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[Continued on next page]

(54) Title: COMMUNICATION SYSTEM USING AN IMPLANTABLE DEVICE

(57) Abstract: The system of the present invention includes an implantable device that can detect high and low frequency current signature. The implantable device can communicate with a communication device that includes a conductive element, an electronic component, and a partial power source in the form of dissimilar materials. Upon contact with a conducting fluid, the communication device is activated.

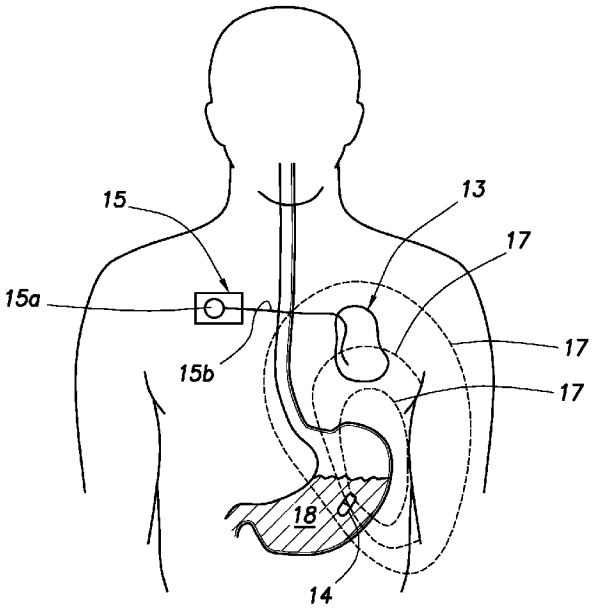

FIG. 1

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COMMUNICATION SYSTEM USING AN IMPLANTABLE DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This application is a continuation-in-part of U.S. Application No. 13/180,539 filed July 11, 2011 and entitled "Communication System Using an Implantable Device", 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 on November 2, 2006 as WO Publication 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 COMMUNICATION SYSTEM WITH REMOTE ACTIVATION (; US Application Serial No. 13/180,498 COMMUNICATION SYSTEM WITH MULTIPLE TYPES OF POWER; US Application Serial No. 13/180,525 COMMUNICATION SYSTEM WITH ENHANCED PARTIAL POWER AND METHOD OF MANUFACTURING SAME; US Application Serial No. 13/180,538

POLYPHARMACY CO-PACKAGED MEDICATION DOSING UNIT INCLUDING COMMUNICATION SYSTEM THEREFOR; and US Application Serial No. 13/180,507 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 communication between an implantable lead and an ingestible device.

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. Another aspect of the present invention is that the ingestible circuitry communicated with devices implanted in the patient. Thus, upon ingestion information can be received from or sent to the implantable device from the ingestible circuitry.

BRIEF DESCRIPTION OF THE FIGURES

[009] Fig. 1 shows an event indicator system in communication with an implanted device in according to the teaching of the present invention.

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

[018] FIG. 7 is a functional block diagram of a demodulation circuit that performs coherent demodulation that may be present in a receiver, according to one aspect.

[019] FIG. 8 illustrates a functional block diagram for a beacon module within a receiver, according to one aspect.

[020] FIG. 9 is a block diagram of the different functional modules that may be present in a receiver, according to one aspect.

[021] FIG. 10 is a block diagram of a receiver, according to one aspect.

[022] FIG. 11 provides a block diagram of a high frequency signal chain in a receiver, according to one aspect.

[023] FIG. 12 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

[024] 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. The term “implantable” includes any device that is fully implanted or partially implanted as well as devices that are surgically placed within

the body, such a lead in the heart, and devices that are place under the skin or do not require surgery to be inserted into the body.

[025] 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.

[026] Referring now to Fig. 1, an ingestible capsule 14, which includes a system of the present invention, is shown inside the body. The capsule 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 capsule 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. Additionally, the system of the present invention may be ingested without a pharmaceutical product via a carrier capsule that includes only the system with no other active agent. For example, the system may be used to program an implantable device 15.

[027] The implantable device 15 includes at least one of a pacemaker 15a (sometimes referred to as a can) and a lead 15b. An example of the lead is disclosed in US Patent No. 7,214,189, entitled “Methods and Apparatus for Tissue Activation and Monitoring”, the entire disclosure of which is incorporated herein by reference. As the system of the capsule 14 is activated, a current signature 17 flows through the user’s body as discussed in detail below at least with respect to Fig. 5. The current path can take any path 17. As the current reaches the lead 15b, which is positioned in the user’s heart 13, the lead 15b detects and sends the information

to the pacemaker 15a. The pacemaker 15a can decode and determine the information encoded in the current signature. Thus, the system in the capsule 14 is able to send information to the pacemaker and the pacemaker either stores the information for later transmission or transmits the information immediately. In accordance with another aspect of the present invention, the system in the capsule 14 includes programming information for the pacemaker 15a. Thus, upon ingestion of the capsule 14 and activation of the system therein, the current signature of the system will encode information in the current signature produced by the system. The information is then received by the pacemaker 15a through the lead 15b and the pace make 15a is programmed accordingly. The lead and the pacemaker 15 a can detect and decode high frequency information associated with the system as well as detect low frequency information associated with the heart.

[028] Referring now to Fig. 2A, a pharmaceutical product 10, similar to the capsule 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.

[029] 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.

[030] Referring now to Fig. 2B, a pharmaceutical product 20, similar to the capsule 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.

[031] 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.

[032] 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 CuI. 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 μm thick, such as from about

5 to about 100 μm 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.

[033] 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 μm thick, such as from about 5 to about 100 μm 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.

[034] 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 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.

[035] 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. Embodiments 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+) on platinum, gold or other catalytic surfaces
Intercalation compounds	Graphite with Li, K, Ca, Na, Mg	Vanadium oxide Manganese oxide

[036] 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.

[037] 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. 7 to 12, as described hereinafter.

