in Figs. 5, the sensor modules 74 is shown as being electrically coupled to the material 34 and 36 as well as the control device 38. In another aspect, as shown in Fig. 6, the sensor module 74 is electrically coupled to the control device 38 at connection 78. The connection 78 acts as both a source for power supply to the sensor module

74 and a communication channel between the sensor module 74 and the control device 38.

**[060]** Referring now to Fig. 5B, the system 30 includes a pH sensor module 76 connected to a material 39, which is selected in accordance with the specific type of sensing function being performed. The pH sensor module 76 is also connected to the control device 38. The material 39 is electrically isolated from the material 34 by a non-conductive barrier 55. In one aspect, the material 39 is platinum. In operation, the pH sensor module 76 uses the voltage potential difference between the materials 34/36. The pH sensor module 76 measures the voltage potential difference between the material 34 and the material 39 and records that value for later comparison. The pH sensor module 76 also measures the voltage potential difference between the material 39 and the material 36 and records that value for later comparison. The pH sensor module 76 calculates the pH level of the surrounding environment using the voltage potential values. The pH sensor module 76 provides that information to the control device 38. The control device 38 varies the rate of the transfer of mass that produces the ionic transfer and the current flow to encode the information relevant to the pH level in the ionic transfer, which can be detected by a receiver (not shown). Illustrative examples of receivers are shown in Figs. 12 to 17 as described hereinafter. Thus, the system 30 can determine and provide the information related to the pH level to a source external to the environment.

**[061]** As indicated above, the control device 38 can be programmed in advance to output a pre-defined current signature. In another aspect, the system can include a receiver system that can receive programming information when the system is activated. Illustrative examples of receivers are shown in Figs. 12 to 17, as described hereinafter. In another aspect, not shown, the switch 64 and the memory 66 can be combined into one device.

**[062]** In addition to the above components, the system 30 may also include one or other electronic components. Electrical components of interest include, but are not limited to: additional logic and/or memory elements, e.g., in the form of an integrated circuit; a power regulation device, e.g., battery, fuel cell or capacitor; a sensor, a

stimulator, etc.; a signal transmission element, e.g., in the form of an antenna, electrode, coil, etc.; a passive element, e.g., an inductor, resistor, etc.

**[063]** Referring now to Fig. 5C, the system 30 is shown with the skirt portions 35 and 37 secured to the framework 32, as discussed in detail below. In accordance with one aspect of the present invention, the material 34 and the material 36 extend beyond the framework 32 onto the skirt portions 35 and 37. In another example in accordance with the present invention, the materials 34 and 36 can extend to the edge of the skirt portions 35 and 37. The increase in the area of the materials 34 and 36 results in an increase in the power supplied.

**[064]** Referring now to Fig. 7, a cross-sectional view is shown of the system 30 with a first material region 34a and a second material region 36a on the framework 32. The first material region 34a includes an adhering material 86. The adhering material 86 can be any material selected to adhere and hold onto a first material region 88, which material region 88 is made of CuCl in accordance with one aspect of the present invention as discussed above with respect to the first material 34. The second material region 36a includes a transition metal 96 that is made of any transition metal, for example titanium in accordance with one aspect of the present invention. The second material region 36a also includes a second material region 98, which is made of magnesium (Mg) in accordance with one aspect of the present invention as discussed above with respect to the second material 36.

**[065]** Referring now to Fig. 8, an exploded view of the material 86 and the material region 88 is shown. The material 86 is made of a non-reactive and conducting material, for example gold. To enhance the adhesion properties of the material 86 to the material region 88, the material 86 has an unfinished or rough surface. The material 86 is deposited onto the framework 32. Additionally, according to one aspect of the present invention, the material 86 defines a plurality of holes 87 spaced a distance DD from the edge of the framework 32 corresponding to the edge of the material 86. The distance DD is the minimum distance that is needed to separate the holes 87 from the edge of the material 86 and allow all the of the holes 87 to fall within a boundary 89 so that the edge of the material region 88 is not

positioned over any hole; this design enhances the adhesion property and characteristics of the material 86 to the material region 88.

**[066]** Referring now to Fig. 9, a process of securing the metal 96 to the framework 32 is shown. Initially the metal 96 is deposited onto the framework 32. Then the metal 86 with the framework 32 is heated. Then the surface of the metal 96 is cleaned using, for example, an ion gun cleaner. Then the magnesium is deposited onto the cleaned surface of the metal 86 to form the material region 98.

**[067]** In accordance with another aspect of the present invention, a plurality of frameworks 32, as shown in Fig. 1, are built on a wafer 100, as shown in the top view illustration of Fig. 10. The wafer 100 can include any number of frameworks 32. Once the wafer 100 is complete, then each complete framework 32 is cut from the wafer 100 and inserted or press fitted or placed into an opening 112 of Fig. 11 of a sheet 110 to produce the system 12, 22, 30, or 40 as shown and discussed about in accordance with the various aspects of the present invention. The opening 112 is matingly cut to the shape of the framework 32. The sheet 110 is then passed through a punch press (not shown) that punches out each of systems 12, 22, 30, or 40 as noted.

**[068]** In certain aspects, the ingestible circuitry includes a coating layer. In accordance with one aspect of the present invention, the protective coating may be applied to the wafer 100 using a spinning process prior to removal of the framework 32 from the wafer 100 of Fig. 10. In accordance with another aspect of the present invention, the protective coating may be applied to the system, for example the system 30, after being punched out or cut out from the sheet 110 of Fig. 11. The purpose of this coating layer can vary, e.g., to protect the circuitry, the chip and/or the battery, or any components during processing, during storage, or even during ingestion. In such instances, a coating on top of the circuitry may be included. Also of interest are coatings that are designed to protect the ingestible circuitry during storage, but dissolve immediately during use. For example, coatings that dissolve upon contact with an aqueous fluid, e.g. stomach fluid, or the conducting fluid as referenced above. Also of interest are protective processing coatings that are employed to allow the use of processing steps that would otherwise damage certain

components of the device. For example, in aspects where a chip with dissimilar material deposited on the top and bottom is produced, the product needs to be diced. However, the dicing process can scratch off the dissimilar material, and also there might be liquid involved which would cause the dissimilar materials to discharge or dissolve. In such instances, a protective coating on the materials prevents mechanical or liquid contact with the component during processing can be employed.

**[069]** Another purpose of the dissolvable coatings may be to delay activation of the device. For example, the coating that sits on the dissimilar material and takes a certain period of time, e.g., five minutes, to dissolve upon contact with stomach fluid may be employed. The coating can also be an environmentally sensitive coating, e.g., a temperature or pH sensitive coating, or other chemically sensitive coating that provides for dissolution in a controlled fashion and allows one to activate the device when desired. Coatings that survive the stomach but dissolve in the intestine are also of interest, e.g., where one desires to delay activation until the device leaves the stomach. An example of such a coating is a polymer that is insoluble at low pH, but becomes soluble at a higher pH. Also of interest are pharmaceutical formulation protective coatings, e.g., a gel cap liquid protective coating that prevents the circuit from being activated by liquid of the gel cap.

**[070]** Identifiers of interest include two dissimilar electrochemical materials, which act similar to the electrodes (e.g., anode and cathode) of a power source. The reference to an electrode or anode or cathode are used here merely as illustrative examples. The scope of the present invention is not limited by the label used and includes the aspect wherein the voltage potential is created between two dissimilar materials. Thus, when reference is made to an electrode, anode, or cathode it is intended as a reference to a voltage potential created between two dissimilar materials.

**[071]** When the materials are exposed and come into contact with the body fluid, such as stomach acid or other types of fluid (either alone or in combination with a dried conductive medium precursor), a potential difference, that is, a voltage, is generated between the electrodes as a result of the respective oxidation and

reduction reactions incurred to the two electrode materials. A voltaic cell, or battery, can thereby be produced. Accordingly, in aspects of the invention, such power supplies are configured such that when the two dissimilar materials are exposed to the target site, e.g., the stomach, the digestive tract, etc., a voltage is generated.

**[072]** In certain aspects, one or both of the metals may be doped with a non-metal, e.g., to enhance the voltage output of the battery. Non-metals that may be used as doping agents in certain aspects include, but are not limited to: sulfur, iodine and the like.

**[073]** For purposes of illustration, various receivers may be used with various aspects of the present invention. In one example of a receiver, sometimes referred to herein as a “signal receiver”, two or more different demodulation protocols may be employed to decode a given received signal. In some instances, both a coherent demodulation protocol and a differential coherent demodulation protocol may be employed. FIG. 12 provides a functional block diagram of how a receiver may implement a coherent demodulation protocol, according to one aspect of the invention. It should be noted that only a portion of the receiver is shown in FIG. 12. FIG. 12 illustrates the process of mixing the signal down to baseband once the carrier frequency (and carrier signal mixed down to carrier offset) is determined. A carrier signal 2221 is mixed with a second carrier signal 2222 at mixer 2223. A narrow low-pass filter 2220 is applied of appropriate bandwidth to reduce the effect of out-of-bound noise. Demodulation occurs at functional blocks 2225 in accordance with the coherent demodulation scheme of the present invention. The unwrapped phase 2230 of the complex signal is determined. An optional third mixer stage, in which the phase evolution is used to estimate the frequency differential between the calculated and real carrier frequency can be applied. The structure of the packet is then leveraged to determine the beginning of the coding region of the BPSK signal at block 2240. Mainly, the presence of the sync header, which appears as an FM porch in the amplitude signal of the complex demodulated signal is used to determine the starting bounds of the packet. Once the starting point of the packet is determined the signal is rotated at block 2250 on the IQ plane and standard bit identification and eventually decoded at block 2260.

**[074]** In addition to demodulation, the transbody communication module may include a forward error correction module, which module provides additional gain to combat interference from other unwanted signals and noise. Forward error correction functional modules of interest include those described in PCT Application Serial No. PCT/US2007/024225 and published as WO 2008/063626, the disclosure of which is herein incorporated by reference. In some instances, the forward error correction module may employ any convenient protocol, such as Reed-Solomon, Golay, Hamming, BCH, and Turbo protocols to identify and correct (within bounds) decoding errors.

**[075]** In another example, the receiver includes a beacon module as shown in the functional block diagram of FIG. 13. The scheme outlined in FIG. 13 outlines one technique for identifying a valid beacon. The incoming signal 2360 represents the signals received by electrodes, bandpass filtered (such as from 10 KHz to 34 KHz) by a high frequency signaling chain (which encompasses the carrier frequency), and converted from analog to digital. The signal 2360 is then decimated at block 2361 and mixed at the nominal drive frequency (such as, 12.5 KHz, 20 KHz, etc.) at mixer 2362. The resulting signal is decimated at block 2364 and low-pass filtered (such as 5 KHz BW) at block 2365 to produce the carrier signal mixed down to carrier offset--signal 2369. Signal 2369 is further processed by blocks 2367 (fast Fourier transform and then detection of two strongest peaks) to provide the true carrier frequency signal 2368. This protocol allows for accurate determination of the carrier frequency of the transmitted beacon.

**[076]** FIG. 14 provides a block functional diagram of an integrated circuit component of a signal receiver according to an aspect of the invention. In FIG. 14, receiver 2700 includes electrode input 2710. Electrically coupled to the electrode input 2710 are transbody conductive communication module 2720 and physiological sensing module 2730. In one aspect, transbody conductive communication module 2720 is implemented as a high frequency (HF) signal chain and physiological sensing module 2730 is implemented as a low frequency (LF) signal chain. Also shown are CMOS temperature sensing module 2740 (for detecting ambient temperature) and a 3-axis accelerometer 2750. Receiver 2700 also includes a

processing engine 2760 (for example, a microcontroller and digital signal processor), non-volatile memory 2770 (for data storage) and wireless communication module 2780 (for data transmission to another device, for example in a data upload action).

**[077]** FIG. 15 provides a more detailed block diagram of a circuit configured to implement the block functional diagram of the receiver depicted in FIG. 14, according to one aspect of the invention. In FIG. 15, receiver 2800 includes electrodes e1, e2 and e3 (2811, 2812 and 2813) which, for example, receive the conductively transmitted signals by an IEM and/or sense physiological parameters or biomarkers of interest. The signals received by the electrodes 2811, 2812, and 2813 are multiplexed by multiplexer 2820 which is electrically coupled to the electrodes.

**[078]** Multiplexer 2820 is electrically coupled to both high band pass filter 2830 and low band pass filter 2840. The high and low frequency signal chains provide for programmable gain to cover the desired level or range. In this specific aspect, high band pass filter 2830 passes frequencies in the 10 KHz to 34 KHz band while filtering out noise from out-of-band frequencies. This high frequency band may vary, and may include, for example, a range of 3 KHz to 300 KHz. The passing frequencies are then amplified by amplifier 2832 before being converted into a digital signal by converter 2834 for input into high power processor 2880 (shown as a DSP) which is electrically coupled to the high frequency signal chain.

**[079]** Low band pass filter 2840 is shown passing lower frequencies in the range of 0.5 Hz to 150 Hz while filtering out out-of-band frequencies. The frequency band may vary, and may include, for example, frequencies less than 300 Hz, such as less than 200 Hz, including less than 150 Hz. The passing frequency signals are amplified by amplifier 2842. Also shown is accelerometer 2850 electrically coupled to second multiplexer 2860. Multiplexer 2860 multiplexes the signals from the accelerometer with the amplified signals from amplifier 2842. The multiplexed signals are then converted to digital signals by converter 2864 which is also electrically coupled to low power processor 2870.

**[080]** In one aspect, a digital accelerometer (such as one manufactured by Analog Devices), may be implemented in place of accelerometer 2850. Various advantages may be achieved by using a digital accelerometer. For example, because the signals

the digital accelerometer would produce signals already in digital format, the digital accelerometer could bypass converter 2864 and electrically couple to the low power microcontroller 2870--in which case multiplexer 2860 would no longer be required. Also, the digital signal may be configured to turn itself on when detecting motion, further conserving power. In addition, continuous step counting may be implemented. The digital accelerometer may include a FIFO buffer to help control the flow of data sent to the low power processor 2870. For instance, data may be buffered in the FIFO until full, at which time the processor may be triggered to turn awaken from an idle state and receive the data.

**[081]** Low power processor 2870 may be, for example, an MSP430 microcontroller from Texas Instruments. Low power processor 2870 of receiver 2800 maintains the idle state, which as stated earlier, requires minimal current draw--e.g., 10 .mu.A or less, or 1 .mu.A or less.

**[082]** High power processor 2880 may be, for example, a VC5509 digital signal process from Texas Instruments. The high power processor 2880 performs the signal processing actions during the active state. These actions, as stated earlier, require larger amounts of current than the idle state--e.g., currents of 30 .mu.A or more, such as 50 .mu.A or more--and may include, for example, actions such as scanning for conductively transmitted signals, processing conductively transmitted signals when received, obtaining and/or processing physiological data, etc.

**[083]** Also shown in FIG. 13 is flash memory 2890 electrically coupled to high power processor 2880. In one aspect, flash memory 2890 may be electrically coupled to low power processor 2870, which may provide for better power efficiency.

**[084]** Wireless communication element 2895 is shown electrically coupled to high power processor 2880 and may include, for example, a BLUETOOTH.TM. wireless communication transceiver. In one aspect, wireless communication element 2895 is electrically coupled to high power processor 2880. In another aspect, wireless communication element 2895 is electrically coupled to high power processor 2880 and low power processor 2870. Furthermore, wireless communication element 2895 may be implemented to have its own power supply so that it may be turned on and off independently from other components of the receiver--e.g., by a microprocessor.

**[085]** With, for example, an idle state in mind, the following paragraphs provide example configurations of receiver components shown in FIG. 15 during various states of the receiver, according to one aspect of the invention. It should be understood that alternative configurations may be implemented depending on the desired application.

**[086]** In an idle state, for example, the receiver draws minimal current. Receiver 2800 is configured such that low power processor 2870 is in an inactive state (such as idle state) and high power processor 2880 is in an inactive state (such as idle state), and circuit blocks related to peripheral circuitry and their power supplies required during various active states remain off (for example, wireless communication module 2895 and the analog front end). For example, the low power processor may have a 32 KHz oscillator active and may consume a few  $\mu$ A current or less, including 0.5  $\mu$ A or less. In the idle state, the low power processor 2870 may, for example, wait for a signal to transfer to an active state. The signal might be external such as an interrupt or internally generated by one of the device's peripherals, such as a timer. During the high power processor's idle state, the high power processor may, for example, be running off a 32 KHz watch crystal. The high power processor may, for example, wait for a signal to transfer to active state.

**[087]** When the receiver is in the sniff state, low power processor 2870 is in an idle state and high power processor 2880 is in an idle state. In addition, the circuit blocks relating to the analog front end including A/D converter that is needed for the sniff function are on (in other words, the high frequency signal chain). As stated earlier, the beacon signal module may implement various types of sniff signals to achieve low power efficiency.

**[088]** Upon detection of a transmitted signal, a higher power demodulate and decode state may be entered. When the receiver is in the demodulate and decode state, low power processor 2870 is in an active state and high power processor 2880 is in an active state. High power processor 2880 may, for example, be running from a 12 MHz or near crystal oscillator with a PLL-based clock multiplier giving the device a 108 MHz clock speed. The low power processor 2870 may, for example, run off an internal R-C oscillator in the range of 1 MHz to 20 MHz and consume

power in the range of 250 to 300  $\mu$ A per MHz clock speed during active states. The active state allows for processing and any transmissions that may follow. Required transmissions may trigger the wireless communication module to cycle from off to on.

**[089]** When the receiver is in collect ECG and accelerometer state, the circuit blocks relating to the accelerometer and/or ECG signal conditioning chain are on. The high power processor 2880 is in an idle state during collection, and in an active state (for example, running from a 12 MHz or near crystal oscillator with a PLL-based clock multiplier giving the device a 108 MHz clock speed) during processing and transmission. The low power processor 2870 is in an active state during this state and may run off an internal R-C oscillator in the range of 1 MHz to 20 MHz and consume power in the range of 250 to 300  $\mu$ A per MHz clock speed.

**[090]** The low power processor (e.g., MSP shown in FIG. 13) and high power processor (e.g., DSP shown in FIG. 13) may communicate with each other using any convenient communication protocol. In some instances, these two elements, when present, communicate with each via a serial peripheral interface bus (hereinafter "SPI bus"). The following description describes the signaling and messaging scheme implemented to allow the high power processor and low power processor to communicate and send messages back and forth along the SPI bus. For the following description of the communication between the processors, "LPP" and "HPP" are used in place of "low power processor" and "high power processor", respectively, to stay consistent with FIG. 13. The discussion, however, may apply to other processors than those shown in FIG. 13.

**[091]** FIG. 16 provides a view of a block diagram of hardware in a receiver according to an aspect of the invention related to the high frequency signal chain. In FIG. 16, receiver 2900 includes receiver probes (for example in the form of electrodes 2911, 2912 and 2913) electrically coupled to multiplexer 2920. Also shown are high pass filter 2930 and low pass filter 2940 to provide for a band pass filter which eliminates any out-of-band frequencies. In the aspect shown, a band pass of 10 KHz to 34 KHz is provided to pass carrier signals falling within the frequency band. Example carrier frequencies may include, but are not limited to,

12.5 KHz and 20 KHz. One or more carriers may be present. In addition, receiver 2900 includes analog to digital converter 2950--for example, sampling at 500 KHz. The digital signal can thereafter be processed by the DSP. Shown in this aspect is DMA to DSP unit 2960 which sends the digital signal to dedicated memory for the DSP. The direct memory access provides the benefit of allowing the rest of the DSP to remain in a low power mode.

**[092]** An example of a system that includes a receiver is shown in FIG. 17. In FIG. 17, system 3500 includes a pharmaceutical composition 3510 that comprises an ingestible device such as an ingestible event marker, "IEM." Also present in system 3500 is signal receiver 3520. Signal receiver 3520 is configured to detect a signal emitted from the identifier of the IEM 3510. Signal receiver 3520 also includes physiologic sensing capability, such as ECG and movement sensing capability. Signal receiver 3520 is configured to transmit data to a patient's an external device or PDA 3530 (such as a smart phone or other wireless communication enabled device), which in turn transmits the data to a server 3540. Server 3540 may be configured as desired, e.g., to provide for patient directed permissions. For example, server 3540 may be configured to allow a family caregiver 3550 to participate in the patient's therapeutic regimen, e.g., via an interface (such as a web interface) that allows the family caregiver 3550 to monitor alerts and trends generated by the server 3540, and provide support back to the patient, as indicated by arrow 3560. The server 3540 may also be configured to provide responses directly to the patient, e.g., in the form of patient alerts, patient incentives, etc., as indicated by arrow 3565 which are relayed to the patient via PDA 3530. Server 3540 may also interact with a health care professional (e.g., RN, physician) 3555, which can use data processing algorithms to obtain measures of patient health and compliance, e.g., wellness index summaries, alerts, cross-patient benchmarks, etc., and provide informed clinical communication and support back to the patient, as indicated by arrow 3580.

**[093]** It is to be understood that this invention is not limited to particular embodiments or aspects described and, as such, may vary. It is also to be understood that the terminology used herein is for the purpose of describing

particular aspects only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

**[094]** Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges and are also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

**[095]** Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present invention, representative illustrative methods and materials are now described.

**[096]** All publications and patents cited in this specification are herein incorporated by reference as if each individual publication or patent were specifically and individually indicated to be incorporated by reference and are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The citation of any publication is for its disclosure prior to the filing date and should not be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

**[097]** It is noted that, as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of

such exclusive terminology as “solely,” “only” and the like in connection with the recitation of claim elements, or use of a “negative” limitation.

