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Ishikawa et al.

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(45) **Date of Patent: Sep. 25, 2001**

(54) **WIRELESS EKG**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(22) Filed: **Jan. 6, 2000**

Related U.S. Application Data

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(51) **Int. Cl.**[7] **A61B 5/0402**

(52) **U.S. Cl.** **600/509**; 600/377

(58) **Field of Search** 600/373, 374, 600/377, 509

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,564,429 10/1996 Bornn et al. 128/696

FOREIGN PATENT DOCUMENTS

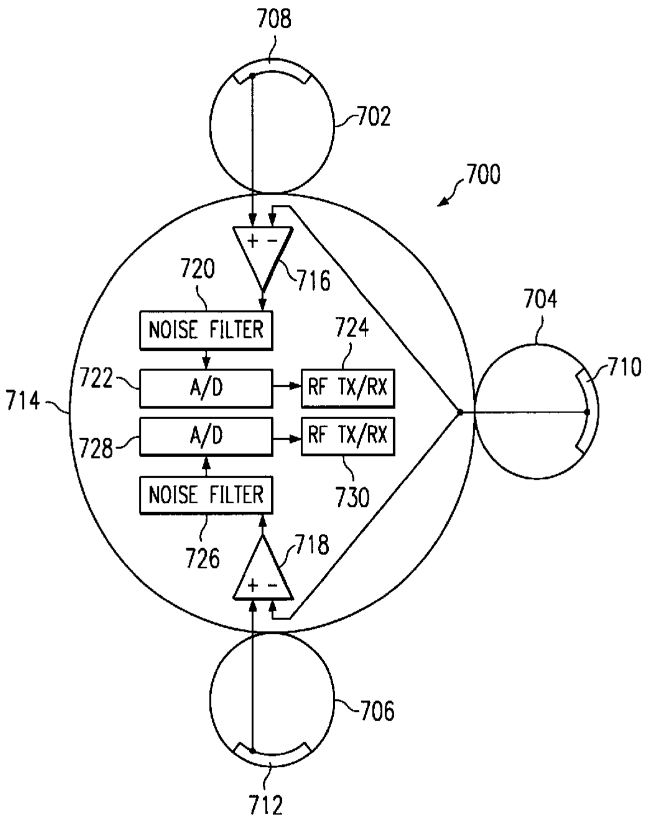
0 617 914 A1	10/1994	(EP)	A61B/5/0402
0 738 496 A1	10/1996	(EP)	A61B/5/00
0 209 804	1/1997	(EP)	A61B/5/07
WO 94/01039	1/1994	(WO)	A61B/5/04
WO 98/25090	6/1998	(WO)	F27B/15/00

Primary Examiner—Scott M. Getzow
(74) *Attorney, Agent, or Firm*—Howison, Chauza, Thoma, Handley & Arnott, L.L.P.

(57) **ABSTRACT**

A wireless electrocardiogram monitor utilizing a cooperative association of miniature semiconductor balls. A side view of a surface mount cardiac monitor system (**200**) shows three semiconductor electrode balls (**202**), (**204**), and (**206**) contacting a central communication ball (**208**) for electrical communication therebetween. Each of the electrode balls (**202**), (**204**), and (**206**) have fabricated thereon a respective electrode (**210**), (**212**), and (**214**) for receiving electrical signals from the heart. The electrode signals are passed to the central communication ball (**208**) for processing, filtering, digital conversion, and transmission therefrom to a remote control system being operated by a medical technician. The data can then be displayed to medical personnel.