[038] 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.

[039] 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.

[040] 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.

[041] 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.

[042] 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.

[043] 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.7 to 12 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 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.

[044] 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.

[045] 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. 7 to 12, as described hereinafter. 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.

[046] 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 travel between material 34 to material 36 and through the conducting fluid that is 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.

[047] The system 30 also includes a unit 75. The unit 75 includes communication functions and in accordance with the various aspects of the present invention can act as any of the following: a receiver, a transmitter, or a transceiver. Thus, another device that is external to the system 30, such as a cell phone, an implanted device, a device attached to the user's body, or a device placed under the user's skin can communicate with the system 30 through the unit 75. The unit 75 is also electrically connected to the materials 34 and 36. In accordance with one aspect of the present invention, any device that is external to the system 30 may communicate with either the unit 75 or the control module 38 using current flow through the environment surrounding the system 30. For example, a patch or receiver that is attached to the user's body, a cell phone or device being held by the user, or an implanted device, any of which can generate a current signature through the user's body. The current signature can include information that is encoded therein. The current signature is detected by the system 30, using the unit 75 or the control module 38, and decoded to allow communication to the system 30 from the device external to system 30. Accordingly, the external device can send a signal to the unit 75, either wirelessly or through transconduction, that controls the activation of the system 30.

[048] 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.

[049] 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- 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.

[050] 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.

[051] 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.

[052] 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.

[053] 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.

[054] 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.

[055] 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.

[056] 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.7 to 12, 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.

[057] 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. In another aspect, not shown, the switch 64 and the memory 66 can be combined into one device.

[058] 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.

[059] In certain aspects, the ingestible circuitry includes a coating layer. 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. 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.

[060] 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.

[061] 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.

[062] 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.

[063] 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. 7 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. 7. FIG. 7 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.

[064] 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.

[065] In another example, the receiver includes a beacon module as shown in the functional block diagram of FIG. 8. The scheme outlined in FIG. 8 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.

[066] FIG. 9 provides a block functional diagram of an integrated circuit component of a signal receiver according to an aspect of the invention. In FIG. 9, 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).

[067] FIG. 10 provides a more detailed block diagram of a circuit configured to implement the block functional diagram of the receiver depicted in FIG. 9, according to one aspect of the invention. In FIG. 10, 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.

[068] 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.

[069] 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.

[070] 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.

[071] 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.

[072] 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.

[073] Also shown in FIG. 10 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.

[074] 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.

[075] With, for example, an idle state in mind, the following paragraphs provide example configurations of receiver components shown in FIG. 10 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.

[076] 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.

[077] 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.

[078] 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 uA 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.

[079] 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 in 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 uA per MHz clock speed.

[080] The low power processor (e.g., MSP shown in FIG. 10) and high power processor (e.g., DSP shown in FIG. 8) 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. 10. The discussion, however, may apply to other processors than those shown in FIG. 10.

[081] FIG. 11 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. 11, 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.

[082] An example of a system that includes a receiver is shown in FIG. 12. In FIG. 12, 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.

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

[084] 1 An implantable device for communication with a communication device that communicates information using a current signature, the communication device comprising

[085] a support structure;

[086] a first material physically associated with the support structure; and

[087] a second material physically associated with the support structure at a location different from the location of the first material, such that the first material and second material are electrically isolated from each other,

[088] wherein the support structure includes a control module for controlling the conductance between the first material and the second material to produce a high frequency current signature with information and wherein the implantable device can detect and decode the high frequency current signature as well as a low frequency current signature.

[089] 2. The device of clause 1, wherein the low frequency current signature is produced by a user's body.

[090] 3. The device of clause 1 or 2, further comprising a satellite unit including a processor and a plurality of electrodes, wherein at least one electrode receives the high frequency current signature.

[091] 4. A system comprising a device according to any of the preceding clauses, and an implantable device in communication with the communication device, which implantable device includes at least one of a pacemaker and a lead.

[092] 5. A system for communication, the system comprising:

[093] a communication device to communicate information using a current signature, wherein the device comprises:

[094] a support structure;

[095] a first material physically associated with the support structure; and

[096] a second material insulated from the first material and physically associated with the support structure at a location different from the location of the first material, such that the first material and second material are electrically isolated from each other,

[097] wherein the support structure includes a control module for controlling the conductance between the first material and the second material to produce a current signature with information; and

[098] an implantable device associated with a user's body, wherein the implantable device detects and decodes the information produced by the communication device,

[099] wherein the communication device produces the current signature when the communication device in is contact with a conducting fluid.

[0100] 6. The system of clause 5 further comprising a non-conductive membrane secured to the support structure and positioned relative to the first and second materials to facilitate extension of the electrical path between the first and second material.

[0101] 7. The system of clause 5 or 6, wherein the implantable device is at least one of an implantable stimulation device and an implantable sensing device positioned within the heart to provide pacing pulses to the heart.

[0102] 8. The system of any of the clauses 5-7 wherein the implantable device is selected from a group consisting essentially of an implantable neural device and an implantable cardiac device.

[0103] 9. The system of any of the preceding clauses 5-8 further comprising a pharmaceutical product in an ingestible form associated, the pharmaceutical product associated with the communication device.

[0104] 10. The system of any of the preceding clauses 5-9, wherein the communication device is housed within a capsule that disintegrates upon contact with the conducting fluid and wherein the communication device delivers at least one of programming information and an instruction for the implantable device.

[0105] 11. The system according to any of the preceding clauses 5-10 wherein the information includes the identity of the communication device,

and/or wherein the information includes the time of activation of the communication device.

[0106] 12. The system according to any of the preceding clauses 5-11 wherein the implantable device is a detector positioned under the skin for recording information associated with the device.