**[098]** Notwithstanding the claims, the invention is also referred to in the following clauses:

**[099]** 1. A method of manufacturing a communication device including a partial power source, the method comprising the steps of:

**[0100]** depositing a layer of adhesion material onto a first location of a support structure, wherein the layer of adhesion material defines a plurality of holes;

**[0101]** depositing a first material onto the layer of adhesion material, wherein the first material adheres to the adhesion material;

**[0102]** depositing a layer of transition material on a second location of the support structure; and

**[0103]** depositing a second material onto the layer of transition metal, wherein the first material and the second material to represent a voltage potential difference when the first material and the second material come into contact with a conducting fluid.

**[0104]** 2. The method of clause 1, wherein the adhesion material is gold.

**[0105]** 3. The method of clause 2, further comprising the step of roughing the surface of the gold to enhance adhesion property.

**[0106]** 4. The method according to any of the clauses 1-3 wherein the support structure is a silicon based material.

**[0107]** 5. The method according to any of the clauses 1-4 wherein the step of depositing the first material includes evaporating deposition using electron beams.

**[0108]** 6. The method according to any of the preceding clauses wherein the adhesion layer is less than 100 microns thick.

**[0109]** 7. The method according to any of the preceding clauses wherein the step of depositing a layer of transition metal includes the steps of:

**[0110]** depositing the transition metal onto the support structure;

**[0111]** heating the support structure with the transition metal deposit; and

**[0112]** cleaning an exposed surface of the transition metal such that the resulting structure is ready to receive the second material.

**[0113]** 8. The method according to any of the preceding clauses wherein the step of cleaning the exposed surface comprising cleaning with an ion gun.

**[0114]** 9. The method according to any of the preceding clauses further comprising the step of spinning a polymer onto the device to provide a protective coating, preferably wherein the step of depositing includes spinning the device to evenly distribute the polymer on the surface of the device.

**[0115]** 10. The method according to any of the preceding clauses further comprising the step of inserting the device into a non-conducting membrane.

**[0116]** 11. A method of manufacturing a plurality of communication devices, wherein each device includes a non-conducting membrane and a partial power source device, the method comprising the steps of:

**[0117]** cutting a plurality of openings into a sheet of non-conducting material to produce an assembly membrane sheet, wherein the shape of each opening corresponds to the shape of a framework of the device; and

**[0118]** inserting one partial power source device selected from the plurality of partial power source devices into each opening of the assembly membrane to produce a loaded membrane sheet, wherein each partial power source device is prepared according to a process that includes the step of depositing a layer of transition metal on an opposite surface of the support structure from a surface having an adhesion material.

**[0119]** 12. The method of clause 11 further comprising the steps of:

**[0120]** depositing a layer of non-reactive material onto the loaded membrane sheet on a side opposite the transition metal to produce an adhesion membrane sheet, wherein the layer of non-reactive material defines a plurality of holes;

**[0121]** depositing a first material onto the adhesion membrane sheet on the side with the adhesive material, wherein the first material adheres to the non-reactive material;

**[0122]** depositing a second material onto the layer of transition metal to produce a partial power device sheet, wherein the first material and the second material represent a voltage potential difference.

**[0123]** 13. The method of clause 11 or 12 further comprising the step of defining a plurality of boundaries on the support structure, wherein each boundary corresponds to circuitry of each device.

**[0124]** 14. The method of clause 12 or 13, wherein the step of depositing a layer of non-reactive material further comprises the step of defining a group of holes, wherein each group of holes is contained within one boundary selected from the plurality of boundaries, such that the position of each hole within the group of holes is within the corresponding boundary.

**[0125]** 15. The method according to any of the preceding clauses wherein the transitional metal is titanium.

**[0126]** 16. A device comprising a partial power source for communication, obtainable according to the method of any of the preceding clauses, preferably wherein the device is prepared by a process comprising the steps of:

**[0127]** depositing a layer of adhesion material onto a first location of a support structure, wherein the layer of adhesion material defines a plurality of holes;

**[0128]** depositing a first material onto the adhesion layer, wherein the first material adheres to the adhesion material;

**[0129]**depositing a layer of transition material on a second location of the support structure;

**[0130]**depositing a second material onto the layer of transition metal, wherein the first material and the second material represent a voltage potential difference when the first material and the second material come into contact with a conducting fluid.

**[0131]**As will be apparent to those of skill in the art upon reading this disclosure, each of the individual aspects described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several aspects without departing from the scope or spirit of the present invention. Any recited method can be carried out in the order of events recited or in any other order which is logically possible.

**[0132]**Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it is readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

**[0133]**Accordingly, the preceding merely illustrates the principles of the invention. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the invention and are included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the invention and the concepts contributed by the inventors to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and aspects of the invention as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present invention, therefore, is not intended to be limited to the

exemplary aspects shown and described herein. Rather, the scope and spirit of present invention is embodied by the appended claims.

**What is claimed is:**

1. A method of manufacturing a communication device including a partial power source, the method comprising the steps of:
  - depositing a layer of adhesion material onto a first location of a support structure, wherein the layer of adhesion material defines a plurality of holes;
  - depositing a first material onto the layer of adhesion material, wherein the first material adheres to the layer of adhesion material;
  - depositing a layer of transition material on a second location of the support structure; and
  - depositing a second material onto the layer of transition material, wherein the first material and the second material represent a voltage potential difference when the first material and the second material come into contact with a conducting fluid.
2. The method of claim 1, wherein the layer of adhesion material is gold.
3. The method of claim 1, further comprising the step of roughing the surface of the gold to enhance adhesion property.
4. The method of claim 1, wherein the support structure is a silicon based material.
5. The method of claim 1, wherein the step of depositing the first material includes evaporating deposition using electron beams.
6. The method of claim 2, wherein the layer of adhesion material is less than 100 microns thick.
7. The method of claim 1, wherein the step of depositing a layer of transition material includes the steps of:

depositing the layer of transition material onto the support structure; heating the support structure with the layer of transition material deposit; and cleaning an exposed surface of the layer of transition material such that the resulting structure is ready to receive the second material.

8. The method of claim 7, wherein the step of cleaning the exposed surface further comprises cleaning with an ion gun.
9. The method of claim 1, further comprising the step of spinning a polymer onto the device to provide a protective coating.
10. The method of claim 7, further comprising the step of spinning the device to evenly distribute a polymer on the surface of the device.
11. The method of claim 1, further comprising the step of inserting the device into a non-conducting membrane.
12. A method of manufacturing a plurality of communication devices, wherein each device includes a non-conducting membrane and a partial power source device, the method comprising the steps of:
  - cutting a plurality of openings into a sheet of non-conducting material to produce an assembly membrane sheet, wherein the shape of each opening corresponds to the shape of a framework of the device; and
  - inserting one partial power source device selected from the plurality of partial power source devices into each opening of the assembly membrane to produce a loaded membrane sheet, wherein each partial power source device is prepared according to a process that includes the step of depositing a layer of transition metal on an opposite surface of a support structure from a surface having an adhesion material.

13. The method of claim 12 further comprising the steps of:

depositing a layer of non-reactive material onto the loaded membrane sheet on a side opposite the transition metal to produce an adhesion membrane sheet, wherein the layer of non-reactive material defines a plurality of holes; depositing a first material onto the adhesion membrane sheet on the side with the adhesive material, wherein the first material adheres to the non-reactive material; depositing a second material onto the layer of transition metal to produce a partial power device sheet, wherein the first material and the second material represent a voltage potential difference.

14. The method of claim 13 further comprising the step of defining a plurality of boundaries on the support structure, wherein each boundary corresponds to circuitry of each device.

15. The method of claim 14, wherein the step of depositing a layer of non-reactive material further comprises the step of defining a group of holes, wherein each group of holes is contained within one boundary selected from the plurality of boundaries, such that the position of each hole within the group of holes is within the corresponding boundary.

16. A device comprising a partial power source for communication, wherein the device is prepared by a process comprising the steps of:

depositing a layer of adhesion material onto a first location of a support structure, wherein the layer of adhesion material defines a plurality of holes; depositing a first material onto the layer of adhesion material, wherein the first material adheres to the layer of adhesion material; depositing a layer of transition material onto a second location of the support structure;

depositing a second material onto the layer of transition material, wherein the first material and the second material represent a voltage potential difference when the first material and the second material come into contact with a conducting fluid.

17. The method of claim 1, wherein the transitional material is titanium.
18. A device including a partial power source for communication, wherein the device comprises:  
a support structure made from a silicon material; and  
a CuCl layer deposited on a first location of the support structure using physical vapor deposition.
19. The device of claim 18, wherein the physical vapor deposition is achieved through sputter deposition.
20. The device of claim 18, wherein the physical vapor deposition is achieved through arc deposition.

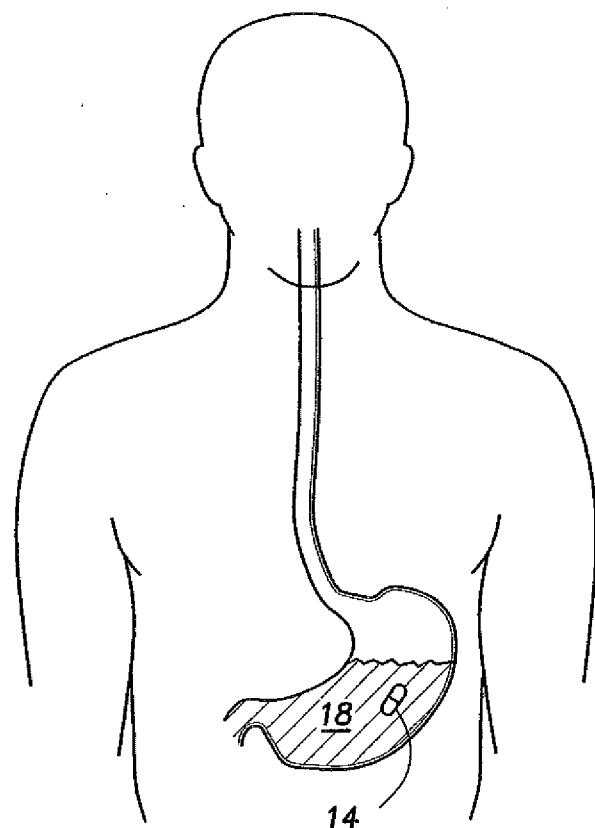
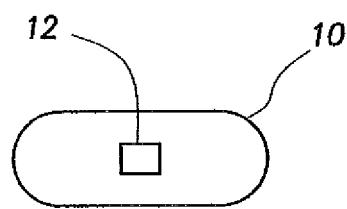
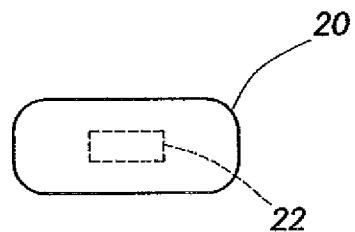
**FIG. 1****FIG. 2A****FIG. 2B**