42 Claims, 12 Drawing Sheets



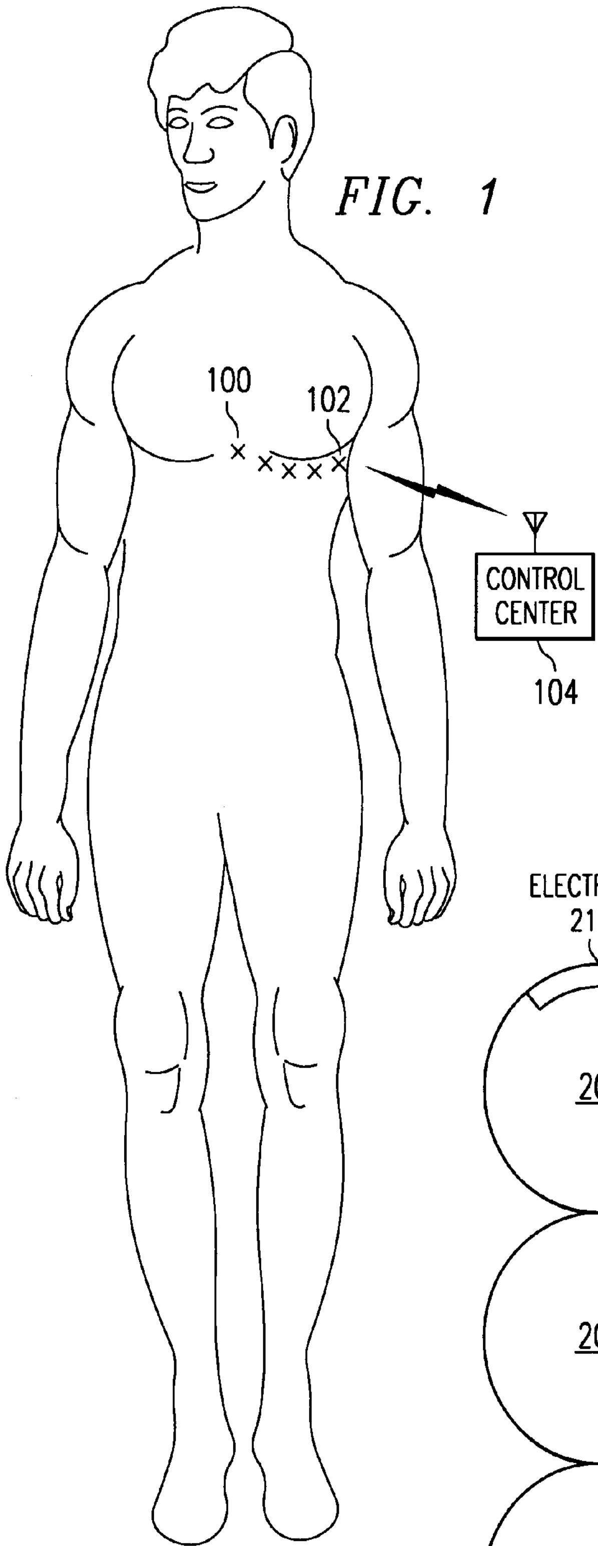


FIG. 1

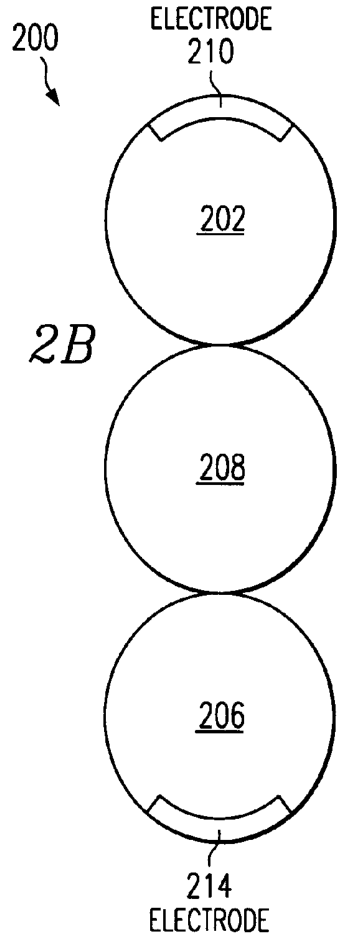


FIG. 2B