[0107] 13. An implantable unit for delivering a pacing pulse and for communication a communication device, the implantable lead comprising:

[0108] at least one conducting wire;

[0109] a processor coupled to the wire, the processor comprising:

[0110] a bus;

[0111] high frequency detection module coupled to the bus for receiving and decoding a high frequency current signature;

[0112] a low frequency detection module coupled to the bus for receiving low frequency current signature;

[0113] a plurality of individually addressable electrodes coupled to the processor, each electrode able to receive at least one of the high frequency current signature and the low frequency current signature, wherein the high frequency current signature includes information encoded therein for communication and the low frequency current signature is related to physiological parameter.

[0114] 14. Device and/or system according to any of the preceding clauses further comprising a pharmaceutical product.

[0115] 15. Use of a voltage potential difference creatable on ingestion of a device or system according to clause 14, to power up control logic within the device, which control logic controls conductance through the conducting fluid between the first and second materials.

[0116] 16. System comprising a device according to any of the clauses 1-3 and a unit according to clause 13.

[0117] 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.

[0118] 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.

[0119] 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.

[0120] 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.

[0121] 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.

[0122] 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.

[0123] 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.

[0124] 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. An implantable device for communication with a communication device that communicates information using a current signature, the communication device comprising:

a support structure;

a first material physically associated with the support structure; and

a second material physically associated with the support structure at a location different from the location of the first material, such that the first material and second material are electrically isolated from each other,

wherein the support structure includes a control module for controlling the conductance between the first material and the second material to produce a high frequency current signature with information and

wherein the implantable device can detect and decode the high frequency current signature as well as a low frequency current signature.

2. The implantable device of claim 1, wherein the low frequency current signature is produced by a user's body.

3. The implantable device of claim 1, further comprising a satellite unit including a processor and a plurality of electrodes, wherein at least one electrode receives the high frequency current signature.

4. A system for communication, the system comprising:

a communication device to communicate information using a current signature, wherein the device comprises:

a support structure;

a first material physically associated with the support structure; and

a second material insulated from the first material and physically associated with the support structure at a location different from the

location of the first material, such that the first material and second material are electrically isolated from each other,

wherein the support structure includes a control module for controlling the conductance between the first material and the second material to produce a current signature with information; and

an implantable device associated with a user's body, wherein the implantable device detects and decodes the information produced by the communication device,

wherein the communication device produces the current signature when the communication device in is contact with a conducting fluid.

5. The system of claim 4 further comprising a non-conductive membrane secured to the support structure and positioned relative to the first and second materials to facilitate extension of the electrical path between the first and second material.

6. The system of claim 5, wherein the implantable device is at least one of an implantable sensing device and an implantable stimulation device positioned within the heart to provide pacing pulses to the heart.

7. The system of claim 5, wherein the implantable device is selected from a group consisting essentially of an implantable neural device and an implantable cardiac device.

8. The system of claim 6, further comprising a pharmaceutical product in an ingestible form associated, the pharmaceutical product associated with the communication device.

9. The system of claim 6, wherein the communication device is housed within a capsule that disintegrates upon contact with the conducting fluid and wherein the communication device delivers at least one of programming information and an instruction for the implantable device.

10. The system of 6, wherein the information includes the identity of the communication device.

11. The system of 6, wherein the information includes the time of activation of the communication device.

12. The system of claim 5 wherein the implantable device is a detector positioned under the skin for recording information associated with the device.

13. An implantable unit to deliver a pacing pulse and to communicate to a communication device, the implantable lead comprising:

at least one conducting wire;

a processor coupled to the wire, the processor comprising:

a bus;

high frequency detection module coupled to the bus for receiving and decoding a high frequency current signature;

a low frequency detection module coupled to the bus for receiving low frequency current signature;

a plurality of individually addressable electrodes coupled to the processor, each electrode able to receive at least one of the high frequency current signature and the low frequency current signature, wherein the high frequency current signature includes information encoded therein for communication and the low frequency current signature is related to physiological parameter.