FIG.3

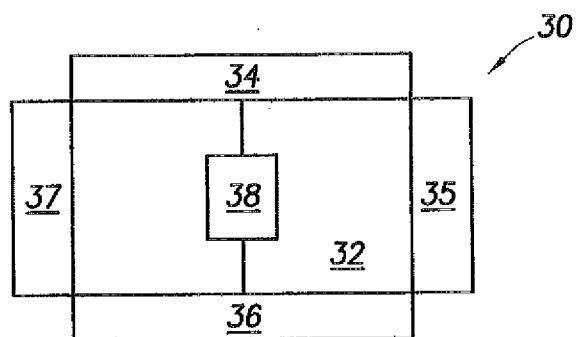


FIG.4

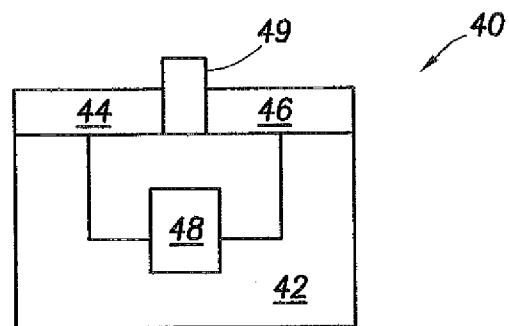


FIG.5A

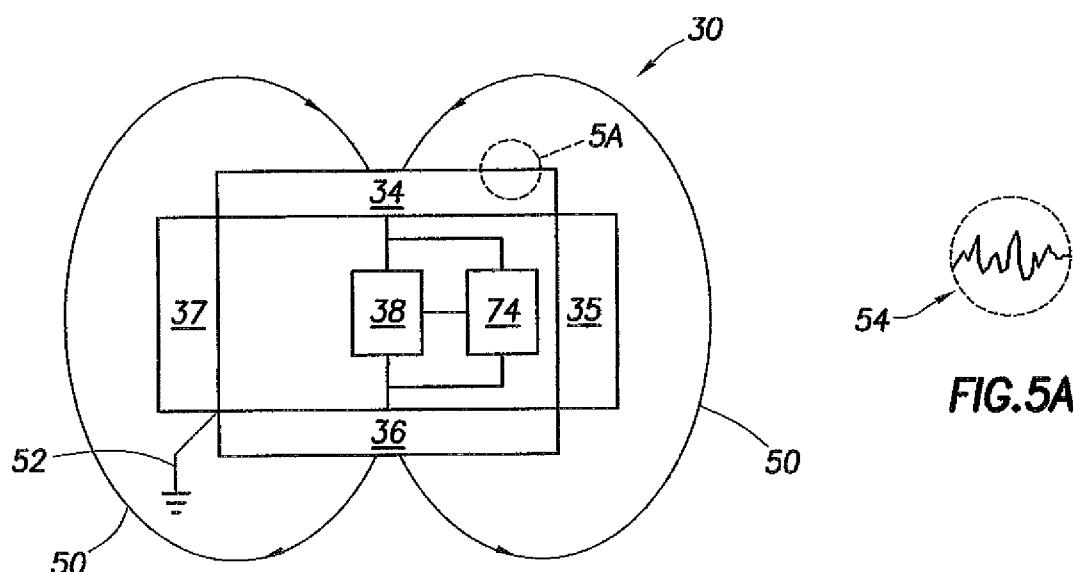


FIG.5

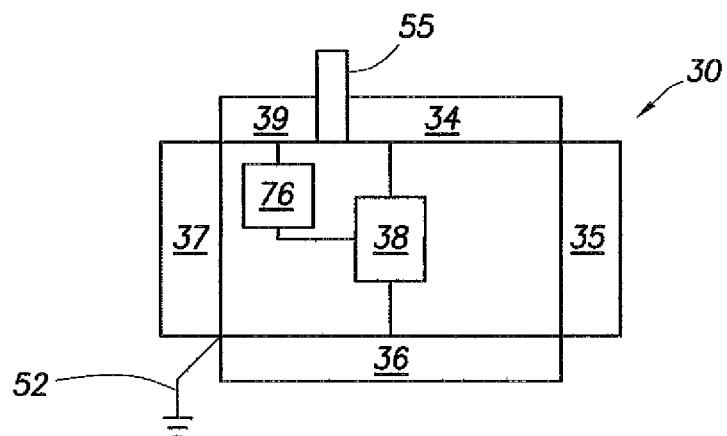


FIG. 5B

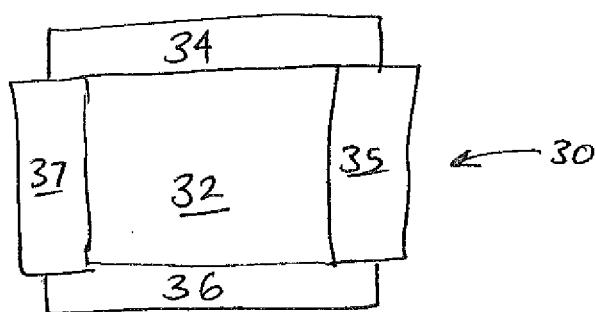


FIG. 5C

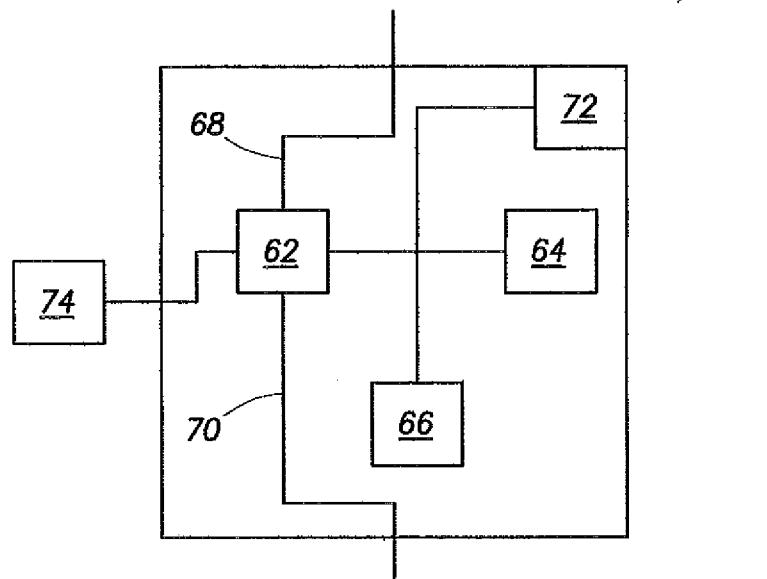


FIG. 6

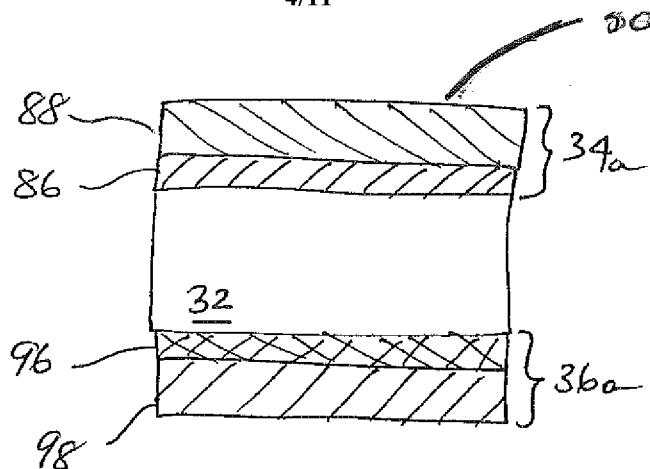


FIG. 7

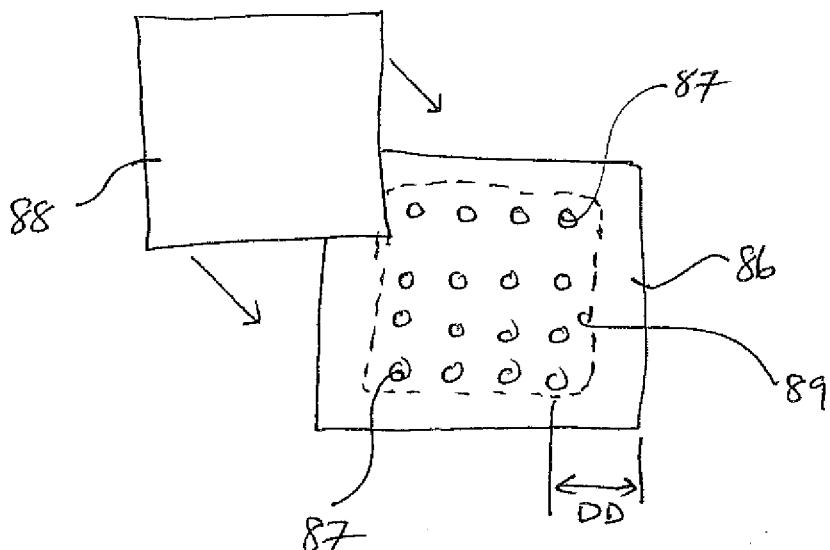


FIG. 8

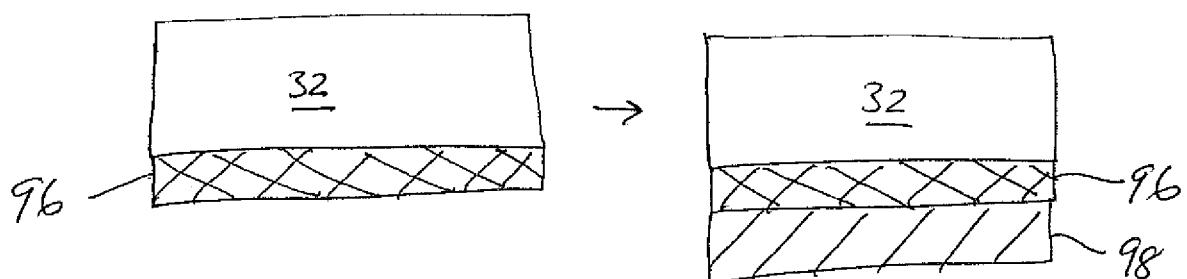


FIG. 9

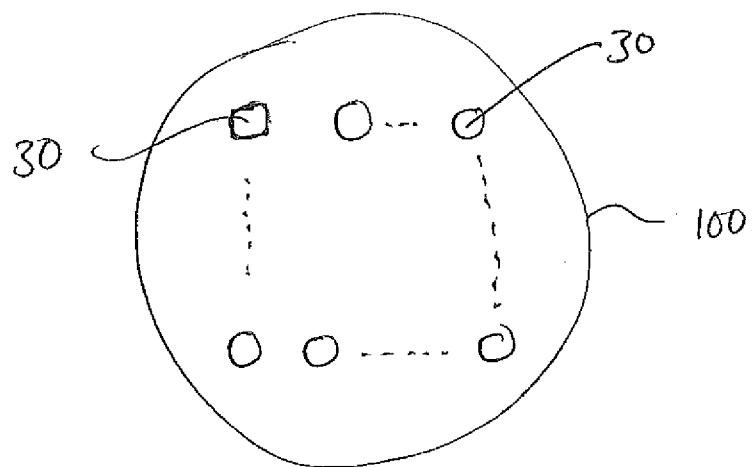


FIG. 10

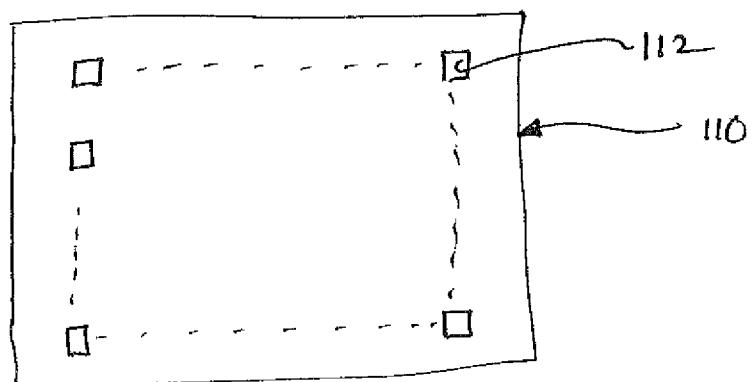


FIG. 11

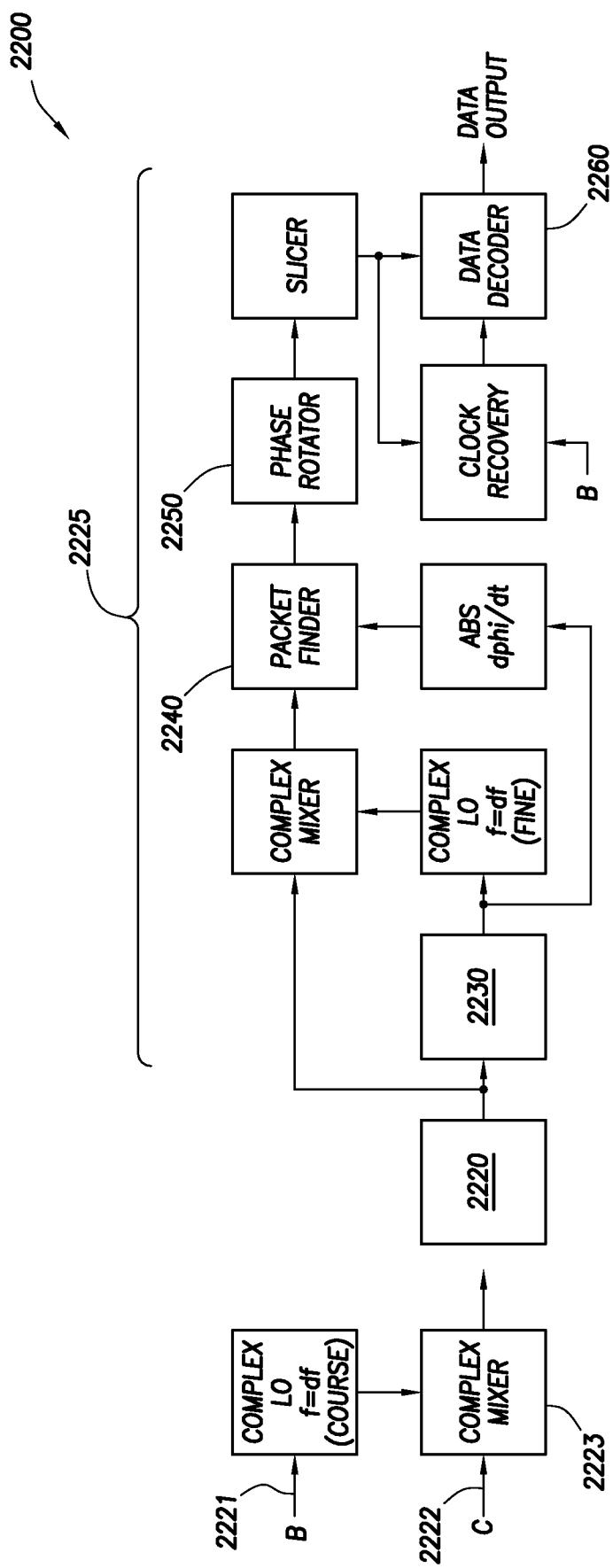


FIG. 12

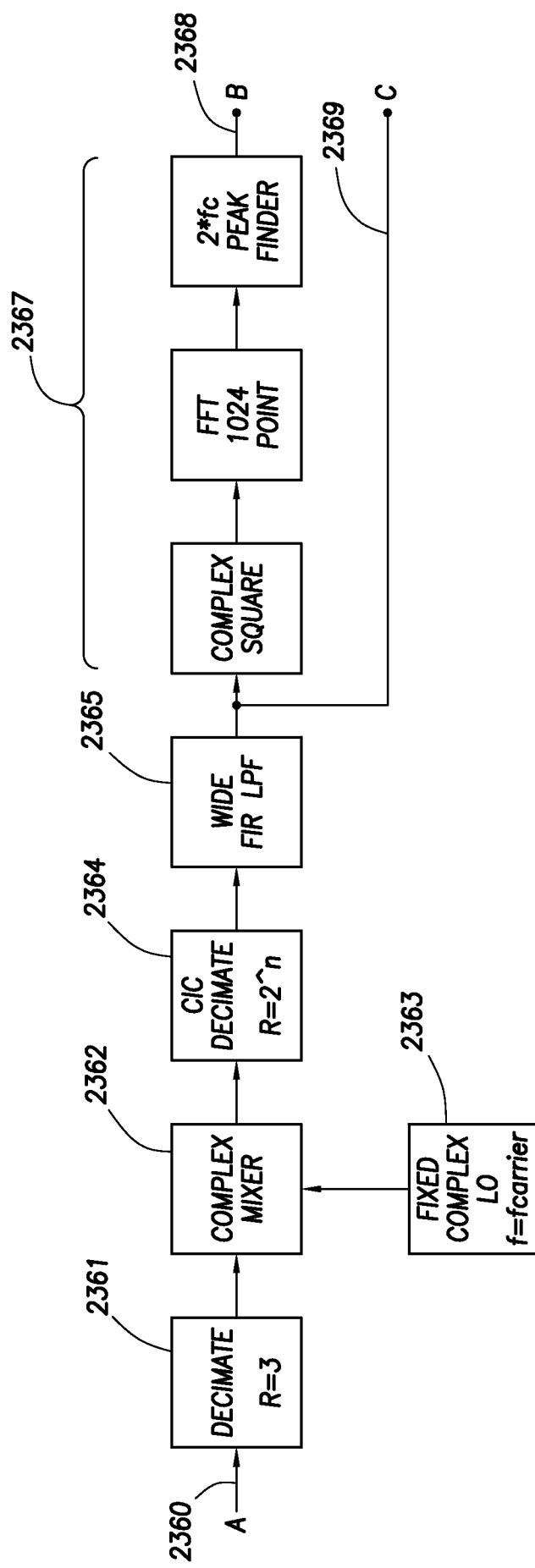
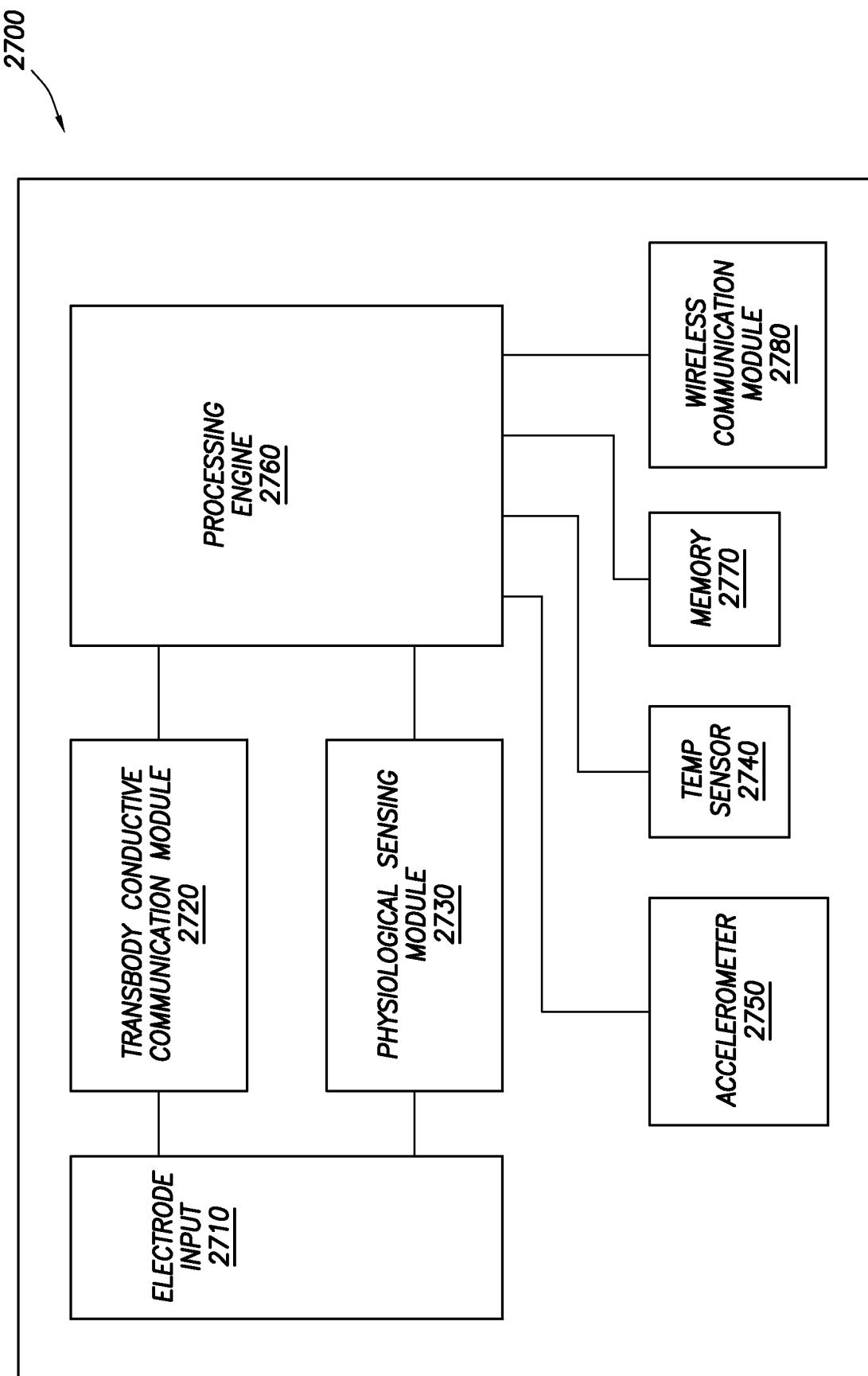


FIG. 13

**FIG. 14**

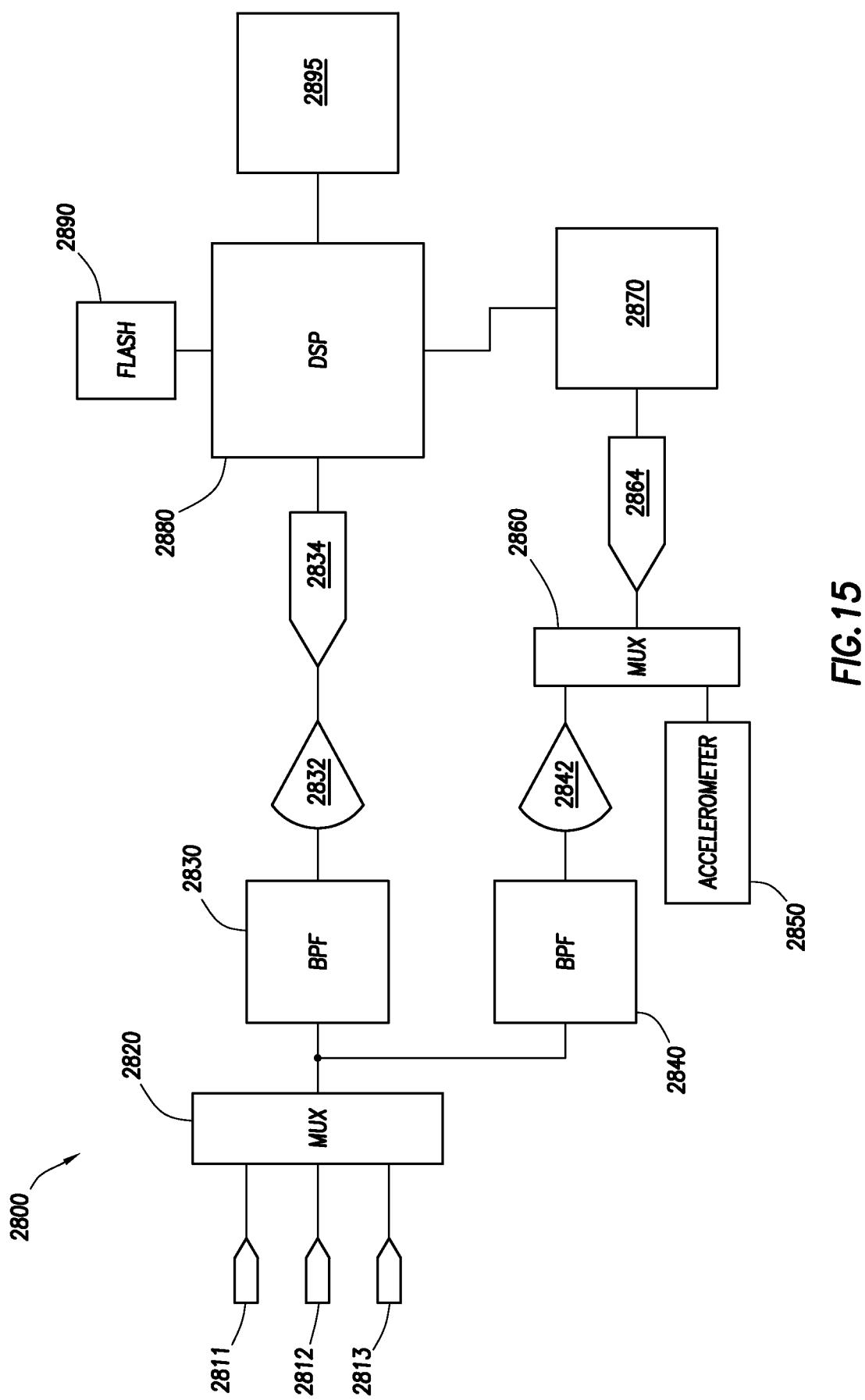


FIG. 15

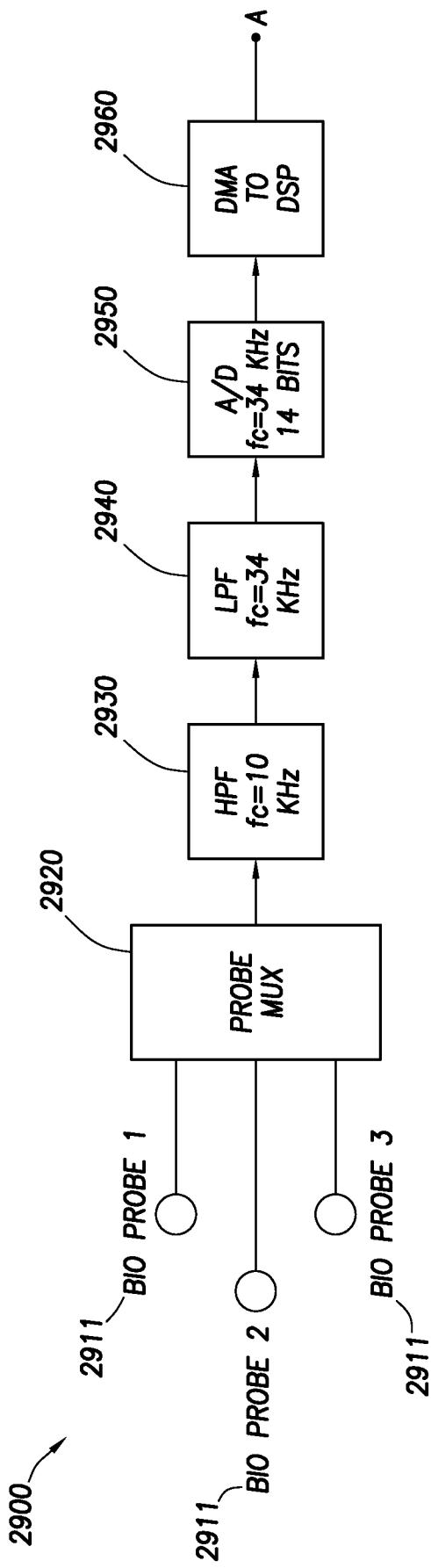
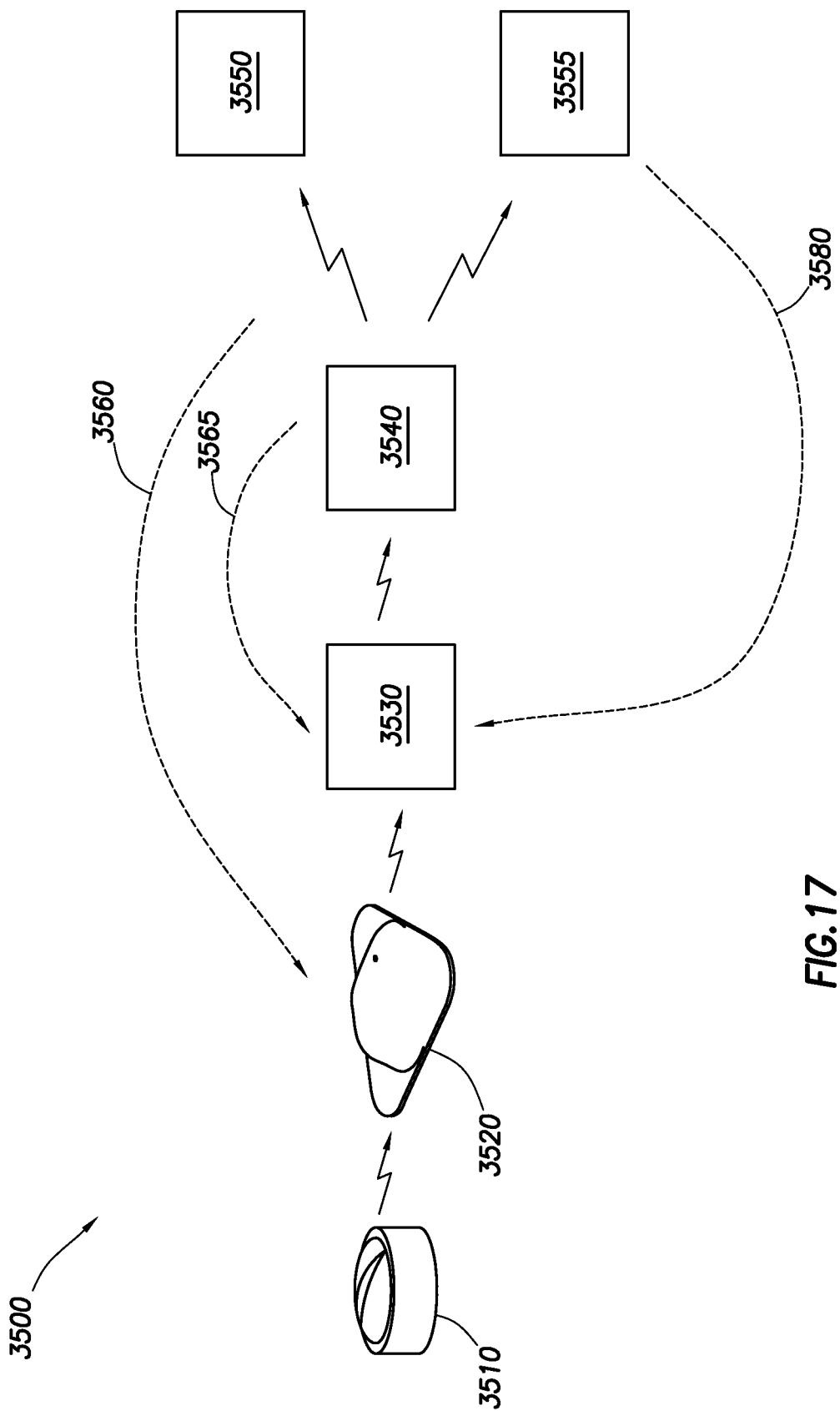


FIG. 16



(43) International Publication Date  
17 January 2013 (17.01.2013)(51) International Patent Classification:  
*A61B 1/273* (2006.01) *H04B 7/24* (2006.01)(21) International Application Number:  
PCT/US2012/046120(22) International Filing Date:  
10 July 2012 (10.07.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
13/180,525 11 July 2011 (11.07.2011) US

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

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,

*[Continued on next page]*

(54) Title: COMMUNICATION SYSTEM WITH ENHANCED PARTIAL POWER SOURCE AND METHOD OF MANUFACTURING SAME

(57) **Abstract:** The system of the present invention includes a conductive element, an electronic component, and a partial power source in the form of dissimilar materials. Upon contact with a conducting fluid, a voltage potential is created and the power source is completed, which activates the system. The electronic component controls the conductance between the dissimilar materials to produce a unique current signature. The system can also measure the conditions of the environment surrounding the system.