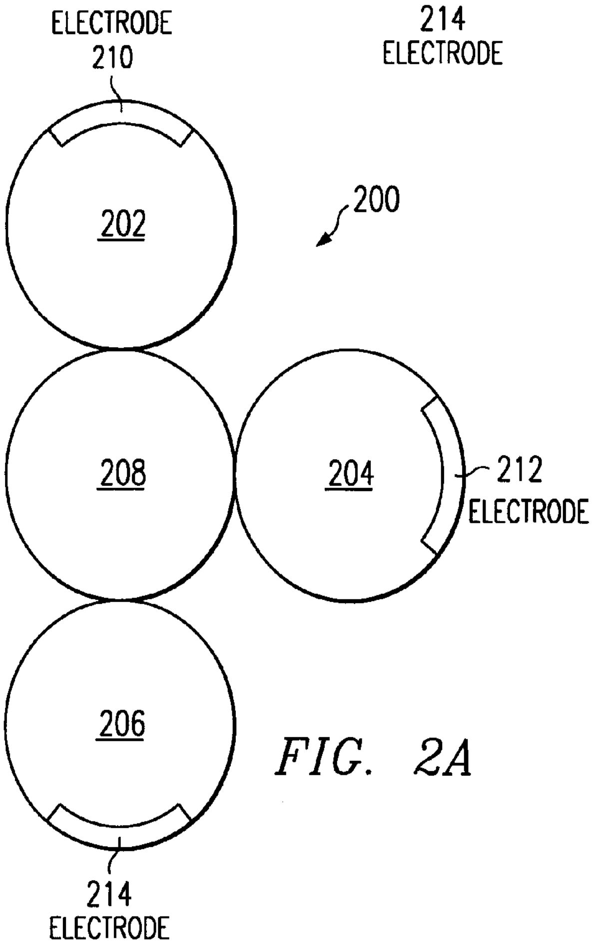


FIG. 2A

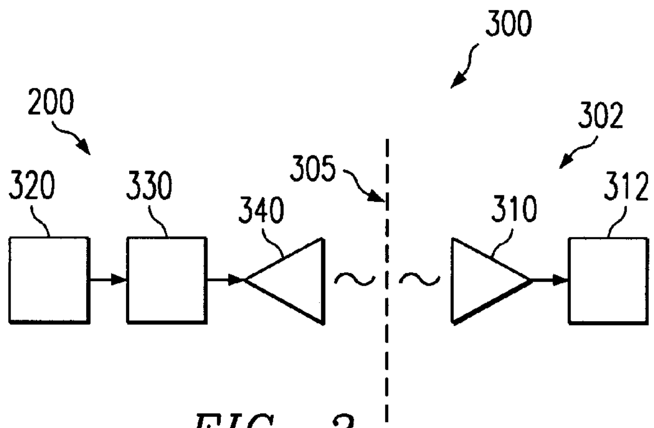


FIG. 3

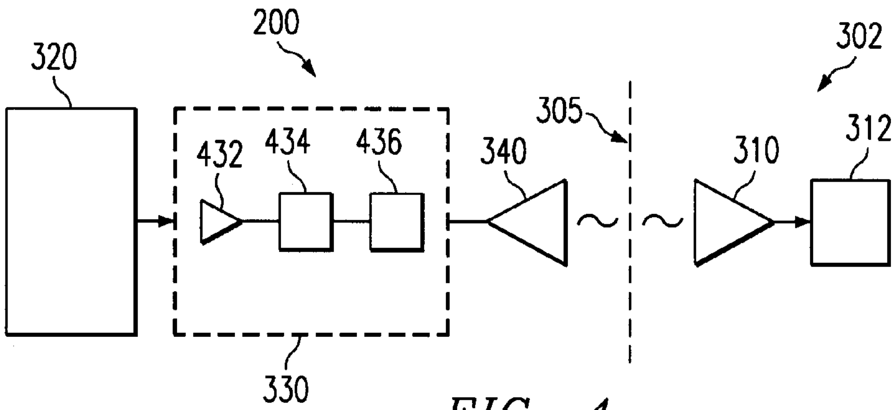


FIG. 4