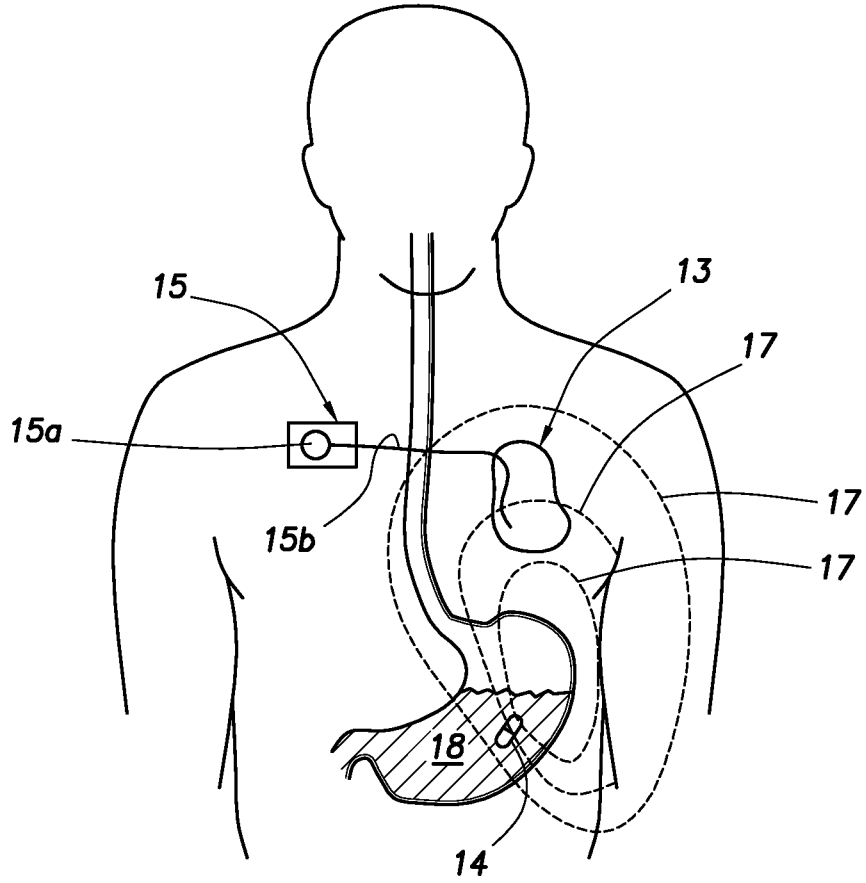

FIG. 1

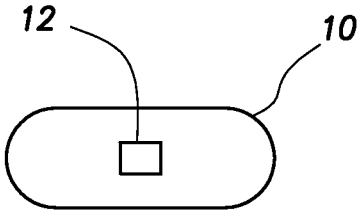

FIG.2A

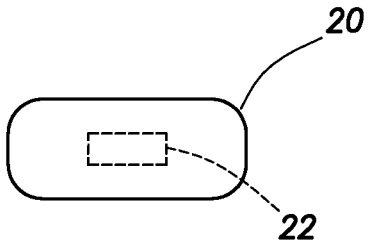

FIG.2B

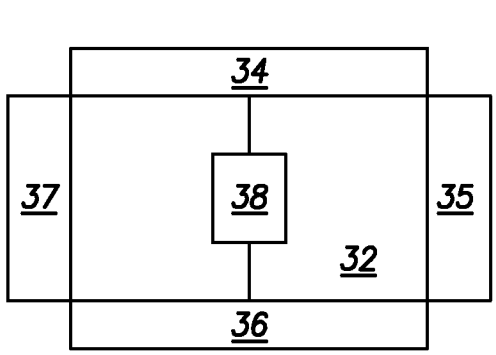

FIG.3

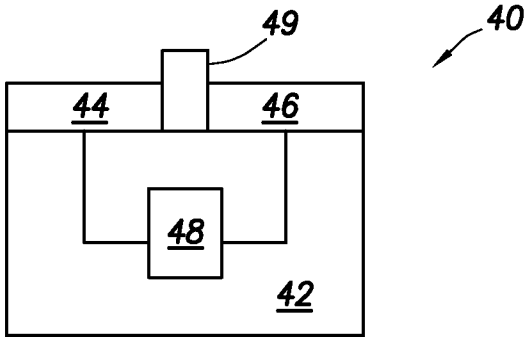

FIG.4

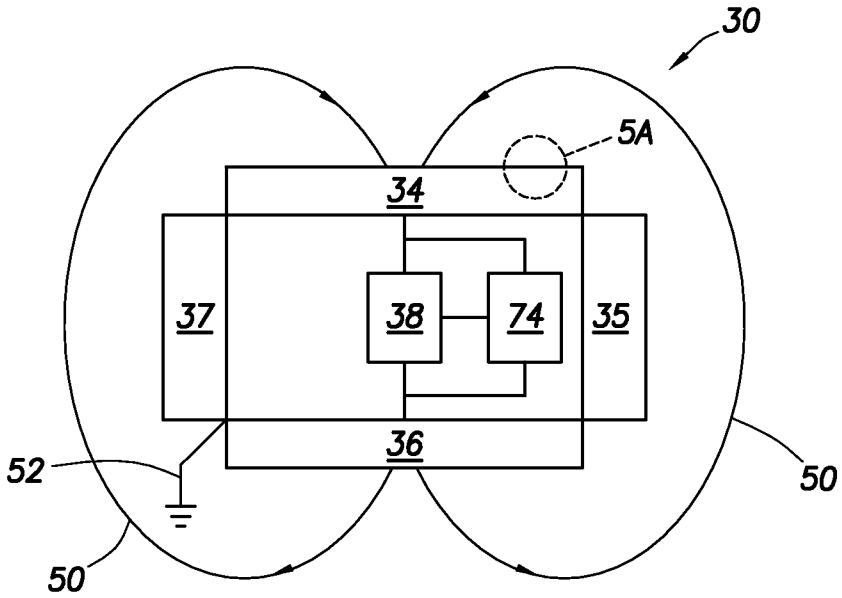

FIG.5

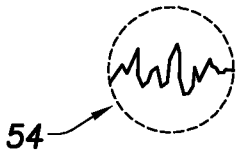

FIG.5A

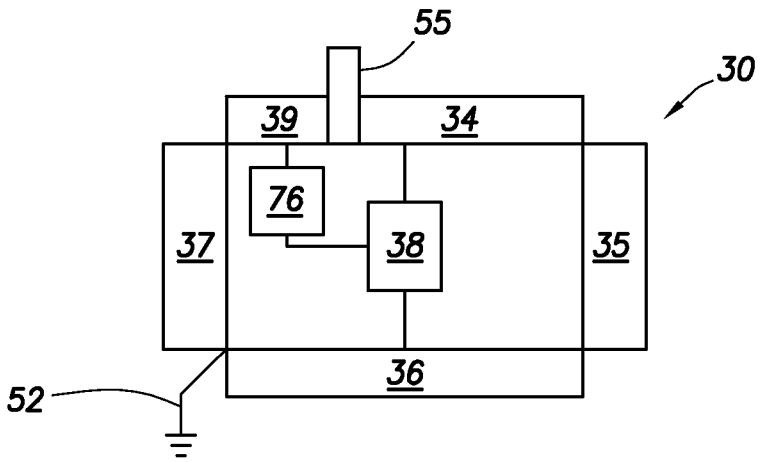

FIG.5B

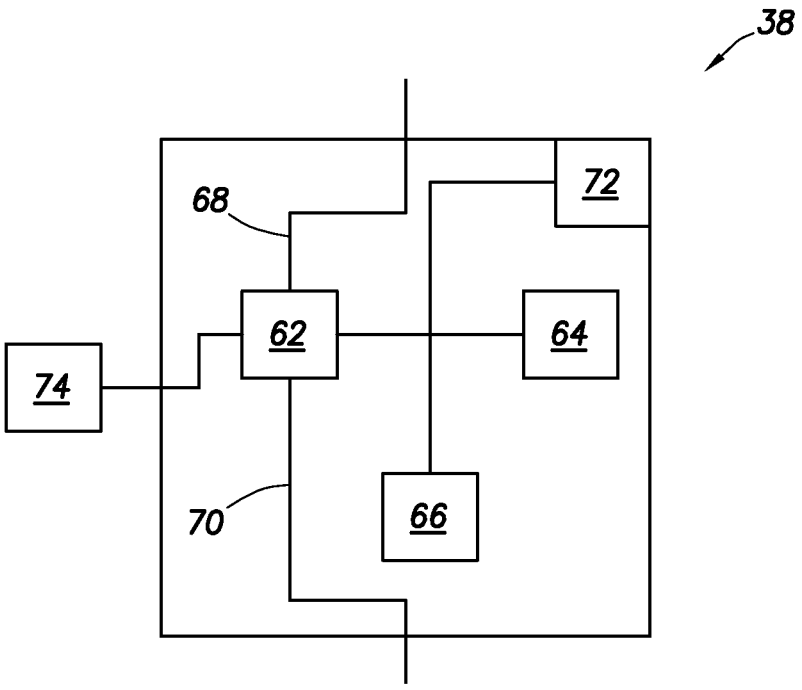

FIG.6

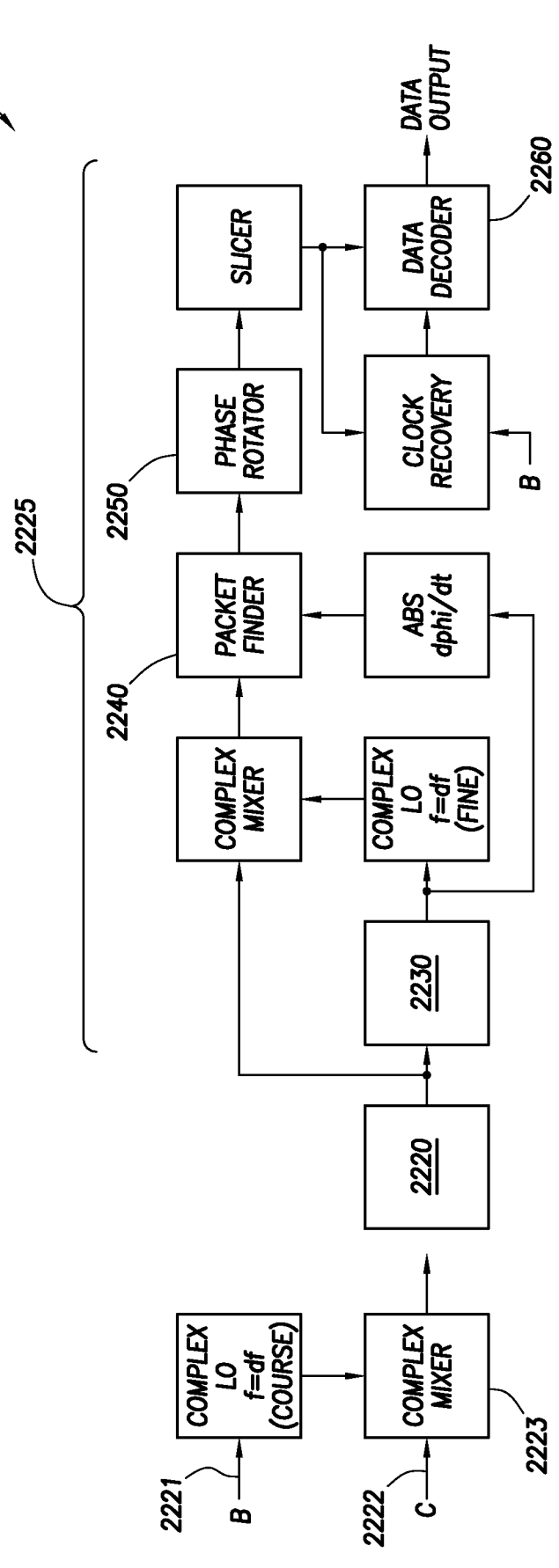