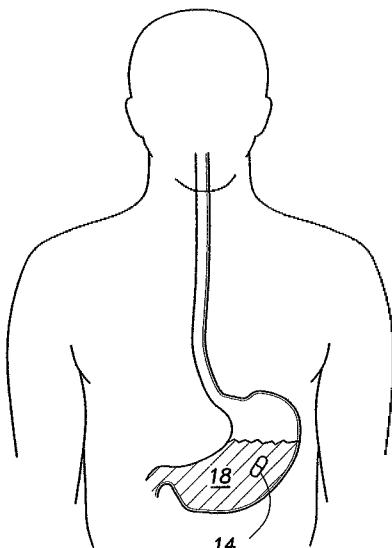


FIG. 1



TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

**(88) Date of publication of the international search report:**

14 March 2013

**Published:**

— *with international search report (Art. 21(3))*

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2012/046120

## A. CLASSIFICATION OF SUBJECT MATTER

*A61B 1/273(2006.01)i, H04B 7/24(2006.01)i*

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

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 1/273; A61P 43/00; A61B 1/00; G06F 19/00; A61K 9/00; A61K 9/20; A61K 9/50

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
Korean utility models and applications for utility models  
Japanese utility models and applications for utility modelsElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
eKOMPASS(KIPO internal) & Keywords: communication, material, transition, titanium, adhesion, body, power source, cutting, membrane

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010-0185055 A1 (ROBERTSON TIMOTHY et al.) 22 July 2010 See abstract; paragraphs [0054]–[0111]; claim 1; and figure 3.	1-2,4-6,16-20 3,7-15
A	WO 2006-116718 A2 (PROTEUS BIOMEDICAL, INC. et al.) 02 November 2006 See abstract; page 36, line 24 &#8211; page 48, line 17; claim 90 and figure 12B.	1-20
A	WO 2010-080765 A2 (PROTEUS BIOMEDICAL, INC. et al.) 15 July 2010 See abstract; paragraph [0002]; claim 11; and figure 1F.	1-20
A	US 2010-0239616 A1 (HAFEZI Hooman et al.) 23 September 2010 See abstract; paragraph [0044]; claim 21; and figure 1.	1-20

 Further documents are listed in the continuation of Box C. See patent family annex.

\* Special categories of cited documents:  
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 "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  
 "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
 "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art  
 "&" document member of the same patent family

Date of the actual completion of the international search  
10 JANUARY 2013 (10.01.2013)

Date of mailing of the international search report

**14 JANUARY 2013 (14.01.2013)**

Name and mailing address of the ISA/KR

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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/US2012/046120**

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010-0185055 A1	22.07.2010	AU 2008-210291 A1 CA 2676407 A1 CN 101686800 A EP 2107883 A2 JP 2010-524512 A KR 10-2009-0105960 A WO 2008-095183 A2	07.08.2008 07.08.2008 31.03.2010 14.10.2009 22.07.2010 07.10.2009 07.08.2008
WO 2006-116718 A2	02.11.2006	AU 2006-239221 A1 CA 2608144 A1 CN 101287411 A0 CN 102379684 A EP 1889198 A2 EP 1920418 A2 EP 2392258 A1 IL186898A IL186898D0 IL214183D0 IL216535D0 JP 05-088978 B2 JP 2008-539047 A JP 2009-506838 A JP 2011-212466 A JP 2012-020178 A JP 2012-183385 A US 2008-0284599 A1 US 2008-0306359 A1 US 2009-0227204 A1 US 2010-0081894 A1 US 2011-0105864 A1 US 2012-001752 A1 US 7978064 B2 WO 2006-116718 A3 WO 2007-028035 A2	02.11.2006 02.11.2006 15.10.2008 21.03.2012 20.02.2008 14.05.2008 07.12.2011 31.01.2012 09.02.2008 31.08.2011 29.12.2011 21.09.2012 13.11.2008 19.02.2009 27.10.2011 02.02.2012 27.09.2012 20.11.2008 11.12.2008 10.09.2009 01.04.2010 05.05.2011 05.01.2012 12.07.2011 02.11.2006 08.03.2007
WO 2010-080765 A2	15.07.2010	AU 2010-203738 A1 CA 2750151 A1 CN 102341101 A EP 2385828 A2 IL213688D0 JP 2012-514798 A KR 10-2011-0112378 A SG172845A1 TW 201036606 A US 2012-011699 A1 WO 2010-080765 A3	21.07.2011 15.07.2010 01.02.2012 16.11.2011 31.07.2011 28.06.2012 12.10.2011 29.08.2011 16.10.2010 19.01.2012 28.10.2010
US 2010-0239616 A1	23.09.2010	EP 2083680 A2 JP 2010-508293 A	05.08.2009 18.03.2010

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/US2012/046120**

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		KR 10-2009-0076941 A SG175681A1 WO 2008-052136 A2	13.07.2009 28.11.2011 02.05.2008



(12) 发明专利申请

(10) 申请公布号 CN 103957773 A

(43) 申请公布日 2014. 07. 30

(21) 申请号 201280043578. 4

代理人 李少丹 湖南省

(22) 申请日 2012. 07. 10

(51) Int. Cl.

(30) 优先权数据

A61B 1/273 (2006. 01)

13/180, 525 2011. 07. 11 US

H04B 7/24 (2006. 01)

(85) PCT国际申请进入国家阶段日

2014. 03. 07

(86) PCT国际申请的申请数据

PCT/US2012/046120 2012. 07. 10

(87) PCT国际申请的公布数据

W02013/009782 EN 2013. 01. 17

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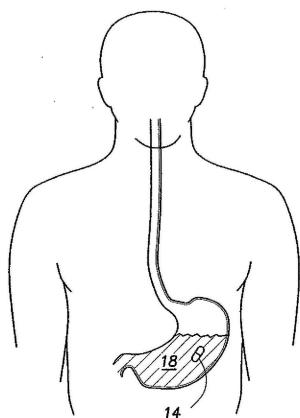
权利要求书2页 说明书17页 附图11页

(54) 发明名称

具有增强型部分电源的通信系统及其制造方法

(57) 摘要

本发明的系统包括传导元件、电子组件和呈相异材料形式的部分电源。在与导电流体接触后，形成电压电势且完成所述电源，这激活所述系统。所述电子组件控制所述相异材料之间的电导性以产生唯一电流签名。所述系统还可以测量包围所述系统的环境的条件。



1. 一种制造包括部分电源的通信装置的方法,所述方法包括以下步骤:

将粘附材料层沉积到支撑结构的第一位置上,其中所述粘附材料层限定有多个孔;

将第一材料沉积到所述粘附材料层上,其中所述第一材料粘附到所述粘附材料层;

将过渡材料层沉积在所述支撑结构的第二位置上;以及

将第二材料沉积到所述过渡材料层上,其中当所述第一材料和所述第二材料与导电流体形成接触时,所述第一材料和所述第二材料呈现电压电势差。

2. 根据权利要求 1 所述的方法,其中所述粘附材料层是金。

3. 根据权利要求 1 所述的方法,进一步包括毛化所述金的表面以增强粘附性质的步骤。

4. 根据权利要求 1 所述的方法,其中所述支撑结构是硅基材料。

5. 根据权利要求 1 所述的方法,其中沉积所述第一材料的步骤包括使用电子束的蒸发沉积。

6. 根据权利要求 2 所述的方法,其中所述粘附材料层的厚度小于 100 微米。

7. 根据权利要求 1 所述的方法,其中沉积过渡材料层的步骤包括以下步骤:

将所述过渡材料层沉积到所述支撑结构上;

加热沉积有所述过渡材料层的所述支撑结构;以及

清洁所述过渡材料层的暴露表面,使得所得结构准备好接纳所述第二材料。

8. 根据权利要求 7 所述的方法,其中所述清洁所述暴露表面的步骤进一步包括用离子枪进行清洁。

9. 根据权利要求 1 所述的方法,进一步包括将聚合物旋涂到所述装置上以提供保护性涂层的步骤。

10. 根据权利要求 7 所述的方法,进一步包括旋转所述装置以将聚合物均匀地分布在所述装置的表面上的步骤。

11. 根据权利要求 1 所述的方法,进一步包括将所述装置插入到不导电膜中的步骤。

12. 一种制造多个通信装置的方法,其中每一装置包括不导电膜和部分电源装置,所述方法包括以下步骤:

在不导电材料片中切出多个开口以产生组装膜片,其中每一开口的形状对应于所述装置的框架的形状;以及

将从多个所述部分电源装置中选出的一个部分电源装置插入到所述组装膜的每一开口中以产生加载膜片,其中根据一种工艺来制备每一部分电源装置,所述工艺包括在支撑结构的与具有粘附材料的表面相反的表面上沉积过渡金属层的步骤。

13. 根据权利要求 12 所述的方法,进一步包括以下步骤:

将不反应材料层沉积到所述加载膜片上位于与所述过渡金属相反的侧面上以产生粘附膜片,其中所述不反应材料层限定有多个孔;

将第一材料沉积到所述粘附膜片上位于具有所述粘附材料的侧面上,其中所述第一材料粘附到所述不反应材料;

将第二材料沉积到所述过渡金属层上以产生部分电力装置片,其中所述第一材料和所述第二材料呈现电压电势差。

14. 根据权利要求 13 所述的方法,其进一步包括在所述支撑结构上限定多个边界的步

骤,其中每一边界对应于每一装置的电路。

15. 根据权利要求 14 所述的方法,其中所述沉积不反应材料层的步骤进一步包括限定孔群组的步骤,其中每一孔群组被包含在从所述多个边界中选出的一个边界以内,使得所述孔群组内的每一孔的位置在对应的边界以内。

16. 一种用于通信的包括部分电源的装置,其中所述装置通过一种工艺来制备,所述工艺包括以下步骤:

将粘附材料层沉积到支撑结构的第一位置上,其中所述粘附材料层限定有多个孔;

将第一材料沉积到所述粘附材料层上,其中所述第一材料粘附到所述粘附材料层;

将过渡材料层沉积到所述支撑结构的第二位置上;

将第二材料沉积到所述过渡材料层上,其中当所述第一材料和所述第二材料与导电流体形成接触时,所述第一材料和所述第二材料呈现电压电势差。

17. 根据权利要求 1 所述的方法,其中所述过渡材料是钛。

18. 一种用于通信的包括部分电源的装置,其中所述装置包括:

支撑结构,其由硅材料制成;以及

CuCl 层,其使用物理气相沉积来沉积在所述支撑结构的第一位置上。

19. 根据权利要求 18 所述的装置,其中所述物理气相沉积是通过溅射沉积来实现的。

20. 根据权利要求 18 所述的装置,其中所述物理气相沉积是通过电弧沉积来实现的。

## 具有增强型部分电源的通信系统及其制造方法

[0001] 相关申请的交叉引用

[0002] 本申请是 2011 年 7 月 11 日提交的名称为“具有增强型部分电源的通信系统及其制造方法 (Communication System with Enhanced Partial Power Source and Method of Manufacturing the Same)” 申请号为 13/180, 525 的美国专利申请的部分接续案, 所述申请号为 13/180, 525 的美国专利申请是 2009 年 9 月 21 日提交的名称为“具有部分电源的通信系统 (Communication System with Partial Power Source)” 并且在 2010 年 4 月 1 日公开的公开号为 US2010-0081894A1 的申请号为 12/564, 017 的美国专利申请的部分接续案, 所述申请号为 12/564, 017 的美国专利申请是 2008 年 6 月 23 日提交的名称为“药物信息系统 (Pharma-Informatics System)” 并且在 2008 年 11 月 20 日公开的美国公开号为 2008-0284599A1 的申请号为 11/912, 475 的美国专利申请的部分接续申请, 所述申请号为 11/912, 475 的美国专利申请是 2006 年 4 月 28 日提交的名称为“药物信息系统 (Pharma-Informatics System)” 并且公开为 WO2006/116718 的 WO 申请的申请号为 PCT/US06/16370 的 PCT 申请的 371 申请, 所述申请依据 35U. S. C. § 119(e), 主张以下申请的申请日期的优先权: 2005 年 4 月 28 日提交的名称为“药物信息系统 (Pharma-Informatics System)” 申请号为 60/675, 145 的美国临时专利申请; 2005 年 6 月 24 日提交的名称为“药物信息系统 (Pharma-Informatics System)” 申请号为 60/694, 078 的美国临时专利申请; 2005 年 9 月 1 日提交的名称为“使用患者身体内的信息的近场无线通信的医学诊断和治疗平台 (Medical Diagnostic And Treatment Platform Using Near-Field Wireless Communication Of Information Within A Patient's Body)” 申请号为 60/713, 680 的美国临时专利申请; 以及 2006 年 4 月 7 日提交的名称为“药物信息系统 (Pharma-Informatics System)” 申请号为 60/790, 335 的美国临时专利申请; 这些申请的公开内容以引用的方式并入本文中。

[0003] 本申请与 2011 年 7 月 11 日提交的以下美国申请相关 (所述美国申请的公开内容以引用的方式并入本文中): 2011 年 7 月 11 日提交的名称为“具有远程激活的通信系统 (COMMUNICATION SYSTEM WITH REMOTE ACTIVATION)” 申请号为 13/180, 516 的美国申请; 2011 年 7 月 11 日提交的名称为“具有多种电力类型的通信系统 (COMMUNICATION SYSTEM WITH MULTIPLE TYPES OF POWER)” 申请号为 13/180, 498 的美国申请; 2011 年 7 月 11 日提交的名称为“使用可植入装置的通信系统 (COMMUNICATION SYSTEM USING AN IMPLANTABLE DEVICE)” 申请号为 13/180, 539 的美国申请; 2011 年 7 月 11 日提交的名称为“使用多味药剂共同包装药物计量单元的通信系统 (COMMUNICATION SYSTEM USING POLYPHARMACY CO-PACKAGED MEDICATION DOSING UNIT)” 申请号为 13/180, 538 的美国申请; 以及 2011 年 7 月 11 日提交的名称为“并入在可摄取产品中的通信系统 (COMMUNICATION SYSTEM INCORPORATED IN AN INGESTIBLE PRODUCT)” 申请号为 13/180, 507 的美国申请。

### 技术领域

[0004] 本发明涉及用于检测事件的通信系统。更具体地说, 本公开包括一种系统, 其包括

具有各种电源和通信方案的装置。

## 背景技术

[0005] 包括电子电路的可摄取装置已被提议用在多种不同医学应用中,所述医学应用包括诊断应用和治疗应用两种。这些装置通常需要用于操作的内部电力供应。此类可摄取装置的实例是可摄取电子胶囊,其在通过身体时收集数据并且将数据发射到外部接收器系统。这类电子胶囊的实例是体内摄像机。可吞食胶囊包括相机系统和光学系统,所述光学系统用于将关注区域成像到相机系统上。发射器发射相机系统的视频输出,并且接收系统接收所发射的视频输出。其它实例包括可摄取成像装置,其具有内部自持电源且从身体内腔或空腔内获得图像。所述装置的电子电路组件由惰性不消化壳体(例如,玻璃壳体)封闭,所述壳体穿过身体内部。其它实例包括可摄取数据记录器胶囊医学装置。所公开的装置的电子电路(例如,传感器、记录器、电池等)容纳在由惰性材料制成的胶囊中。

[0006] 在其它实例中,在药品摄取监视应用中使用易碎射频识别(RFID)标签。为了使RFID标签可操作,每一RFID标签需要内部电力供应。RFID标签是被配置以发射射频信号穿过身体的天线结构。

[0007] 这些现有装置造成的问题是,电源在装置内部,且此类电源的生产成本高,且在电源泄漏或受损的情况下可能对周围环境有害。另外,具有从装置延伸出来的天线是与当在体内使用装置时天线受损或造成问题有关的关心问题。因此,需要具有不需要内部电源和天线的电路的合适系统。

## 发明内容

[0008] 本公开包括一种用于产生指示事件的发生的唯一签名的系统。所述系统包括可以放置在包括导电流体的某些环境内的电路和组件。此类环境的一个实例在容纳导电流体的容器内,例如具有溶液的密封袋,其包括IV袋。另一实例在活生物体(例如动物或人类)的身体内。所述系统是可摄取和/或可消化或部分可消化的。所述系统包括安置在框架上的相异材料,使得当导电流体与相异材料形成接触时,形成电压电势差。电压电势差以及因此电压用以对安置在框架内的控制逻辑上电。离子或电流经由控制逻辑且接着穿过导电流体从第一相异材料流动到第二相异材料以完成电路。控制逻辑控制所述两种相异材料之间的电导性,因此控制或调制电导性。

[0009] 由于可摄取电路是由可摄取且甚至可消化的组分制成的,所以所述可摄取电路产生极少(如果有的话)不需要的副作用,即使当在长期情况下使用时。可以包括的组件的范围的实例是:逻辑和/或存储器元件;操纵器;信号发射元件;以及无源元件,例如电阻器或电感器。支撑件的表面上的一个或一个以上组件可以按任何便利配置来布置。在固体支撑件的表面上存在两个或两个以上组件的情况下,可以提供互连件。可摄取电路的所有组件和支撑件是可摄取的,且在某些例子中,是可消化或部分可消化的。此外,根据用以增强材料的粘附的工艺来制造电路。

## 附图说明

[0010] 图1示出根据本发明的教导的具有事件指示器系统的药物产品,其中所述产品和

事件指示器系统组合位于身体内。

- [0011] 图 2A 示出图 1 的药物产品, 其中事件指示器系统位于药物产品的外部上。
- [0012] 图 2B 示出图 1 的药物产品, 其中事件指示器系统安置在药物产品内部。
- [0013] 图 3 是相反末端上安置有相异金属的事件指示器系统的一个方面的框图表示。
- [0014] 图 4 是同一末端上安置有相异金属且所述相异金属由不导电材料分开的事件指示器系统的另一方面的框图表示。
- [0015] 图 5 示出当图 3 的事件指示器系统与导电液体接触且处于活动状态时穿过导电流体的离子转移或电流路径。
- [0016] 图 5A 示出图 5 的相异材料的表面的分解图。
- [0017] 图 5B 示出具有 pH 传感器单元的图 5 的事件指示器系统。
- [0018] 图 5C 示出根据本发明的另一方面的事件指示器系统。
- [0019] 图 6 是图 3 和图 4 的系统中所使用的控制装置的一个方面的框图说明。
- [0020] 图 7 示出根据本发明的事件指示器系统的横截面侧视图。
- [0021] 图 8 是根据本发明的图 7 的事件指示器系统的两个组件的分解图。
- [0022] 图 9 是根据本发明的图 7 的事件指示器系统的一部分的组装过程。
- [0023] 图 10 示出根据本发明的具有多个事件指示器系统的晶片。
- [0024] 图 11 示出根据本发明的具有用于接纳形成图 7 的事件指示器系统的一部分的装置的孔的不导电膜片。
- [0025] 图 12 是根据一个方面的可以存在于接收器中的执行相干解调的解调电路的功能框图。
- [0026] 图 13 说明根据一个方面的接收器内的信标模块的功能框图。
- [0027] 图 14 是根据一个方面的可以存在于接收器中的不同功能模块的框图。
- [0028] 图 15 是根据一个方面的接收器的框图。
- [0029] 图 16 提供根据一个方面的接收器中的高频信号链的框图。
- [0030] 图 17 提供根据一个方面的可以如何利用包括信号接收器和可摄取事件标示器的系统的图。

## 具体实施方式

[0031] 本公开包括用于指示事件的发生的多个方面。如下文较详细描述, 本发明的系统与导电流体一起使用以指示由所述导电流体与所述系统之间的接触标示的事件。举例来说, 本公开的系统可以与药物产品一起使用, 并且所指示的事件是何时服用或摄取所述产品。术语“摄取”应理解为意指将所述系统以任何方式引入到身体内部。举例来说, 摄取包括简单地将系统放在口中一路直到降结肠。因此, 术语“摄取”指代在将系统引入到含有导电流体的环境时的任何时刻。另一实例将是不导电流体与导电流体混合时的情形。在此类情形中, 所述系统将存在于不导电流体中, 且当两种流体混合时, 所述系统与导电流体形成接触并且所述系统被激活。又一实例将是需要检测某些导电流体是否存在时的情形。在这些例子中, 可以检测所述系统(其将被激活)在导电流体内的存在, 因此将检测到相应流体的存在。

[0032] 再次参看其中系统与由活生物体摄取的产品一起使用的例子, 当服用或摄取包括

所述系统的产品时,装置与身体的导电流体形成接触。当本发明的系统与体液形成接触时,形成电压电势且系统被激活。电源的一部分由装置提供,而电源的另一部分由导电流体提供,这在下文中详细论述。

[0033] 现在参看图 1,示出了在身体内部的包括本发明的系统的可摄取产品 14。产品 14 被配置为呈药丸或胶囊形式的可口服摄取的药物剂型。在摄取后,药丸移动到胃部。在到达胃部后,产品 14 与胃液 18 接触,且经历与胃液 18 中的各种物质(例如盐酸和其它消化剂)的化学反应。参考药物环境来论述本发明的系统。然而,本发明的范围不限于此。本发明可以用于其中存在或通过混合产生导电流体的两种或两种以上组分而变得存在导电流体的任何环境。

[0034] 现在参看图 2A,示出了类似于图 1 的产品 14 的药物产品 10,其具有系统 12,例如可摄取事件标示器或离子发射模块。本发明的范围不受产品 10 的形状或类型限制。举例来说,所属领域的技术人员将清楚,产品 10 可以为胶囊、缓释口服剂、药片、凝胶帽、舌下药片或可以与系统 12 组合的任何口服剂产品。在所参考的方面中,产品 10 使用已知的将微装置紧固到药物产品外部的方法来使系统 12 紧固到外部。用于将微装置紧固到产品的方法的实例在以下申请中公开:2009 年 1 月 1 日提交的名称为“可摄取事件标示器的高产量生产(HIGH-THROUGHPUT PRODUCTION OF INGESTIBLE EVENT MARKERS)”申请号为 61/142,849 的美国临时申请;以及 2009 年 5 月 12 日提交的名称为“包括识别符和可摄取组件的可摄取事件标示器(INGESTIBLE EVENT MARKERS COMPRISING AN IDENTIFIER AND AN INGESTIBLE COMPONENT)”申请号为 61/177,611 的美国临时申请,每一个申请的全部公开内容以引用的方式并入本文中。一旦被摄取,系统 12 便与体液形成接触且系统 12 被激活。系统 12 利用电压电势差来上电,且此后调制电导性以创建唯一且可识别的电流签名。激活后,系统 12 控制电导性且因此控制电流流动以产生电流签名。

[0035] 存在延迟系统 12 的激活的各种理由。为了延迟系统 12 的激活,系统 12 可以被涂覆有屏蔽材料或保护层。所述层在一段时间后溶解,进而允许系统 12 在产品 10 已经到达目标位置时被激活。

[0036] 现在参看图 2B,示出类似于图 1 的产品 14 的药物产品 20,其具有系统 22,例如可摄取事件标示器或可识别发射模块。本发明的范围不受系统 22 被引入到的环境限制。举例来说,系统 22 可以封闭在附加于/独立于药物产品来服用的胶囊中。所述胶囊可以仅仅是用于系统 22 的载体,并且可以不含有任何产品。此外,本发明的范围不受产品 20 的形状或类型限制。举例来说,所属领域的技术人员将清楚,产品 20 可以为胶囊、缓释口服剂、药片、凝胶帽、舌下药片或任何口服剂产品。在所参考的方面中,产品 20 使系统 22 安置在产品 20 内部或紧固到产品 20 的内部。在一个方面中,系统 22 紧固到产品 20 的内壁。当系统 22 安置在凝胶胶囊内部时,那么凝胶胶囊的内含物是不导电凝胶液体。另一方面,如果凝胶胶囊的内含物是导电凝胶液体,那么在替代方面中,系统 22 被涂覆有保护罩以防止被凝胶胶囊内含物不必要地激活。如果胶囊的内含物是干燥粉末或微球体,那么系统 22 安置或放置在胶囊内。如果产品 20 是药片或硬药丸,那么系统 22 被固持在药片内部的恰当位置处。一旦被摄取,含有系统 22 的产品 20 便溶解。系统 22 与体液形成接触,且系统 22 被激活。取决于产品 20,系统 22 可以安置在中心附近或周边附近位置中,这取决于系统 22 的开始摄取与激活的时刻之间的希望的激活延迟。举例来说,用于系统 22 的中心位置意味着

系统 22 将需要较长时间来与导电液体接触,因此系统 22 将需要较长时间来激活。因此,将需要较长时间来检测事件的发生。

[0037] 现在参看图 3,在一个方面中,图 2A 的系统 12 和图 2B 的系统 22 被更详细地示出为系统 30。系统 30 可以与任何药物产品联合使用,如上文所提及,以确定何时患者服用所述药物产品。如上文所指示,本发明的范围不受环境和与系统 30 一起使用的产品限制。举例来说,系统 30 可以放置在胶囊内,且胶囊放置在导电液体内。胶囊将接着在一段时间后溶解并且将系统 30 释放到导电液体中。因此,在一个方面中,胶囊将含有系统 30 而没有产品。那么此类胶囊可以用于存在导电液体的任何环境中以及与任何产品一起使用。举例来说,胶囊可以丢到填充有喷气燃料、盐水、番茄酱、机油或任何类似产品的容器中。另外,可以在摄取任何药物产品的同时摄取含有系统 30 的胶囊以便记录事件的发生,例如何时服用所述产品。

[0038] 在与药物产品组合的系统 30 的特定实例中,在摄取产品或药丸时,系统 30 被激活。系统 30 控制电导性以产生被检测的唯一电流签名,进而表示已经服用所述药物产品。系统 30 包括框架 32。框架 32 是用于系统 30 的底盘,且多个组件附接到框架 32、沉积在框架 32 上或紧固到框架 32。在系统 30 的这个方面中,可消化材料 34 与框架 32 物理上相关联。材料 34 可以化学沉积在框架上、蒸发到框架上、紧固到框架或构建在框架上,其全部可以在本文中称为关于框架 32 “沉积”。材料 34 沉积在框架 32 的一个侧面上。可以用作材料 34 的关注材料包括但不限于 :Cu 或 CuI。材料 34 通过物理气相沉积、电沉积或等离子沉积以及其它协议来沉积。材料 34 可以为约 0.05 到约 500  $\mu\text{m}$  厚,例如约 5 到约 100  $\mu\text{m}$  厚。形状由阴影掩模沉积或光刻和蚀刻来控制。另外,尽管只示出一个区用于沉积所述材料,但每一系统 30 可以根据需要含有两个或两个以上可以沉积材料 34 的电学唯一区。下文中关于图 7 到图 9 较详细地论述用于将材料沉积到框架 32 上的各种方法。

[0039] 在不同侧面(其为如图 3 所示的相反侧面)上,沉积另一可消化材料 36,使得材料 34 和 36 相异。虽然未图示,但所选择的不同侧面可以为与针对材料 34 所选择的侧面邻接的侧面。本发明的范围不受所选择的侧面限制,并且术语“不同侧面”可以意指不同于第一选定侧面的多个侧面中的任一个。此外,尽管系统的形状被示出为正方形,但形状可以为任何几何上适合的形状。材料 34 和 36 被选择以使得其在系统 30 与导电液体(例如体液)接触时产生电压电势差。用于材料 36 的关注材料包括但不限于 :Mg、Zn 或其它负电性金属。如上文关于材料 34 所指示,材料 36 可以化学沉积在框架上、蒸发到框架上、紧固到框架或构建在框架上。而且,粘附层可能是必要的,以帮助材料 36 (以及材料 34,在需要时) 粘附到框架 32。用于材料 36 的典型粘附层是 Ti、TiW、Cr 或类似材料。阳极材料和粘附层可以通过物理气相沉积、电沉积或等离子沉积来沉积。材料 36 可以为约 0.05 到约 500  $\mu\text{m}$  厚,例如约 5 到约 100  $\mu\text{m}$  厚。然而,本发明的范围既不受任何材料的厚度限制,也不受用以将材料沉积或紧固到框架 32 的工艺的类型限制。

[0040] 根据所陈述的公开内容,材料 34 和 36 可以为具有不同电化学电势的任何成对材料。另外,在体内使用系统 30 的方面中,材料 34 和 36 可以为能被吸收的维生素。更具体地说,材料 34 和 36 可以由适合于系统 30 将在其中进行操作的环境的任何两种材料制成。举例来说,当与可摄取产品一起使用时,材料 34 和 36 为可摄取的具有不同电化学电势的任何成对材料。说明性实例包括当系统 30 与离子溶液(例如胃酸)接触时的例子。合适的材

料不限于金属,且在某些方面中,成对的材料选自金属和非金属,例如,由金属(例如 Mg)与盐(例如 CuCl 或 CuI)组成的对。关于活性电极材料,具有适当不同的电化学电势(电压)和低界面电阻的任何配对的物质(金属、盐或嵌入化合物)是合适的。

[0041] 关注的材料和配对包括但不限于以下表 1 中所报告的那些。在一个方面中,所述金属中的一种或两种可以被掺杂有非金属,例如,以便增强在所述材料与导电液体形成接触时在所述材料之间形成的电压电势。在某些方面中可以用作掺杂剂的非金属包括但不限于:硫和碘等。在另一方面中,材料为作为阳极的碘化铜(CuI)和作为阴极的镁(Mg)。本发明的多个方面使用对人体无害的电极材料。

[0042]

表 1

	阳极	阴极
金属	镁、锌、钠、锂、铁	
盐		铜盐: 碘化物、氯化物、溴化物、硫酸盐、甲酸盐、(其它可能的阴离子)  $Fe^{3+}$ 盐: 例如, 正磷酸盐、焦磷酸盐、(其它可能的阴离

[0043]

		子)  铂、金或其它催化表面上的 氧或氢离子 (H+)
插入化合物	具有 Li、K、Ca、Na、Mg 的石墨	氧化钒  氧化锰

[0044] 因此,当系统 30 与导电液体接触时,在材料 34 与 36 之间通过导电液体形成电流路径,图 5 中示出一个实例。控制装置 38 紧固到框架 32 且电耦接到材料 34 和 36。控制装置 38 包括电子电路,例如能够控制并更改材料 34 与 36 之间的电导性的控制逻辑。

[0045] 在材料 34 与 36 之间形成的电压电势提供用于操作所述系统的电力以及产生穿过导电流体和系统的电流流动。在一个方面中,系统在直流电模式中操作。在替代方面中,系统控制电流的方向以使得电流方向以循环方式反转,类似于交流电。在系统到达导电流体或电解液时,其中流体或电解液成分由生理流体(例如,胃酸)提供,材料 34 与 36 之间的用于电流流动的路径在系统 30 外部完成;穿过系统 30 的电流路径由控制装置 38 控制。电流

路径的完成允许电流流动,且接收器(未图示)又可以检测到电流的存在并辨识到系统 30 已经激活且希望的事件正在发生或已经发生。图 12 到图 17 中描述接收器的说明性实例,如下文所描述。

[0046] 在一个方面中,所述两种材料 34 和 36 在功能上类似于直流电源(例如电池)所需要的两个电极。导电液体充当完成电源所需要的电解液。所描述的完成的电源由系统 30 的材料 34 与 36 之间的电化学反应限定且由身体的流体启动。完成的电源可以被视为在例如胃液、血液或其它体液的离子或导电溶液和一些组织中进行电化学电导的电源。另外,环境可以为不同于身体的某物,且液体可以为任何导电液体。举例来说,导电流体可以为盐水或基于金属的涂料。

[0047] 在某些方面中,这两种材料通过额外材料层来与周围环境隔离。因而,当屏蔽物溶解且这两种相异材料暴露于目标场所时,产生电压电势。

[0048] 在某些方面中,完整电源或电力供应由活性电极材料、电解液和非活性材料(例如集电器、封装等)组成。活性材料是具有不同电化学电势的任何成对材料。合适的材料不限于金属,且在某些方面中,成对材料选自金属和非金属,例如,由金属(例如 Mg)与盐(例如 CuI)组成的对。关于活性电极材料,具有适当不同的电化学电势(电压)和低界面电阻的任何配对的物质(金属、盐或嵌入化合物)是合适的。

[0049] 多种不同材料可以用作形成电极的材料。在某些方面中,电极材料被选择以在与目标生理场所(例如,胃部)接触后提供电压,所述电压足以驱动识别符的系统。在某些方面中,在电源的金属与目标生理场所接触后由电极材料提供的电压为 0.001V 或更高,包括 0.01V 或更高,诸如 0.1V 或更高,例如,0.3V 或更高,包括 0.5 伏或更高,且包括 1.0 伏或更高,其中在某些方面中,电压在约 0.001 到约 10 伏的范围内,例如从约 0.01 到约 10V。

[0050] 再次参看图 3,材料 34 和 36 提供电压电势以激活控制装置 38。一旦控制装置 38 被激活或上电,控制装置 38 便可以按唯一方式更改材料 34 与 36 之间的电导性。通过更改材料 34 与 36 之间的电导性,控制装置 38 能够控制穿过包围系统 30 的导电液体的电流的量值。这产生可以由接收器(未图示)检测并测量的唯一电流签名,所述接收器可以安置在身体内部或外部。图 12 到图 17 中示出接收器的说明性实例,如下文所描述。除了控制所述材料之间的电流路径的量值之外,使用不导电材料、膜或“裙缘”还用来增大电流路径的“长度”,因此用以升压电导路径,如 2008 年 9 月 25 日提交的名称为“具有虚拟偶极信号放大的体内装置(In-Body Device with Virtual Dipole Signal Amplification)”申请号为 12/238,345 的美国专利申请中所公开,所述专利申请的全部内容以引用的方式并入本文中。或者,贯穿本文公开内容,术语“不导电材料”、“膜”和“裙缘”可以与术语“电流路径延长器”互换使用,而不会影响本文中的本发明方面和权利要求书的范围。分别在 35 和 37 处的部分示出的裙缘可以与框架 32 相关联,例如,紧固到框架 32。裙缘的各种形状和配置被预期属于本发明的范围内。举例来说,系统 30 可以全部或部分地由裙缘包围,且裙缘可以沿着系统 30 的中心轴线或相对于中心轴线偏心安置。因此,如本文所主张的本发明的范围不受裙缘的此形状或大小限制。此外,在其它方面中,材料 34 和 36 可以被一个裙缘分开,所述裙缘安置在材料 34 与 36 之间的任何限定的区中。

[0051] 现在参看图 4,在另一方面中,图 2A 的系统 12 和图 2B 的系统 22 被更详细地示出为系统 40。系统 40 包括框架 42。框架 42 类似于图 3 的框架 32。在系统 40 的这个方面

中,可消化或可溶解材料 44 沉积在框架 42 的一个侧面的一部分上。在框架 42 的同一侧面的不同部分处,沉积另一可消化材料 46,使得材料 44 和 46 相异。更具体地说,材料 44 和 46 被选择以使得他们在与导电液体(例如体液)接触时形成电压电势差。因此,当系统 40 与导电液体接触和 / 或部分接触时,那么在材料 44 与 46 之间穿过导电液体形成电流路径,在图 5 中示出一个实例。控制装置 48 紧固到框架 42 且电耦接到材料 44 和 46。控制装置 48 包括能够控制材料 44 与 46 之间的电导路径的一部分的电子电路。材料 44 和 46 由不导电裙缘 49 分开。裙缘 49 的各种实例在以下申请中公开:2009 年 4 月 28 日提交的名称为“高度可靠的可摄取事件标示器及其使用方法(HIGHLYRELIABLE INGESTIBLE EVENT MARKERS AND METHODS OF USING SAME)”申请号为 61/173,511 的美国临时申请;和 2009 年 4 月 28 日提交的名称为“具有包括活性剂的信号放大器的可摄取事件标示器(INGESTIBLE EVENT MARKERS HAVING SIGNAL AMPLIFIERS THAT COMPRIZE AN ACTIVE AGENT)”申请号为 61/173,564 的美国临时申请;以及 2008 年 9 月 25 日提交的名称为“具有虚拟偶极信号放大的体内装置(IN-BODY DEVICE WITH VIRTUAL DIPOLE SIGNAL AMPLIFICATION)”申请号为 12/238,345 的美国申请;每一申请的全部公开内容以引用的方式并入本文中。

[0052] 一旦控制装置 48 被激活或上电,控制装置 48 便可以更改材料 44 与 46 之间的电导性。因此,控制装置 48 能够控制穿过包围系统 40 的导电液体的电流的量值。如上文关于系统 30 所指出的,与系统 40 相关联的唯一电流签名可以由接收器(未图示)检测以标示系统 40 的激活。图 12 到图 17 中示出接收器的说明性实例,如下文所描述。

[0053] 为了增大电流路径的“长度”,更改裙缘 49 的大小。电流路径越长,接收器就可以越容易检测电流。

[0054] 现在参看图 5,图 3 的系统 30 被示出为处于激活状态且与导电液体接触。系统 30 通过接地触点 52 来接地。举例来说,当系统 30 与导电流体接触时,导电流体提供接地。系统 30 还包括传感器模块 74,其相关于图 6 更详细地描述。离子或电流路径 50 在材料 34 到材料 36 之间延伸且流动穿过与系统 30 接触的导电流体。在材料 34 与 36 之间形成的电压电势是通过材料 34/36 与导电流体之间的化学反应来形成的。

[0055] 如果环境的条件改变为变得对通信有利,如由环境的测量所确定,那么单元 75 向控制装置 38 发送信号以更改材料 34 与 36 之间的电导性来允许使用系统 30 的电流签名进行通信。因此,如果系统 30 已经被去激活且环境的阻抗适合于通信,那么系统 30 可以被再次激活。

[0056] 现在参看图 5A,这示出材料 34 的表面的分解图。在一个方面中,材料 34 的表面不是平坦的,而是不规则表面。所述不规则表面增大材料的表面面积,且因此增大与导电流体形成接触的面积。在一个方面中,在材料 34 的表面处,在材料 34 与周围导电流体之间存在电化学反应,使得与导电流体交换物质。此处所使用的术语“物质”包括可以作为在材料 34 上发生的电化学反应的一部分添加或从导电流体移除的任何离子或非离子种类。一个实例包括其中材料是 CuCl 且当与导电流体接触时 CuCl 转换为 Cu 金属(固体)且 Cl<sup>-</sup> 被释放到溶液中的例子。正离子到导电流体中的流动由电流路径 50 描绘。负离子在相反方向上流动。以类似方式,存在涉及材料 36 的电化学反应,其导致从导电流体释放或移除离子。在这个实例中,材料 34 处的负离子释放以及材料 36 的正离子释放通过由控制装置 38 控制的电流流动而彼此相关。反应速率以及因此离子发射速率或电流由控制装置 38 控制。控制

装置 38 可以通过更改其内部电导性来增大或降低离子流的速率, 这更改阻抗以及因此材料 34 和 36 处的电流流动和反应速率。通过控制反应速率, 系统 30 可以在离子流中编码信息。因此, 系统 30 使用离子发射或流动来编码信息。

[0057] 控制装置 38 可以改变离子流或电流的持续时间, 同时保持电流或离子流量值接近恒定, 这类似于频率被调制且振幅恒定时。而且, 控制装置 38 可以改变离子流速率的等级或电流流动的量值, 同时保持持续时间接近恒定。因此, 使用持续时间改变以及更改速率或量值的各种组合, 控制装置 38 在电流或离子流中编码信息。举例来说, 控制装置 38 可以使用但不限于以下技术中的任一种, 包括二进制相移键控(PSK)、频率调制、振幅调制、启闭键控和具有启闭键控的 PSK。

[0058] 如上文所指示, 本文中所公开的各种方面(例如图 3 的系统 30 和图 4 的系统 40)包括作为控制装置 38 或控制装置 48 的一部分的电子组件。可以存在的组件包括但不限于: 逻辑和 / 或存储器元件、集成电路、电感器、电阻器和用于测量各种参数的传感器。每一组件可以紧固到框架和 / 或另一组件。支撑件的表面上的组件可以按任何便利配置来布置。在固体支撑件的表面上存在两个或两个以上组件的情况下, 可以提供互连件。

[0059] 如上文所指示, 系统(例如控制装置 30 和 40)控制相异材料之间的电导性以及因此离子流或电流的速率。通过以特定方式更改电导性, 系统能够在离子流和电流签名中编码信息。离子流或电流签名用以唯一地识别特定系统。另外, 系统 30 和 40 能够产生各种不同的唯一图案或签名, 因此提供额外信息。举例来说, 基于第二电导性更改图案的第二电流签名可以用以提供额外信息, 所述信息可以与物理环境相关。为了进一步说明, 第一电流签名可以为维持芯片上的振荡器的非常低的电流状态, 且第二电流签名可以为至少为与第一电流签名相关联的电流状态的十倍高的电流状态。

[0060] 现在参看图 6, 示出控制装置 38 的框图表示。装置 30 包括控制模块 62、计数器或时钟 64 以及存储器 66。另外, 控制装置 38 被示出为包括传感器模块 72 以及传感器模块 74(其在图 5 中提及)。控制模块 62 具有电耦接到材料 34 的输入 68 以及电耦接到材料 36 的输出 70。控制模块 62、时钟 64、存储器 66 和传感器模块 72/74 还具有电力输入(一些未图示)。当系统 30 与导电流体接触时, 用于这些组件中的每一种的电力由通过材料 34 和 36 与导电流体之间的化学反应产生的电压电势来供应。控制模块 62 通过更改系统 30 的整体阻抗的逻辑来控制电导性。控制模块 62 电耦接到时钟 64。时钟 64 向控制模块 62 提供时钟周期。基于控制模块 62 的编程特征, 当设定数目的时钟周期已经过去时, 控制模块 62 更改材料 34 与 36 之间的电导性特征。重复进行这个循环, 进而控制装置 38 产生唯一电流签名特征。控制模块 62 还电耦接到存储器 66。时钟 64 和存储器 66 两者由在材料 34 与 36 之间形成的电压电势供电。

[0061] 控制模块 62 还电耦接到传感器模块 72 和 74 并且与之通信。在所示出的方面中, 传感器模块 72 是控制装置 38 的一部分, 且传感器模块 74 是单独组件。在替代方面中, 可以使用传感器模块 72 和 74 中的任一个种而没有另一个, 且本发明的范围不受传感器模块 72 或 74 的结构或功能位置限制。另外, 系统 30 的任何组件可以在功能上或结构上移动、组合或重新安置, 而不会限制所主张的本发明的范围。因此, 有可能具有单个结构, 例如处理器, 其经设计以执行所有以下模块的功能: 控制模块 62、时钟 64、存储器 66 和传感器模块 72 或 74。另一方面, 使这些功能组件中的每一种定位在电链接且能够通信的独立结构中也