2200
2225
2221
B
2222
C
COMPLEX LO f=df (COURSE)
COMPLEX MIXER
2223
2220
2230
COMPLEX MIXER
COMPLEX LO f=df (FINE)
2240
PACKET FINDER
ABS dphi/dt
2250
PHASE ROTATOR
CLOCK RECOVERY
B
SLICER
DATA DECODER
2260
DATA OUTPUT

FIG.7

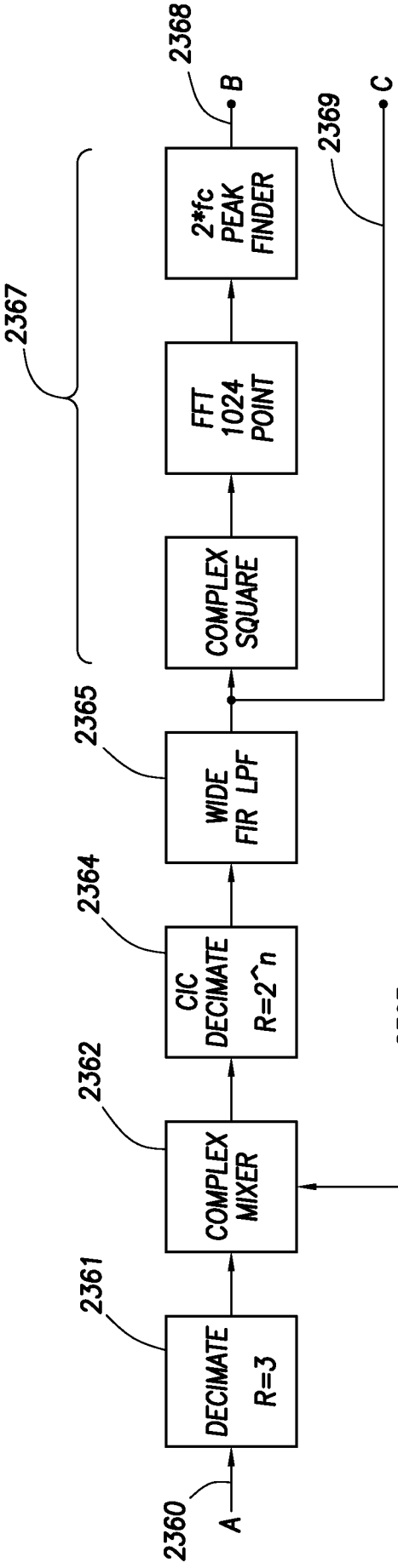
2360
A
2361
DECIMATE
R=3
2362
COMPLEX
MIXER
2363
FIXED
COMPLEX
LO
f=fcarrier
2364
CIC
DECIMATE
R=2^n
2365
WIDE
FIR LPF
2367
COMPLEX
SQUARE
FFT
1024
POINT
2368
2*fc
PEAK
FINDER
B
2369
C