在本发明的范围内。

[0062] 再次参看图 6, 传感器模块 72 或 74 可以包括以下传感器中的任一种: 温度、压力、pH 值和导电性。在一个方面中, 传感器模块 72 或 74 从环境中收集信息且将模拟信息传递到控制模块 62。控制模块接着将模拟信息转换为数字信息, 且在电流流动或产生离子流的物质转移的速率中编码所述数字信息。在另一方面中, 传感器模块 72 或 74 从环境中收集信息且将模拟信息转换为数字信息, 接着将数字信息传递到控制模块 62。在图 5 所示的方面中, 传感器模块 74 被示出为电耦接到材料 34 和 36 以及控制装置 38。在另一方面中, 如图 6 所示, 传感器模块 74 在连接 78 处电耦接到控制装置 38。连接 78 既充当针对传感器模块 74 的电力供应源又充当传感器模块 74 与控制装置 38 之间的通信信道。

[0063] 现在参看图 5B, 系统 30 包括连接到材料 39 的 pH 传感器模块 76, 其是根据正在执行的特定类型的感测功能来选择的。pH 传感器模块 76 还连接到控制装置 38。材料 39 通过不传导阻挡层 55 来与材料 34 电隔离。在一个方面中, 材料 39 是铂。在操作中, pH 传感器模块 76 使用材料 34/36 之间的电压电势差。pH 传感器模块 76 测量材料 34 与材料 39 之间的电压电势差, 且记录其值以供稍后比较。pH 传感器模块 76 还测量材料 39 与材料 36 之间的电压电势差, 且记录其值以供稍后比较。pH 传感器模块 76 使用所述电压电势值来计算周围环境的 pH 值。pH 传感器模块 76 将此信息提供给控制装置 38。控制装置 38 改变产生离子转移的物质转移的速率和电流流动以便在离子转移中编码与 pH 值相关的信息, 所述信息可以由接收器(未图示)检测。图 12 到图 17 中示出接收器的说明性实例, 如下文所描述。因此, 系统 30 可以确定与 pH 值相关的信息并将其提供给在环境外部的源。

[0064] 如上文所指示, 可以预先编程控制装置 38 以输出预定义电流签名。在另一方面中, 系统可以包括接收器系统, 该接收器系统可以在系统被激活时接收编程信息。图 12 到图 17 中示出接收器的说明性实例, 如下文所描述。在另一方面(未图示)中, 开关 64 和存储器 66 可以组合成一个装置。

[0065] 除了以上组件之外, 系统 30 还可以包括一个或其它电子组件。所关注的电组件包括但不限于: 额外逻辑和 / 或存储器元件, 例如, 呈集成电路的形式; 电力调节装置, 例如, 电池、燃料电池或电容器; 传感器、激励器等; 信号发射元件, 例如, 呈天线、电极、线圈等的形式; 无源元件, 例如, 电感器、电阻器等。

[0066] 现在参看图 5C, 系统 30 被示出为具有紧固到框架 32 的裙缘部分 35 和 37, 如下文详细论述。根据本发明的一个方面, 材料 34 和材料 36 延伸超过框架 32 到达裙缘部分 35 和 37 上。在根据本发明的另一实例中, 材料 34 和 36 可以延伸到裙缘部分 35 和 37 的边缘。材料 34 和 36 的面积增大导致所供应的电力增大。

[0067] 现在参看图 7, 示出系统 30 的横截面图, 其具有位于框架 32 上的第一材料区 34a 和第二材料区 36a。第一材料区 34a 包括粘附材料 86。粘附材料 86 可以为被选择以粘附并固持到第一材料区 88 上的任何材料, 根据本发明的一个方面, 所述材料区 88 由 CuCl 制成, 如上文关于第一材料 34 所论述。第二材料区 36a 包括过渡金属 96, 其由任何过渡金属制成, 例如根据本发明的一个方面为钛。第二材料区 36a 还包括第二材料区 98, 根据本发明的一个方面, 其由镁(Mg) 制成, 如上文关于第二材料 36 所论述。

[0068] 现在参看图 8, 示出材料 86 和材料区 88 的分解图。材料 86 由不反应的导电材料制成, 例如金。为了增强材料 86 到材料区 88 的粘附性质, 材料 86 具有未加工或粗糙的表

面。材料 86 沉积到框架 32 上。另外,根据本发明的一个方面,材料 86 限定有多个孔 87,其与框架 32 的对应于材料 86 的边缘的边缘间隔开距离 DD。距离 DD 是使孔 87 与材料 86 的边缘分开且允许所有孔 87 落入边界 89 内所需要的最小距离,以使得材料区 88 的边缘不安置在任何孔的上方;这种设计增强了材料 86 到材料区 88 的粘附性质和特征。

[0069] 现在参看图 9,示出将金属 96 紧固到框架 32 的过程。最初,将金属 96 沉积到框架 32 上。接着,加热金属 86 与框架 32。接着,使用(例如)离子枪清洁器来清洁金属 96 的表面。接着,将镁沉积到金属 86 的清洁表面上以形成材料区 98。

[0070] 根据本发明的另一方面,在晶片 100 (如图 10 的俯视图说明中所示)上构建多个框架 32 (如图 1 所示)。晶片 100 可以包括任何数目的框架 32。一旦晶片 100 完成,接着便从晶片 100 切出每一完整框架 32 且将其插入或压配或放置到图 11 的片 110 的开口 112 中以产生系统 12、22、30 或 40,如根据本发明的各种方面所示出和论述的。开口 112 贴合地切割成框架 32 的形状。接着使片 110 通过压力机(未图示),其冲压出系统 12、22、30 或 40 中的每一种,如所提及。

[0071] 在某些方面中,可摄取电路包括涂层。根据本发明的一个方面,可以在从图 10 的晶片 100 移除框架 32 之前使用旋涂工艺向晶片 100 涂覆保护性涂层。根据本发明的另一方面,可以在从图 11 的片 110 冲压出或切出之后向系统(例如,系统 30)涂覆保护性涂层。这个涂层的用途可以变化,例如,用以在处理期间、在储存期间或甚至在摄取期间保护电路、芯片和/或电池或者任何组件。在这些例子中,可以包括位于电路顶部的涂层。还关注的是经设计以在储存期间保护可摄取电路但在使用期间立即溶解的涂层。举例来说,在与含水流体(例如,胃液)或如上文所提及的导电流体接触后溶解的涂层。还关注的是被采用以允许使用处理步骤否则会损坏装置的某些组件的保护性处理涂层。举例来说,在生产顶部和底部上沉积有相异材料的芯片的方面中,需要将产品切成方块。然而,切块过程可能会划掉相异材料,并且还可能涉及到会致使相异材料脱落或溶解的液体。在这些例子中,可以采用所述材料上的保护性涂层,其防止在处理期间与组件形成机械或液体接触。

[0072] 可溶解涂层的另一用途可以用来延迟装置的激活。举例来说,可以采用处于相异材料上且在与胃液接触后花特定时间周期(例如,五分钟)来溶解的涂层。涂层还可以为环境敏感性涂层,例如,温度或 pH 敏感性涂层,或提供用于以受控形式溶解且允许在需要时激活装置的其它化学敏感性涂层。在胃部中留存但在肠道中溶解的涂层也是受关注的,例如,在需要延迟激活直到装置离开胃部为止的情况下。此类涂层的实例是在低 pH 下不能溶解但在较高 pH 下变得能溶解的聚合物。还关注的是药物剂型保护性涂层,例如,凝胶帽液体保护性涂层,其防止电路由凝胶帽的液体激活。

[0073] 所关注的识别符包括两种相异电化学材料,其类似于电源的电极(例如,阳极和阴极)来起作用。对电极或阳极或阴极的参考在本文中仅仅用作说明性实例。本发明的范围不受所使用的标签限制,且包括其中在两种相异材料之间形成电压电势这一方面。因此,在参考电极、阳极或阴极时,希望用作对在两种相异材料之间形成的电压电势的参考。

[0074] 当材料暴露且与体液(例如胃酸或其它类型的流体)(单独地或与干燥传导性介质前体组合地)形成接触时,由于这两种电极材料所遭受的相应氧化和还原反应而在电极之间产生电势差,即电压。可以进而产生伏打电池或电池。因此,在本发明的多个方面中,此类电力供应被配置以使得当这两种相异材料暴露于目标场所(例如,胃部、消化道等)时,产

生电压。

[0075] 在某些方面中,一种或两种金属可以被掺杂有非金属,例如,以增强电池的电压输出。可以在某些方面中用作掺杂剂的非金属包括但不限于:硫和碘等。

[0076] 出于说明目的,可以与本发明的各种方面一起使用各种接收器。在接收器(本文中有时称为“信号接收器”)的一个实例中,可以采用两个或两个以上不同解调协议来解码给定接收信号。在一些例子中,可以采用相干解调协议和差分相干解调协议两种。图 12 提供根据本发明的一个方面的接收器可以如何实施相干解调协议的功能框图。应注意,图 12 中仅示出接收器的一部分。图 12 说明一旦确定载波频率(以及缩混到载波偏移的载波信号)便将信号缩混到基带的过程。在混频器 2223 处将载波信号 2221 与第二载波信号 2222 混合。应用具有恰当带宽的窄低通滤波器 2220 来减少界外噪声(out-of-bound noise)效应。在功能框 2225 处根据本发明的相干解调方案来发生解调。确定复信号的展开相位 2230。可以应用任选的第三混频器级,其中使用相位演变来估计所计算的载波频率与真实的载波频率之间的频率差异。接着在框 2240 处利用数据包的结构来确定 BPSK 信号的编码区的开始。主要使用同步标头的存在来确定数据包的开始边界,所述同步标头呈现为复解调信号的振幅信号中的 FM 边沿。一旦确定数据包的开始点,便在框 2250 处在 IQ 平面和标准位识别上旋转信号并且最终在框 2260 处解码所述信号。

[0077] 除了解调之外,穿体通信模块(transbody communication module)可以包括前向误差校正模块,所述模块提供额外增益来抗击来自其它有害信号和噪声的干扰。所关注的前向误差校正功能模块包括在申请号为 PCT/US2007/024225 公开为 WO2008/063626 的 PCT 申请中所描述的那些模块,所述申请的公开内容以引用的方式并入本文中。在一些例子中,前向误差校正模块可以采用例如里德-索罗门(Reed-Solomon)、格雷(Golay)、汉明(Hamming)、BCH 和涡轮(Turbo)协议等任何便利的协议来识别和校正(在界限内)解码误差。

[0078] 在另一实例中,接收器包括信标模块,如图 13 的功能框图中所示。图 13 中概述的方案概述了一种用于识别有效信标的技术。传入信号 2360 表示由电极接收、由高频信令链(其包括载波频率)带通滤波(例如从 10KHz 到 34KHz)且从模拟转换到数字的信号。接着在框 2361 处对信号 2360 进行抽取(decimate)且在混频器 2362 处在标称驱动频率(例如 12.5KHz、20KHz 等)下对信号 2360 进行混频。在框 2364 处对所得信号进行抽取且在框 2365 处对所得信号进行低通滤波(例如 5KHz BW)以产生缩混到载波偏移的载波信号——信号 2369。信号 2369 进一步由框 2367(快速傅里叶变换且接着检测两个最强峰值)处理以提供真实载波频率信号 2368。这种协议允许准确地确定所发射的信标的载波频率。

[0079] 图 14 提供根据本发明的一方面的信号接收器的集成电路组件的功能框图。在图 14 中,接收器 2700 包括电极输入 2710。电耦接到电极输入 2710 的是穿体传导通信模块 2720 和生理感测模块 2730。在一个方面中,穿体传导通信模块 2720 被实施为高频(HF)信号链,且生理感测模块 2730 被实施为低频(LF)信号链。还示出了 CMOS 温度感测模块 2740(用于检测周围温度)和 3 轴加速计 2750。接收器 2700 还包括处理引擎 2760(例如,微控制器和数字信号处理器)、非易失性存储器 2770(用于数据存储)和无线通信模块 2780(用于将数据发射到另一装置,例如在数据上载动作中)。

[0080] 图 15 提供根据本发明的一个方面的被配置以实施图 14 中所描绘的接收器的功能框图的电路的较详细框图。在图 15 中,接收器 2800 包括电极 e1、e2 和 e3(2811、2812 和

2813),其例如接收由 IEM 传导性发射的信号且 / 或感测关注的生理参数或生物标示器。电极 2811、2812 和 2813 所接收的信号由多路复用器 2820 进行多路复用,所述多路复用器电耦接到电极。

[0081] 多路复用器 2820 电耦接到高带通滤波器 2830 和低带通滤波器 2840 两者。高频信号链和低频信号链提供可编程增益以覆盖希望的层级或范围。在这个特定方面中,高带通滤波器 2830 使在 10KHz 到 34KHz 带中的频率通过,而滤出来自带外频率的噪声。这个高带通滤波器可以变化,且可以包括(例如)3KHz 到 300KHz 的范围。通频(passingfrequency)接着由放大器 2832 放大,之后由转换器 2834 转换为数字信号以供输入到高功率处理器 2880 (示出为 DSP) 中,所述高功率处理器电耦接到高频信号链。

[0082] 低带通滤波器 2840 被示出为使在 0.5Hz 到 150Hz 的范围内的较低频率通过,而滤出带外频率。所述频带可以变化,且可以包括(例如)低于 300Hz 的频率,例如低于 200Hz,包括低于 150Hz。通频信号由放大器 2842 放大。还示出了加速计 2850,其电耦接到第二多路复用器 2860。多路复用器 2860 将来自加速计的信号与来自放大器 2842 的放大信号进行多路复用。经多路复用的信号接着由转换器 2864 转换为数字信号,所述转换器 2864 还电耦接到低功率处理器 2870。

[0083] 在一个方面中,数字加速计(例如由模拟器件公司(Analog Devices)制造的数字加速计)可以代替加速计 2850 来实施。可以通过使用数字加速计来实现各种优点。举例来说,因为数字加速计将产生已经呈数字格式的信号,所以数字加速计可以绕开转换器 2864 且电耦接到低功率微控制器 2870——在所述情况下,将不再需要多路复用器 2860。而且,数字信号可以被配置以在检测到运动时将其自身接通,从而进一步保存电力。另外,可以实施连续步骤计数。数字加速计可以包括 FIFO 缓冲器来帮助控制发送到低功率处理器 2870 的数据流。举例来说,数据可以在 FIFO 中缓冲,直到满为止,此时处理器可以被触发来从闲置状态唤醒且接收所述数据。

[0084] 举例来说,低功率处理器 2870 可以为来自德州仪器公司(Texas Instruments)的 MSP430 微控制器。接收器 2800 的低功率处理器 2870 维持闲置状态,如早先陈述的,这需要最小电流汲取,例如,10.  $\mu$ A 或更少,或 1.  $\mu$ A 或更少。

[0085] 举例来说,高功率处理器 2880 可以为来自德州仪器公司(Texas Instruments)的 VC5509 数字信号处理器。高功率处理器 2880 在活动状态期间执行信号处理动作。如早先陈述的,这些动作需要比闲置状态多的电流量,例如 30.  $\mu$ A 或更多的电流,例如 50.  $\mu$ A 或更多,且举例来说,可以包括诸如以查找传导性发射的信号的扫描、在接收到时处理传导性发射的信号、获得和 / 或处理生理数据等动作。

[0086] 图 13 中还示出快闪存储器 2890,其电耦接到高功率处理器 2880。在一个方面中,快闪存储器 2890 可以电耦接到低功率处理器 2870,其可以提供较好的功率效率。

[0087] 无线通信元件 2895 被示出为电耦接到高功率处理器 2880,且可以包括(例如) BLUETOOTH. TM. 无线通信收发器。在一个方面中,无线通信元件 2895 电耦接到高功率处理器 2880。在另一方面中,无线通信元件 2895 电耦接到高功率处理器 2880 和低功率处理器 2870。此外,无线通信元件 2895 可以被实施为具有其自己的电力供应,使得其可以独立于接收器的其它组件来接通和断开,例如,通过微处理器。

[0088] 记住(例如)闲置状态,以下段落提供根据本发明的一个方面的图 15 所示的接收器

组件在接收器的各种状态期间的实例配置。应理解,可以依据希望的应用来实施替代性配置。

[0089] 举例来说,在闲置状态下,接收器汲取最少电流。接收器 2800 被配置以使得低功率处理器 2870 处于不活动状态(例如,闲置状态),且高功率处理器 2880 处于不活动状态(例如闲置状态),且与外围电路相关的电路块及其在各种活动状态期间所需要的电力供应保持断开(例如,无线通信模块 2895 和模拟前端)。举例来说,低功率处理器可以使 32KHz 振荡器活动且可以消耗几  $\mu$ A 电流或更少,包括 0.5  $\mu$ A 或更少。在闲置状态下,低功率处理器 2870 可以(例如)等待信号转变为活动状态。信号可以在外部,例如中断,或由装置的外围设备之一(例如定时器)在内部产生。在高功率处理器的闲置状态期间,高功率处理器可以(例如)关闭 32KHz 钟表晶体。举例来说,高功率处理器可以等待信号转变为活动状态。

[0090] 当接收器处于监听状态(sniff state)时,低功率处理器 2870 处于闲置状态,且高功率处理器 2880 处于闲置状态。另外,与监听功能所需要的模拟前端(包括 A/D 转换器)相关的电路块均接通(换句话说,高频信号链)。如早先陈述的,信标信号模块可以实施各种类型的监听信号来实现低功率效率。

[0091] 在检测到发射信号后,可以进入较高功率解调与解码状态。当接收器处于解调与解码状态时,低功率处理器 2870 处于活动状态,且高功率处理器 2880 处于活动状态。举例来说,高功率处理器 2880 可以从具有基于 PLL 的时钟倍频器的 12MHz 或附近晶体振荡器运行,从而给予装置 108MHz 时钟速度。举例来说,在活动状态期间,低功率处理器 2870 可以关闭在 1MHz 到 20MHz 的范围内的内部 R-C 振荡器,且消耗在 250 到 300uA/MHz 时钟速度的范围内的电力。活动状态允许进行处理以及可以跟随的任何发射。所需要的发射可以触发无线通信模块从断开循环到接通。

[0092] 当接收器处于收集 ECG 和加速计状态时,与加速计和 / 或 ECG 信号调节链相关的电路块接通。高功率处理器 2880 在收集期间处于闲置状态,且在处理和发射期间处于活动状态(例如,从具有基于 PLL 的时钟倍频器的 12MHz 或附近晶体振荡器运行,从而给予装置 108MHz 时钟速度)。低功率处理器 2870 在这种状态期间处于活动状态,且可以关闭在 1MHz 到 20MHz 的范围内的内部 R-C 振荡器,且消耗在 250 到 300uA/MHz 时钟速度的范围内的电力。

[0093] 低功率处理器(例如,图 13 所示的 MSP)和高功率处理器(例如,图 13 所示的 DSP)可以使用任何便利的通信协议来彼此通信。在一些例子中,这两个元件在存在时经由串行外围接口总线(下文中称为“SPI 总线”)来彼此通信。以下描述内容描述了经实施以允许高功率处理器和低功率处理器沿着 SPI 总线通信且来回发送消息的信令和消息接发方案。针对以下对处理器之间的通信的描述,分别使用“LPP”和“HPP”来代替“低功率处理器”和“高功率处理器”,以保持与图 13 一致。然而,所述论述可以适用于除图 13 所示的处理器之外的其它处理器。

[0094] 图 16 提供与高频信号链相关的根据本发明的一方面的接收器中的硬件的框图的视图。在图 16 中,接收器 2900 包括接收器探针(例如,呈电极 2911、2912 和 2913 的形式),其电耦接到多路复用器 2920。还示出高通滤波器 2930 和低通滤波器 2940 以提供消除任何带外频率的带通滤波器。在所示出的方面中,提供 10KHz 到 34KHz 的带通以使落入所述频

带内的载波信号通过。实例载波频率可以包括但不限于 12.5KHz 和 20KHz。可以存在一个或一个以上载波。另外,接收器 2900 包括模 / 数转换器 2950, 例如, 在 500KHz 下取样。此后可以由 DSP 处理数字信号。在这个方面中示出 DMA 至 DSP 单元 2960, 其将数字信号发送到用于 DSP 的专用存储器。直接存储器存取提供允许 DSP 的其余部分保持处于低功率模式的益处。

[0095] 图 17 中示出包括接收器的系统的实例。在图 17 中, 系统 3500 包括药物合成物 3510, 该药物合成物 3510 包括可摄取装置, 例如可摄取事件标示器“IEM”。系统 3500 中还存在信号接收器 3520。信号接收器 3520 被配置以检测从 IEM3510 的识别符发射的信号。信号接收器 3520 还包括生理感测能力, 例如 ECG 和移动感测能力。信号接收器 3520 被配置以将数据发射到患者的外部装置或 PDA3530 (例如智能电话或其它具无线通信功能的装置), 其又将数据发射到服务器 3540。服务器 3540 可以根据需要来配置, 例如, 以提供患者定向许可。举例来说, 服务器 3540 可以被配置以允许家庭护理者 3550 (例如) 经由允许家庭护理者 3550 监视由服务器 3540 产生的警报和趋势的接口 (例如网络接口) 来参与患者的治疗方案, 并且返回向患者提供支持, 如由箭头 3560 所指示。服务器 3540 还可以被配置以将响应直接提供给患者, 例如, 以患者警报、患者激励等的形式, 如由箭头 3565 所指示, 所述响应经由 PDA3530 中继到患者。服务器 3540 还可以与健康护理专业人员 (例如, RN、内科医生) 3555 交互, 健康护理专业人员可以使用数据处理算法来获得患者健康和配合度量度, 例如健康指数总结、警报、跨患者基准等, 且返回向患者提供所通知的临床沟通和支持, 如由箭头 3580 所指示。