FIG.8

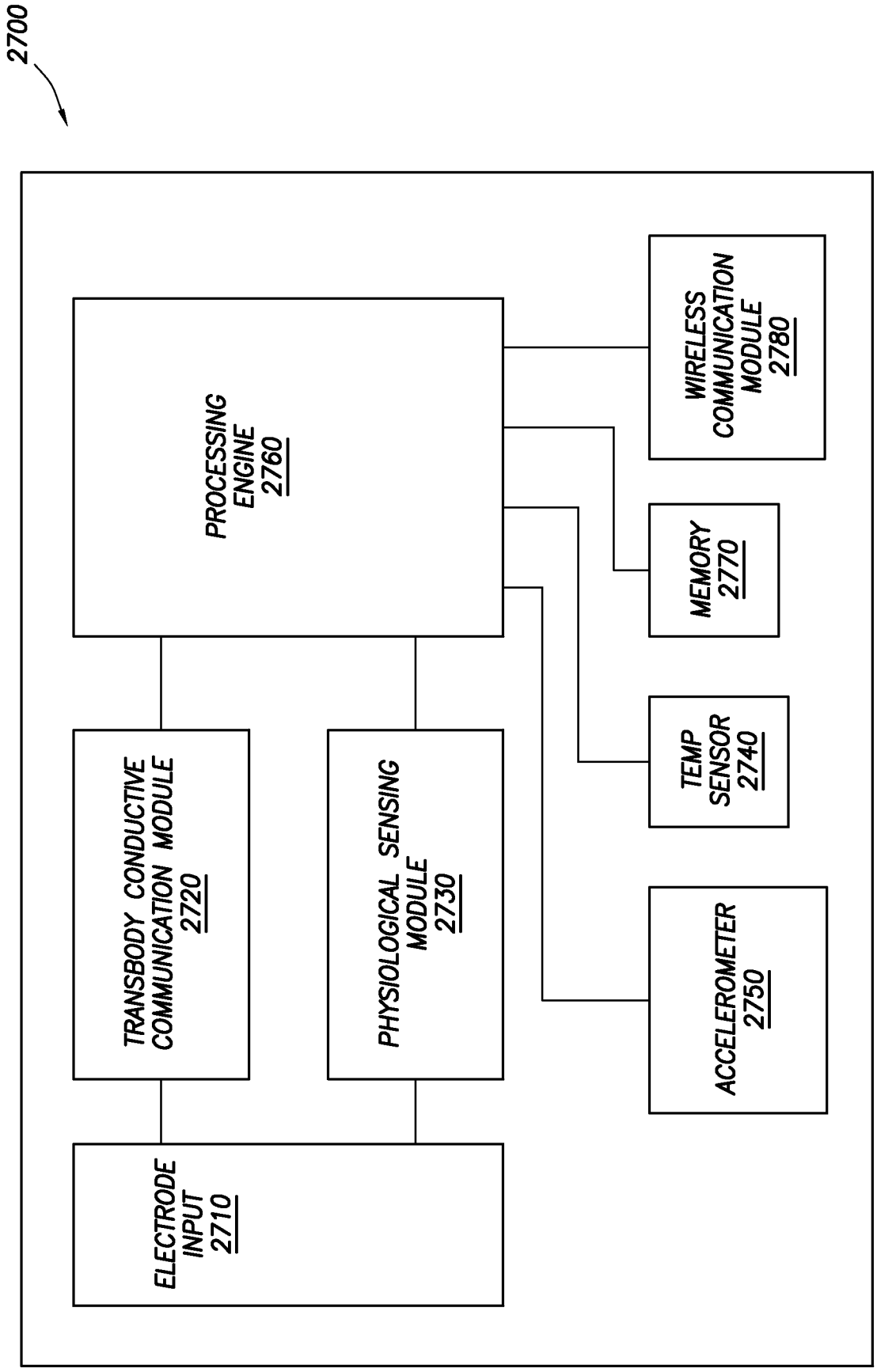
2700
PROCESSING ENGINE 2760
WIRELESS COMMUNICATION MODULE 2780
MEMORY 2770
TEMP SENSOR 2740
ACCELEROMETER 2750
TRANSBODY CONDUCTIVE COMMUNICATION MODULE 2720
PHYSIOLOGICAL SENSING MODULE 2730
ELECTRODE INPUT 2710

FIG.9

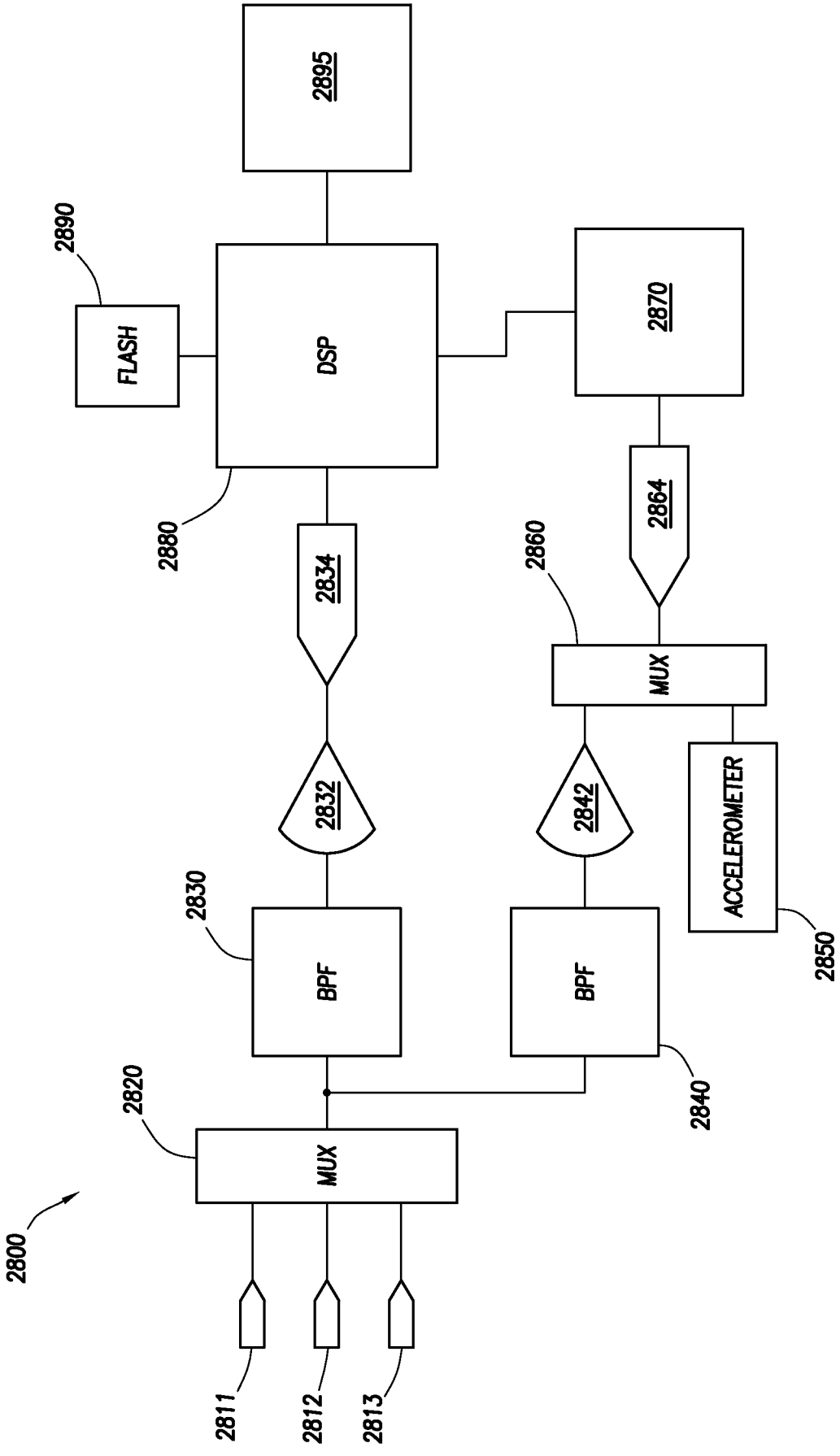
2895
2890
FLASH
DSP
2870
2880
2834
2864
2860
MUX
2832
2842
ACCELEROMETER
2830
BPF
BPF
2850
2820
2840
MUX
2800
2811
2812
2813

FIG. 10

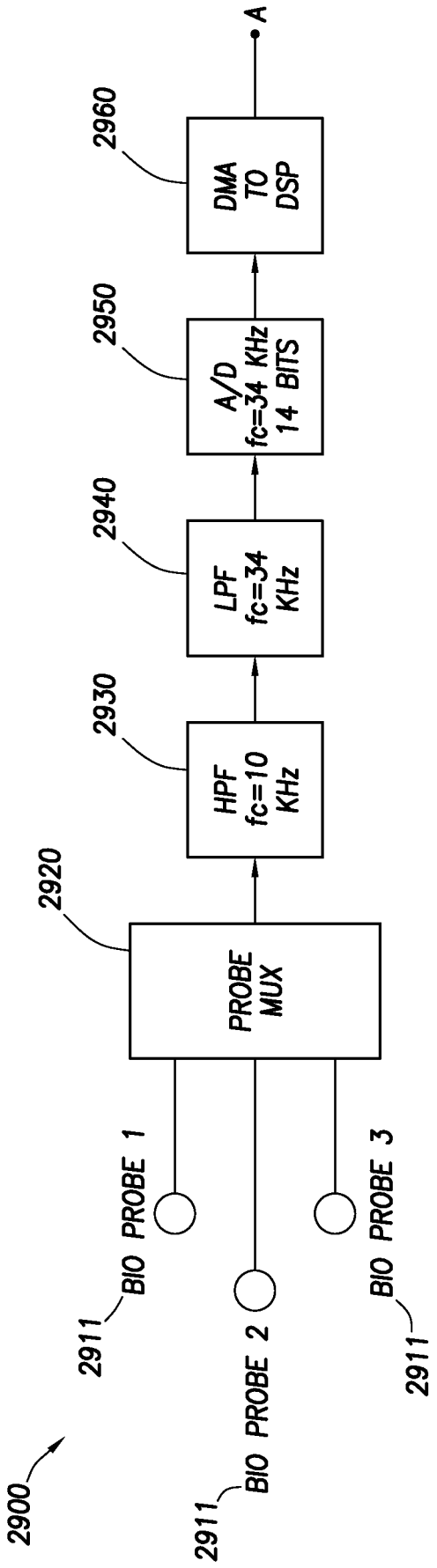
2900
2911
BIO PROBE 2
2911
BIO PROBE 1
2911
BIO PROBE 3
2920
PROBE MUX
2930
HPF fc=10 KHz
2940
LPF fc=34 KHz
2950
A/D fc=34 KHz 14 BITS
2960
DMA TO DSP
A