[0096] 应理解, 本发明不限于所描述的特定实施例或方面, 且因而可以变化。还应理解, 本文中所使用的术语仅出于描述特定方面的目的, 且不希望具限制性, 因为本发明的范围将仅由所附权利要求书限制。

[0097] 在提供值范围的情况下, 应理解, 在所述范围的上限与下限之间的每一居间值 (精确到下限的单位的十分之一, 除非上下文清楚地另有规定) 以及那个所陈述范围内的任何其它所陈述值或居间值均涵盖在本发明内。这些较小范围的上限和下限可以独立地包括在所述较小范围内, 且也涵盖在本发明内, 服从所陈述范围中的任何特殊排除的界限。在所陈述的范围包括所述界限中的一者或两者的情况下, 排除那些所包括的界限中的任一者或两者的范围也包括在本发明中。

[0098] 除非另有定义, 否则本文中所使用的所有技术和科学术语均具有本发明所属的领域的技术人员通常所理解的相同意思。尽管类似或等效于本文所描述的方法和材料的任何方法和材料也可以用于实践或测试本发明, 但现在描述代表性说明性方法和材料。

[0099] 本说明书中所引用的所有公开案和专利以引用的方式并入本文中, 如同每一单独公开案或专利被特定且个别地指明以引用的方式并入, 且以引用的方式并入本文中以公开并描述引用所述公开案所结合的方法和 / 或材料。任何公开案的引用是为了公开在申请日期之前的公开案, 且不应解释为承认本发明因为在先发明而无权先于所述公开案。另外, 所提供的公开日期可能不同于实际公开日期, 所述实际公开日期可能需要独立确认。

[0100] 请注意, 如本文中和所附权利要求书中所使用, 单数形式“一”和“所述”包括复数对象, 除非上下文清楚地另有规定。进一步注意到, 权利要求书可以被撰写为排除任何任选元件。因而, 这个陈述希望充当关于权利要求元素的叙述使用例如“单独地”、“仅仅”等排

他性术语或使用“不利”限制的前提基础。

- [0101] 不管权利要求书如何,本发明还涉及以下条款:
- [0102] 1. 一种制造包括部分电源的通信装置的方法,所述方法包括以下步骤:
- [0103] 将粘附材料层沉积到支撑结构的第一位置上,其中所述粘附材料层限定有多个孔;
- [0104] 将第一材料沉积到所述粘附材料层上,其中所述第一材料粘附到所述粘附材料;
- [0105] 将过渡材料层沉积在所述支撑结构的第二位置上;以及
- [0106] 将第二材料沉积到所述过渡金属层上,其中当所述第一材料和所述第二材料与导电流体形成接触时,所述第一材料和所述第二材料呈现电压电势差。
- [0107] 2. 根据条款1所述的方法,其中所述粘附材料是金。
- [0108] 3. 根据条款2所述的方法,进一步包括毛化所述金的表面以增强粘附性质的步骤。
- [0109] 4. 根据条款1到3中任一条款所述的方法,其中所述支撑结构是硅基材料。
- [0110] 5. 根据条款1到4中任一条款所述的方法,其中沉积所述第一材料的步骤包括使用电子束的蒸发沉积。
- [0111] 6. 根据前述条款中任一条款所述的方法,其中所述粘附层的厚度小于100微米。
- [0112] 7. 根据前述条款中任一条款所述的方法,其中沉积过渡金属层的步骤包括以下步骤:
- [0113] 将所述过渡金属沉积到所述支撑结构上;
- [0114] 加热沉积有所述过渡金属的所述支撑结构;以及
- [0115] 清洁所述过渡金属的暴露表面,使得所得结构准备好接纳所述第二材料。
- [0116] 8. 根据前述条款中任一条款所述的方法,其中所述清洁所述暴露表面的步骤包括用离子枪进行清洁。
- [0117] 9. 根据前述条款中任一条款所述的方法,进一步包括将聚合物旋涂到所述装置上以提供保护性涂层的步骤,优选地其中所述沉积步骤包括旋转所述装置以将所述聚合物均匀地分布在所述装置的表面上。
- [0118] 10. 根据前述条款中任一条款所述的方法,进一步包括将所述装置插入到不导电膜中的步骤。
- [0119] 11. 一种制造多个通信装置的方法,其中每一装置包括不导电膜和部分电源装置,所述方法包括以下步骤:
- [0120] 在不导电材料片中切出多个开口以产生组装膜片,其中每一开口的形状对应于所述装置的框架的形状;以及
- [0121] 将从多个所述部分电源装置中选出的一个部分电源装置插入到所述组装膜的每一开口中以产生加载膜片,其中根据一种工艺来制备每一部分电源装置,所述工艺包括在支撑结构的与具有粘附材料的表面相反的表面上沉积过渡金属层的步骤。
- [0122] 12. 根据条款11所述的方法,进一步包括以下步骤:
- [0123] 将不反应材料层沉积到所述加载膜片上位于与所述过渡金属相反的侧面上以产生粘附膜片,其中所述不反应材料层限定有多个孔;
- [0124] 将第一材料沉积到所述粘附膜片上位于具有所述粘附材料的侧面上,其中所述第

一材料粘附到所述不反应材料；

[0125] 将第二材料沉积到所述过渡金属层上以产生部分电力装置片,其中所述第一材料和所述第二材料呈现电压电势差。

[0126] 13. 根据条款 11 或 12 所述的方法,进一步包括在所述支撑结构上限定多个边界的步骤,其中每一边界对应于每一装置的电路。

[0127] 14. 根据条款 12 或 13 所述的方法,其中所述沉积不反应材料层的步骤进一步包括限定孔群组的步骤,其中每一孔群组被包含在从所述多个边界中选出的一个边界以内,使得所述孔群组内的每一孔的位置在对应的边界以内。

[0128] 15. 根据前述条款中任一条款所述的方法,其中所述过渡金属是钛。

[0129] 16. 一种用于通信的包括部分电源的装置,所述装置可以依据根据前述条款中任一条款所述的方法来获得,优选地其中所述装置通过如下工艺来制备,该工艺包括以下步骤:

[0130] 将粘附材料层沉积到支撑结构的第一位置上,其中所述粘附材料层限定有多个孔;

[0131] 将第一材料沉积到所述粘附层上,其中所述第一材料粘附到所述粘附材料;

[0132] 将过渡材料层沉积在所述支撑结构的第二位置上;

[0133] 将第二材料沉积到所述过渡金属层上,其中当所述第一材料和所述第二材料与导电流体形成接触时,所述第一材料和所述第二材料呈现电压电势差。

[0134] 如所属领域的技术人员在阅读本公开后将容易明白,本文中所描述和说明的个体方面中的每一个具有可以在不脱离本发明的范围或精神的情况下容易与其它若干方面的任一个的特征分离或组合的离散组件和特征。所叙述的任何方法可以按所叙述的事件的次序或按逻辑上可能的任何其它次序来实行。

[0135] 虽然已经出于使理解清楚的目的而借助于说明和实例来以某种细节描述了前述发明,但所属领域的技术人员鉴于本发明的教导而易于明白,在不脱离所附权利要求书的精神或范围的情况下,可以对本发明做出某些改变和修改。

[0136] 因而,前述内容仅仅说明本发明的原理。将了解,所属领域的技术人员将能够构想出各种布置,虽然本文中未明确地描述或示出,但所述各种布置体现本发明的原理且包括在其精神和范围内。此外,本文中所叙述的所有实例和条件语言主要希望帮助读者理解本发明的原理和发明人贡献来促进此项技术的概念,且应解释为不限于这些明确叙述的实例和条件。此外,本文中叙述本发明的原理和方面以及其特定实例的所有陈述希望包括其结构和功能等效物两者。另外,希望此类等效物包括当前已知的等效物以及将来开发的等效物,即,不管结构如何而执行相同功能的所开发的任何元件。因此,本发明的范围不希望限于本文中所示出和描述的示范性方面。而是,本发明的范围和精神由所附权利要求书体现。

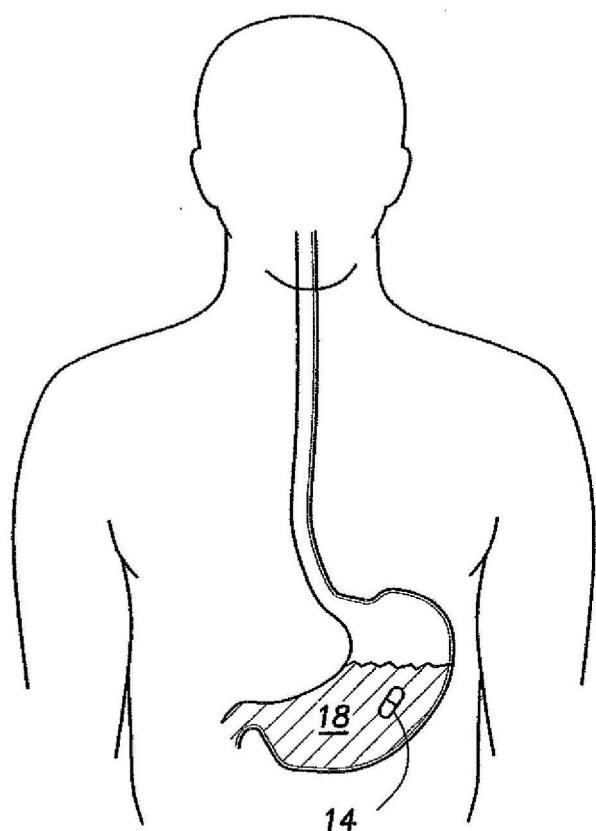


图 1

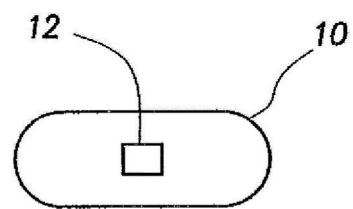


图 2A

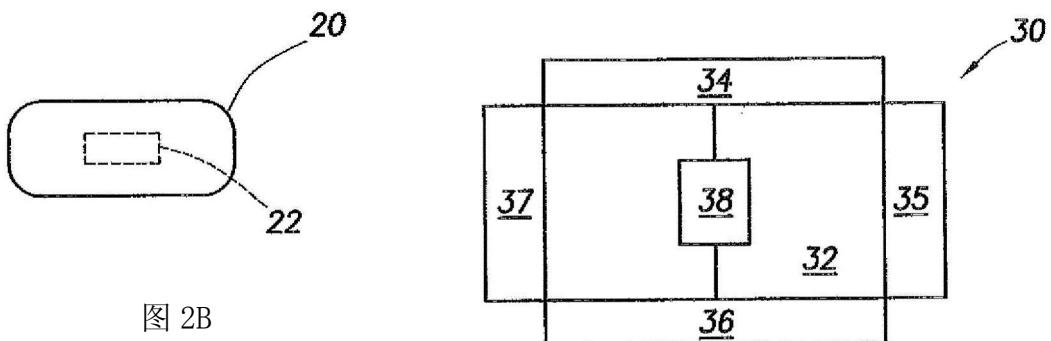


图 2B

图 3

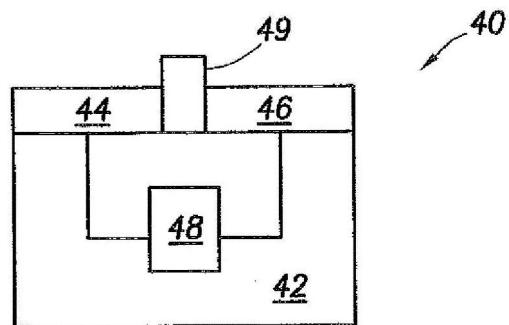


图 4

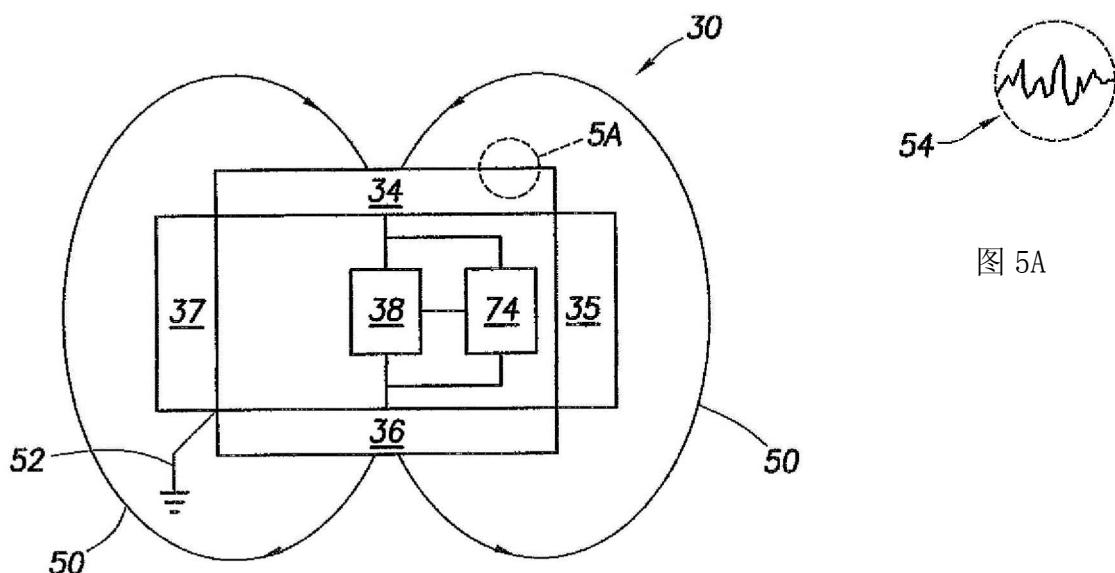


图 5A

图 5

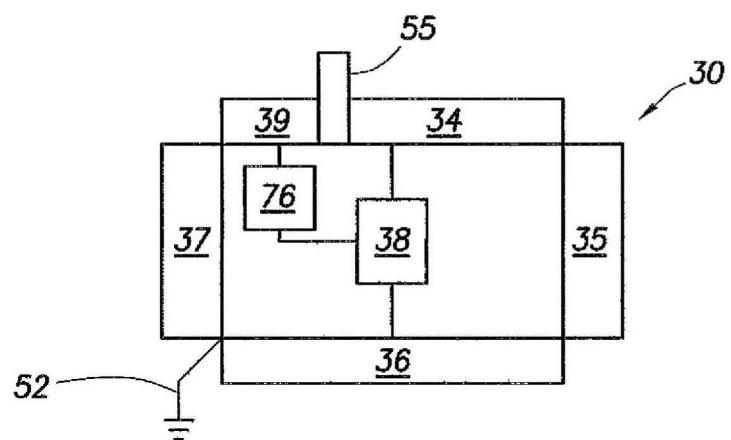


图 5B

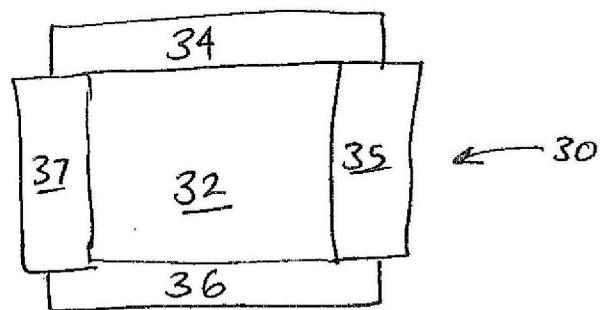


图 5C

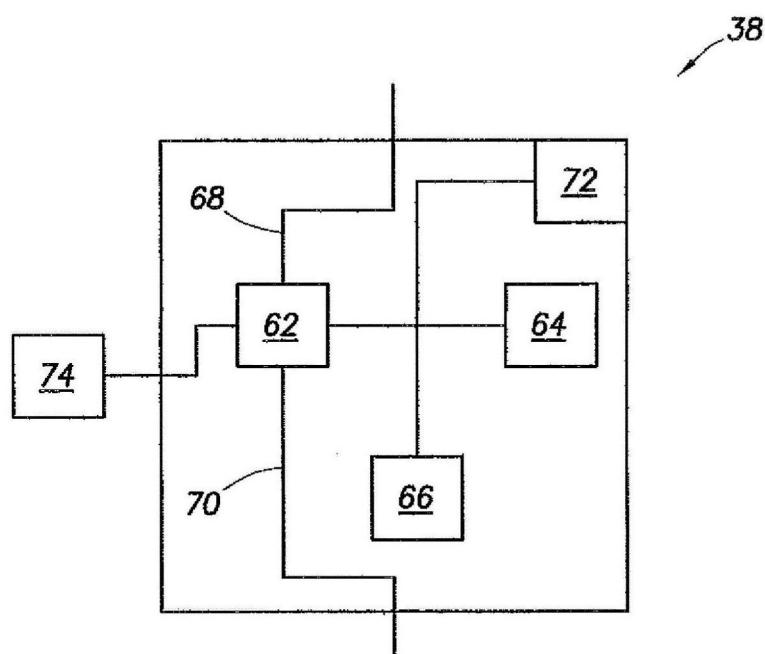


图 6

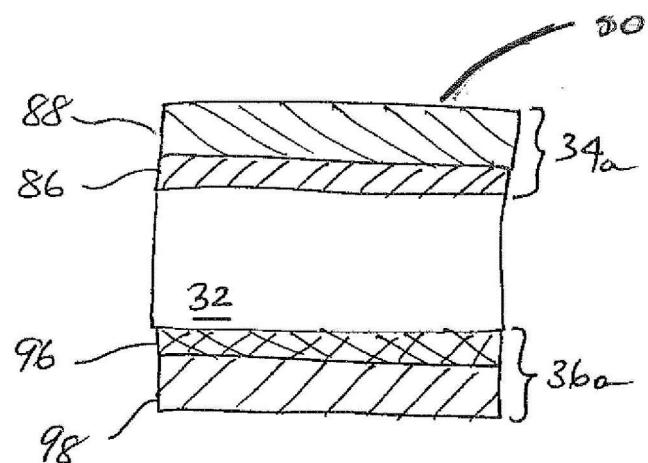


图 7

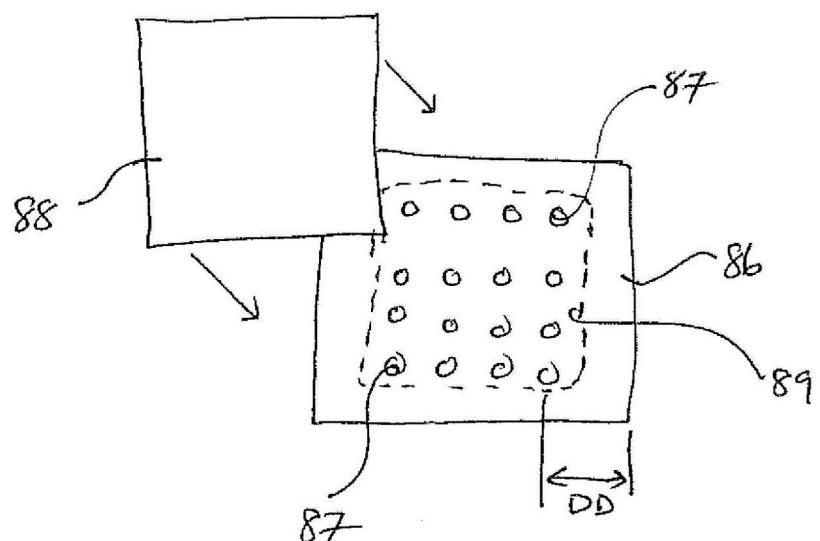


图 8

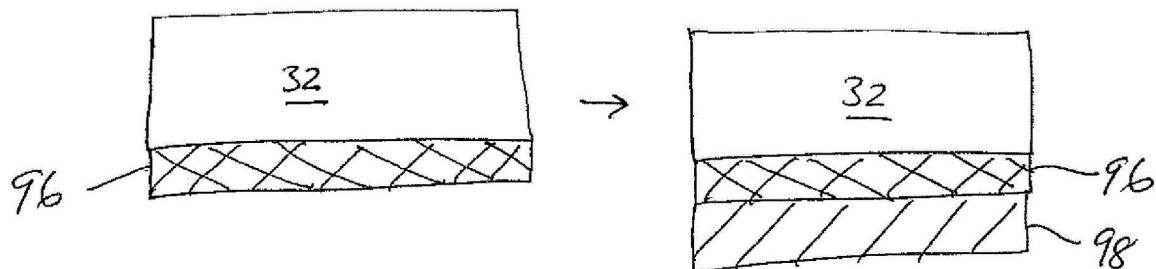


图 9

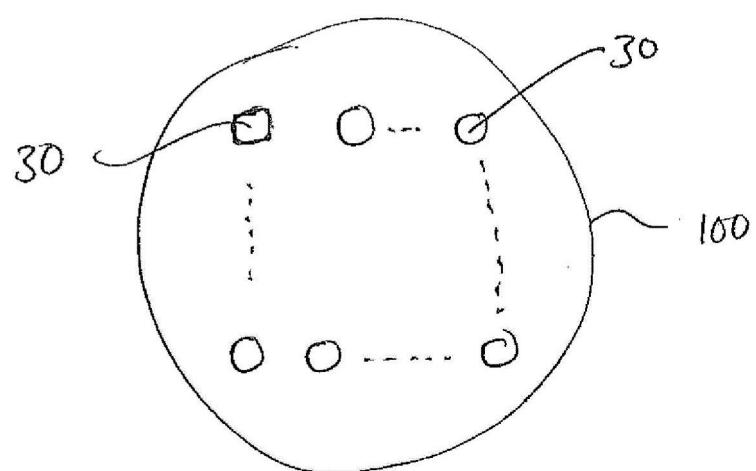


图 10

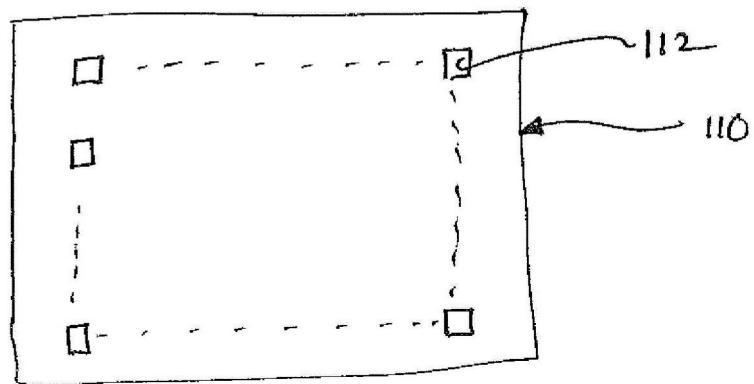


图 11

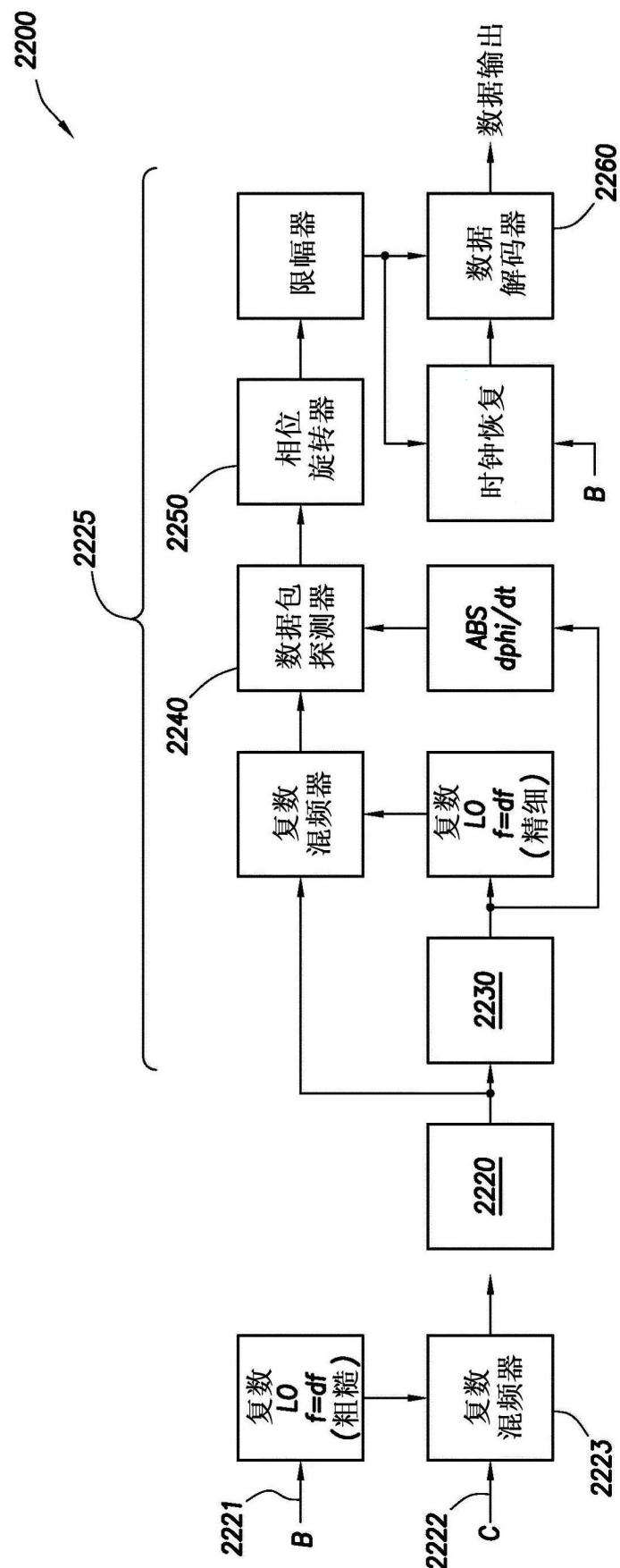


图 12

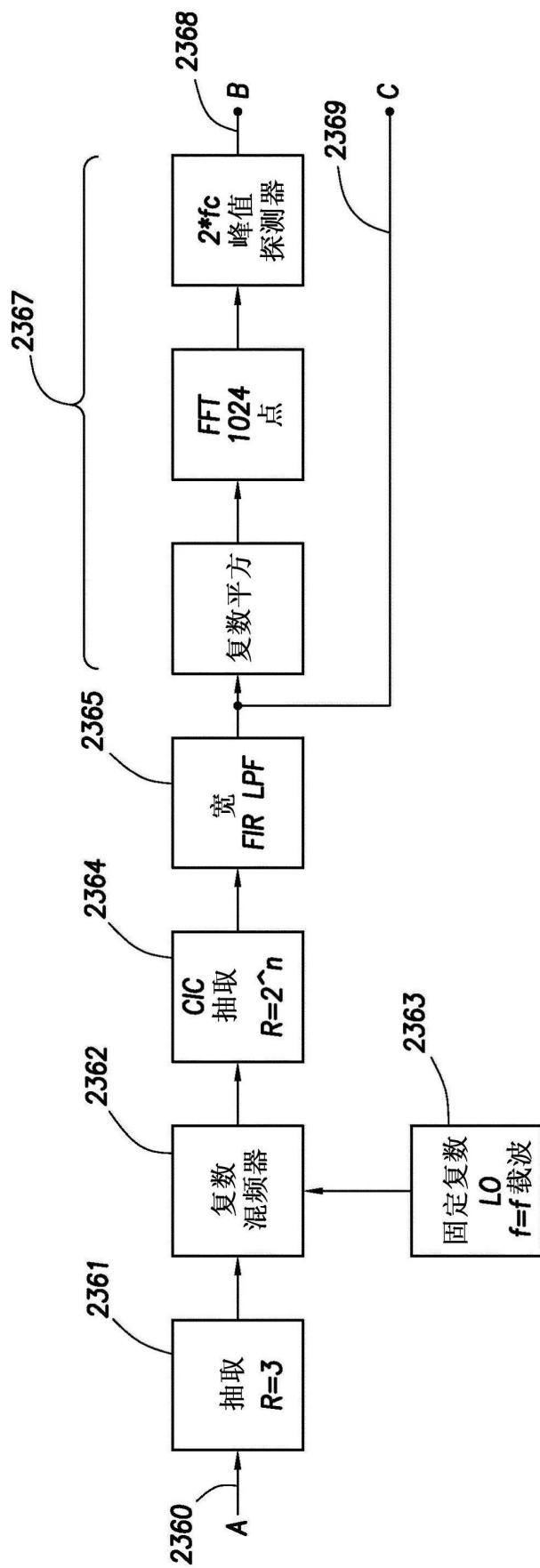


图 13

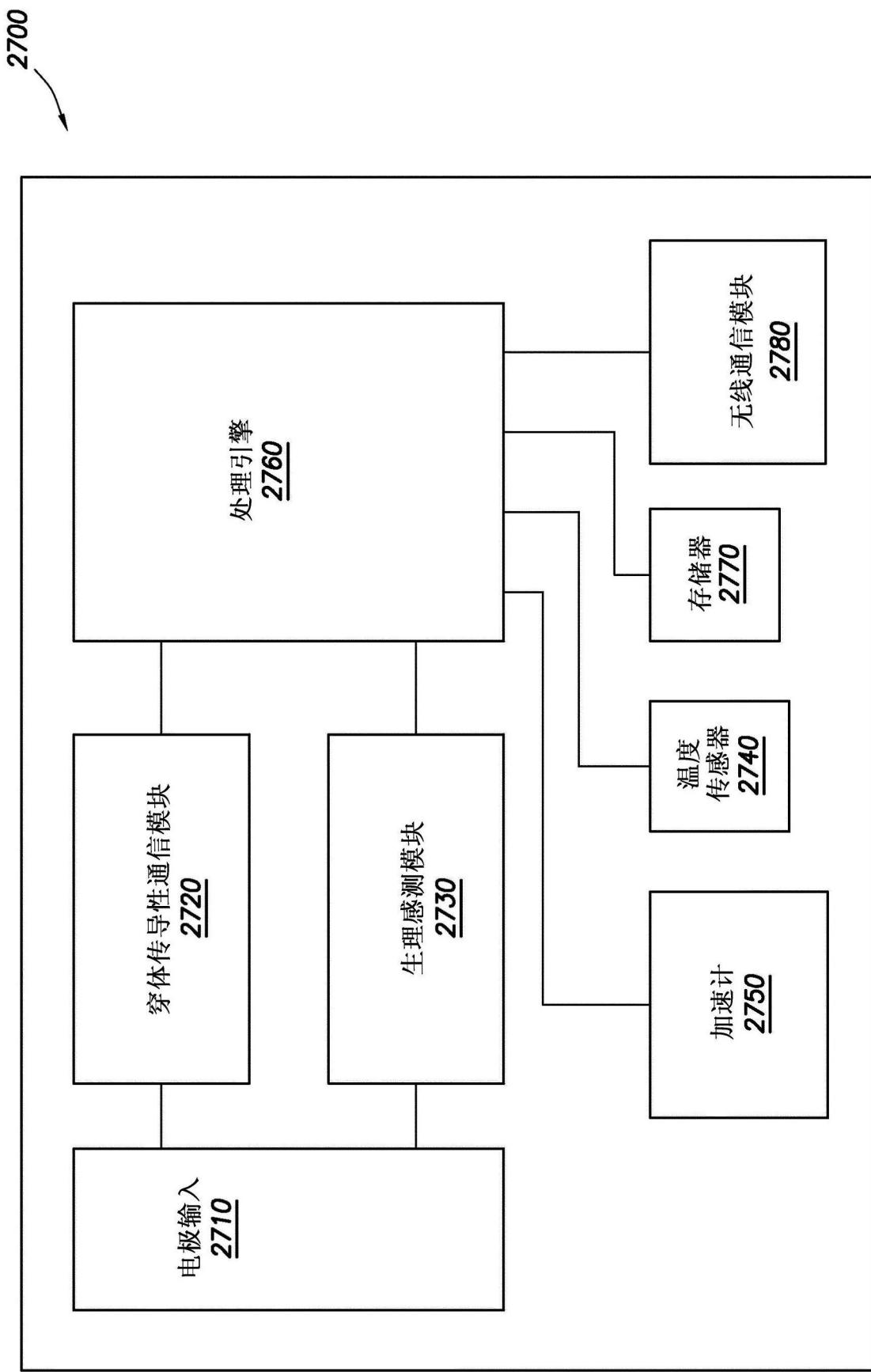


图 14

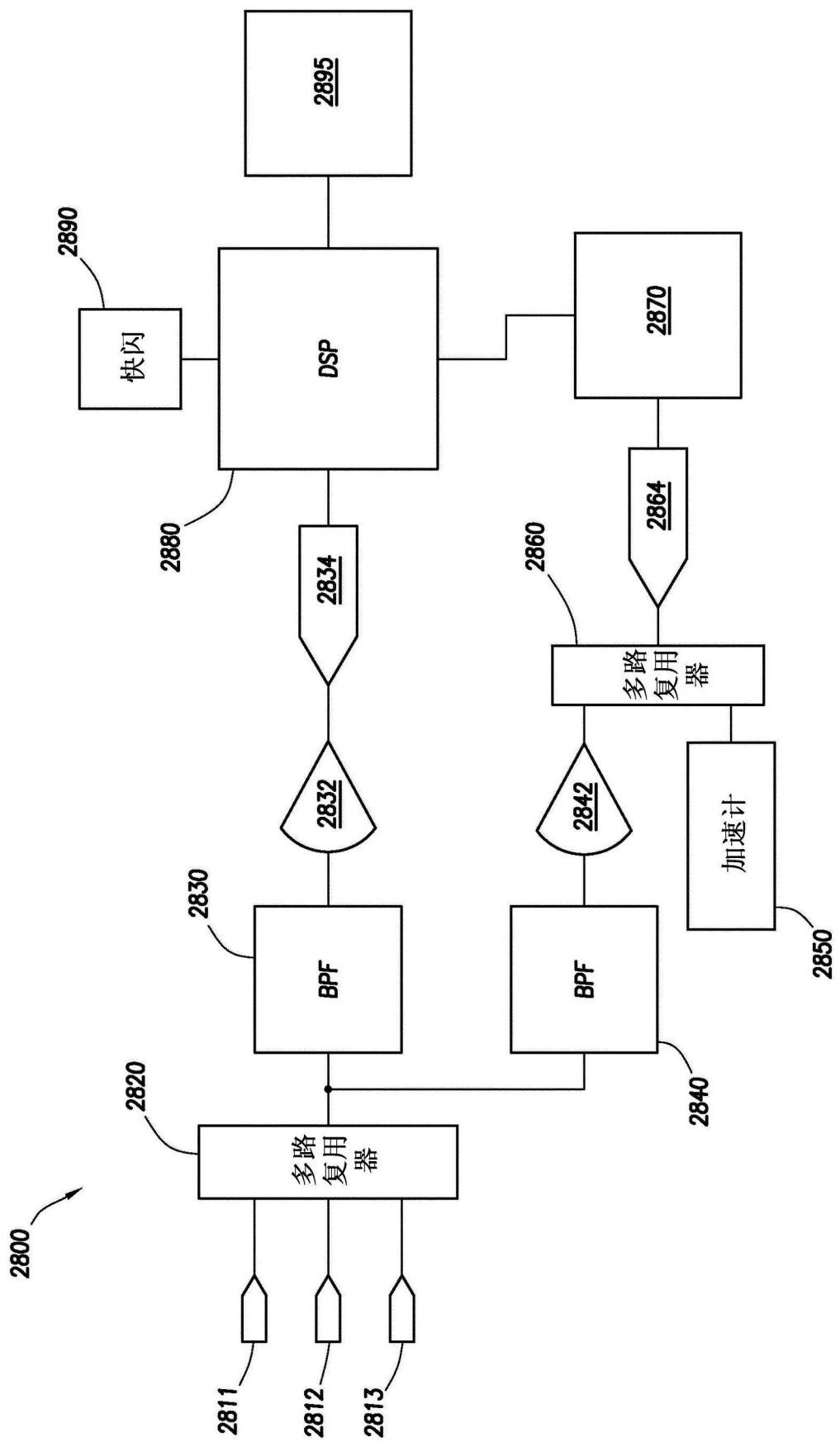


图 15

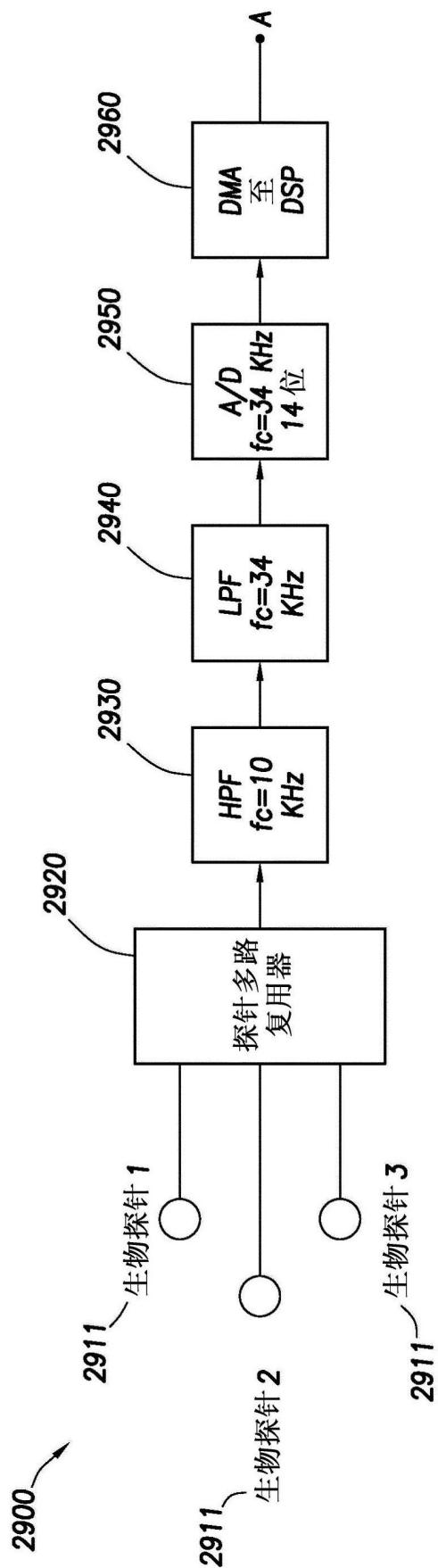


图 16

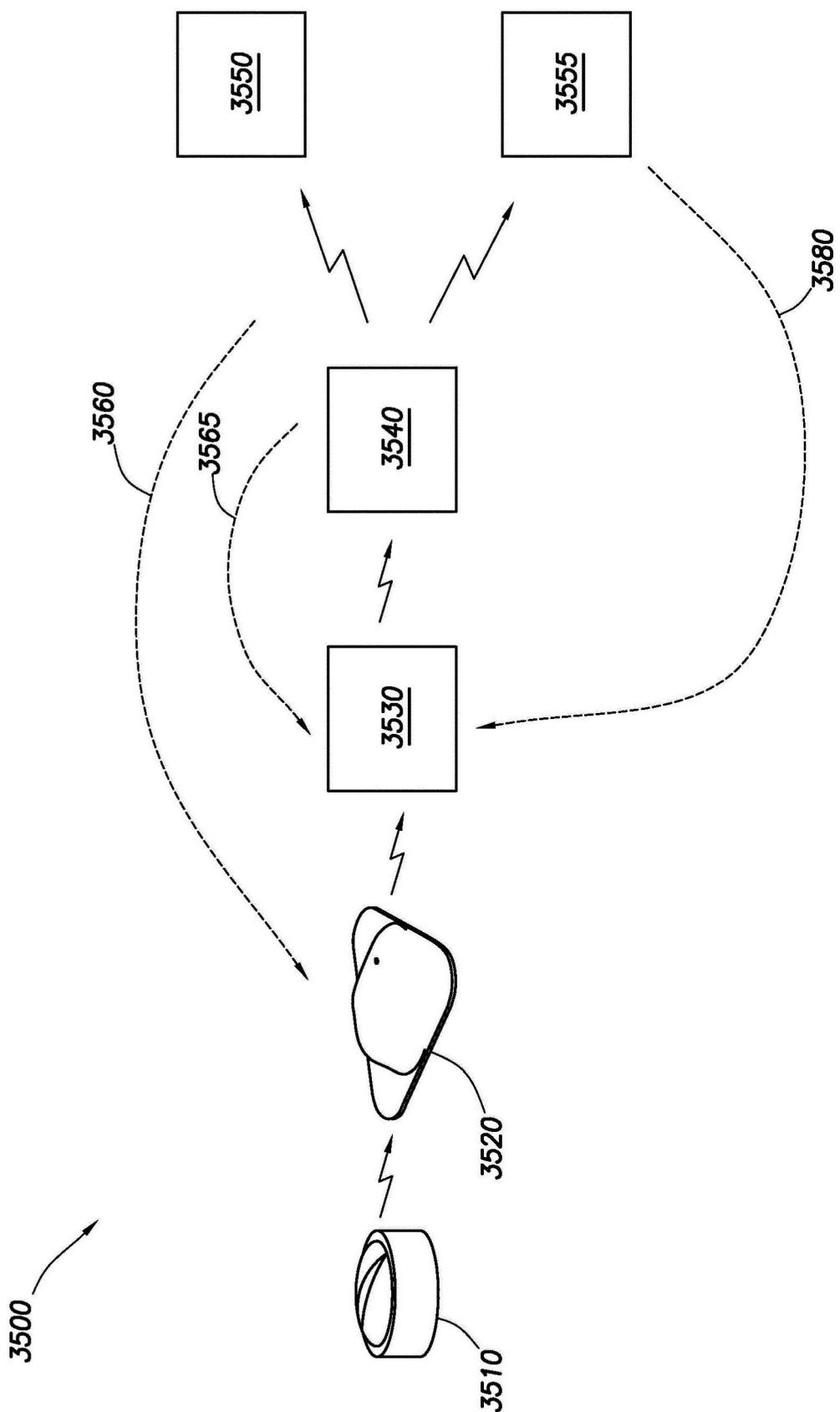


图 17

## **Abstract**

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The system of the present invention includes a conductive element, an electronic component, and a partial power source in the form of dissimilar materials. Upon contact with a conducting fluid, a voltage potential is created and the power source is completed, which activates the system. The electronic component controls the conductance between the dissimilar materials to produce a unique current signature. The system can also measure the conditions of the environment surrounding the system.