FIG.11

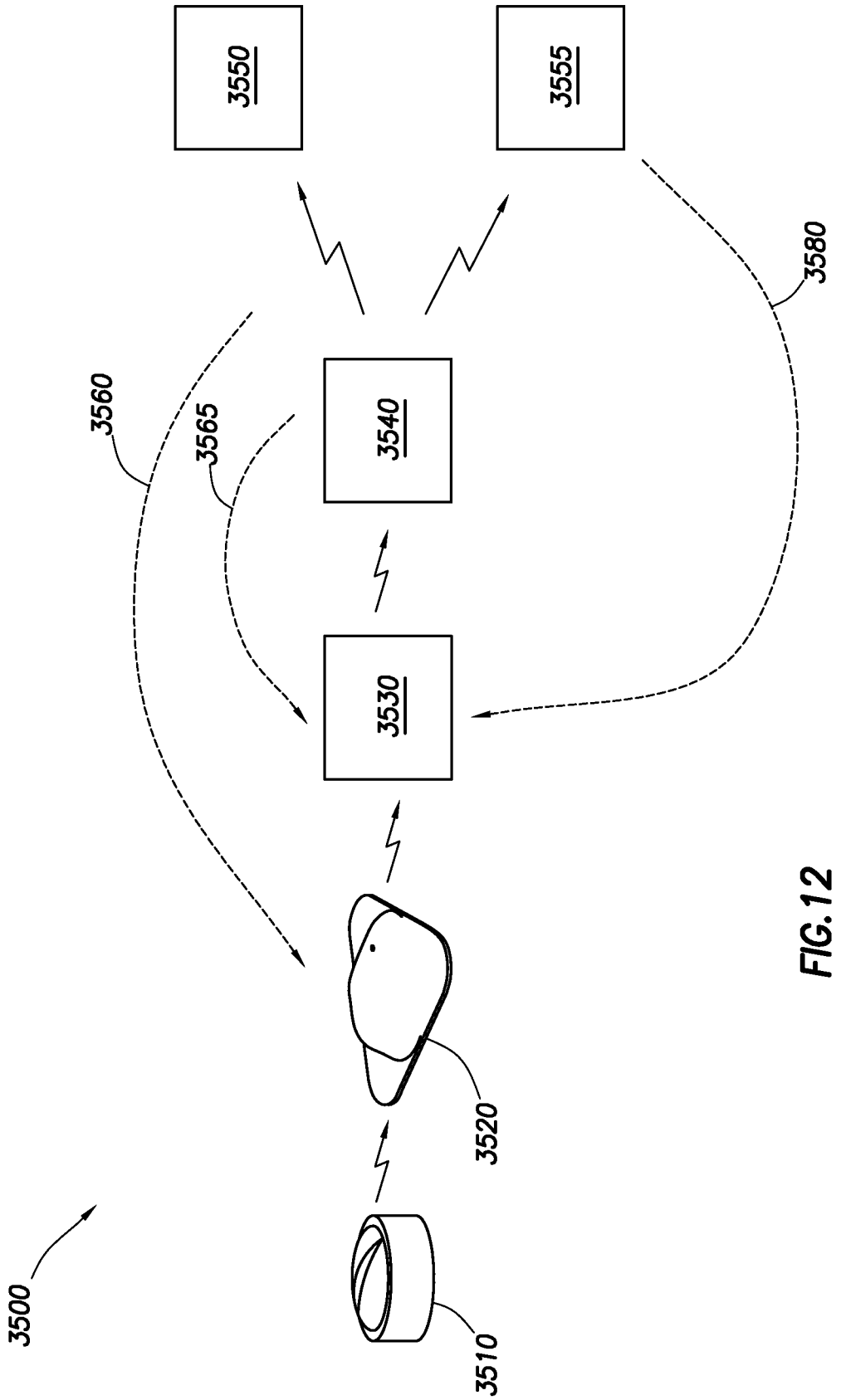

FIG. 12

专利名称(译)	使用可植入设备的通信系统		
公开(公告)号	EP2731494A4	公开(公告)日	2015-08-05
申请号	EP2012810728	申请日	2012-07-10
[标]申请(专利权)人(译)	普罗秋斯数字健康公司		
申请(专利权)人(译)	PROTEUS数字医疗，INC.		
当前申请(专利权)人(译)	PROTEUS数字医疗，INC.		
[标]发明人	THOMPSON TODD ZDEBLICK MARK J BEHZADI YASHAR COSTELLO BENEDICT ROBERTSON TIMOTHY HAFEZI HOOMAN SAVAGE GEORGE		
发明人	THOMPSON, TODD ZDEBLICK, MARK J. BEHZADI, YASHAR COSTELLO, BENEDICT ROBERTSON, TIMOTHY HAFEZI, HOOMAN SAVAGE, GEORGE		
IPC分类号	A61B5/00 A61B1/273 A61B5/05 H04B7/24		
CPC分类号	A61B5/0028 A61B5/073 A61B5/076 A61B5/14539 A61B5/4839 A61B2560/0214 A61J3/007 A61N1/37288 G16H40/67 H01Q1/273 G06F19/3418		
代理机构(译)	DUXBURY，STEPHEN		
优先权	13/180539 2011-07-11 US		
其他公开文献	EP2731494A2		
外部链接	Espacenet		

摘要(译)

本发明的系统包括可植入设备，其可以检测高频和低频电流特征。可植入设备可以与通信设备通信，该通信设备包括导电元件，电子组件和不同材料形式的部分电源。在与导电流体接触时，通信装置被激活。