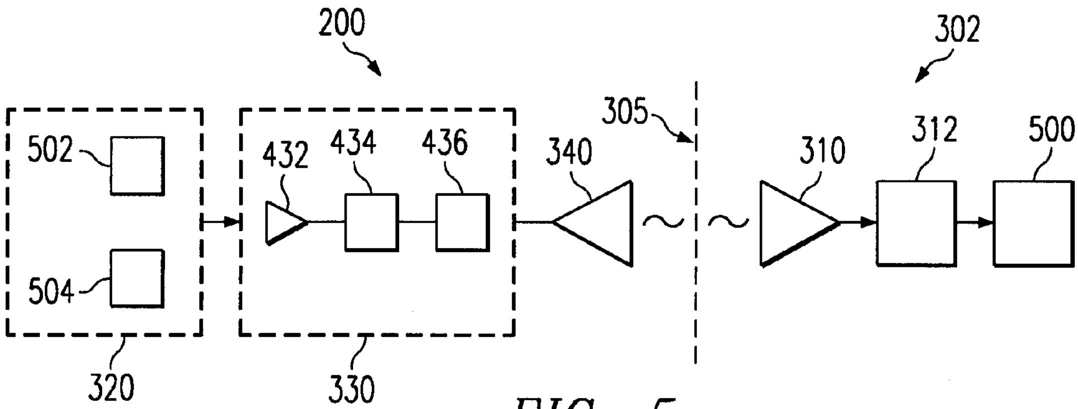


FIG. 5

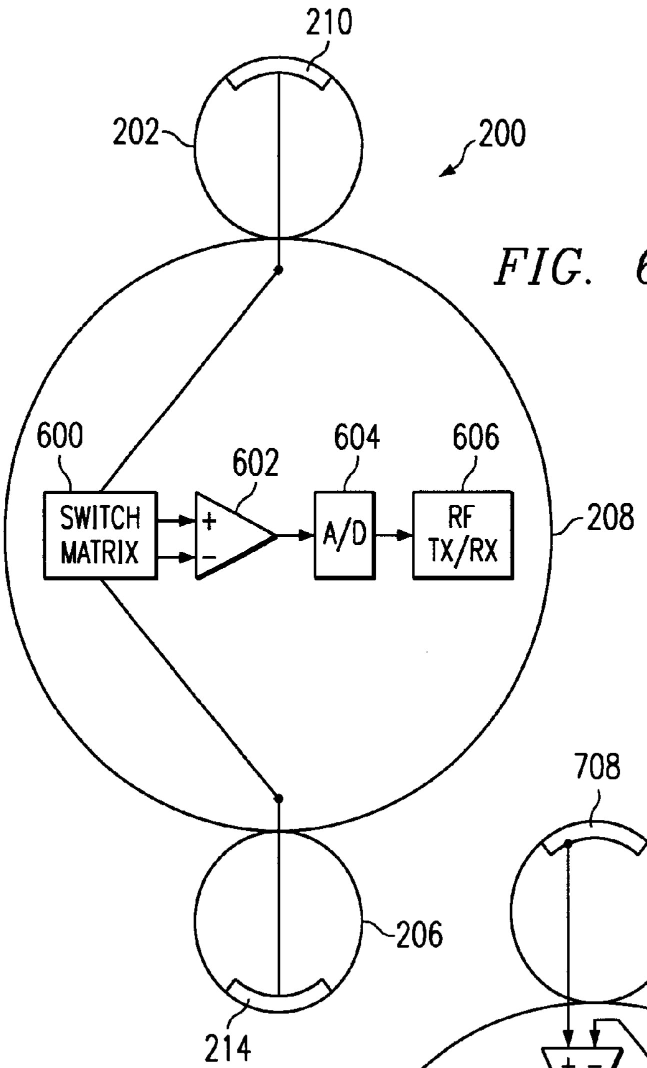

210
202
200
600
602
604
606
SWITCH MATRIX
+
−
A/D
RF TX/RX
208
206
214

FIG. 6

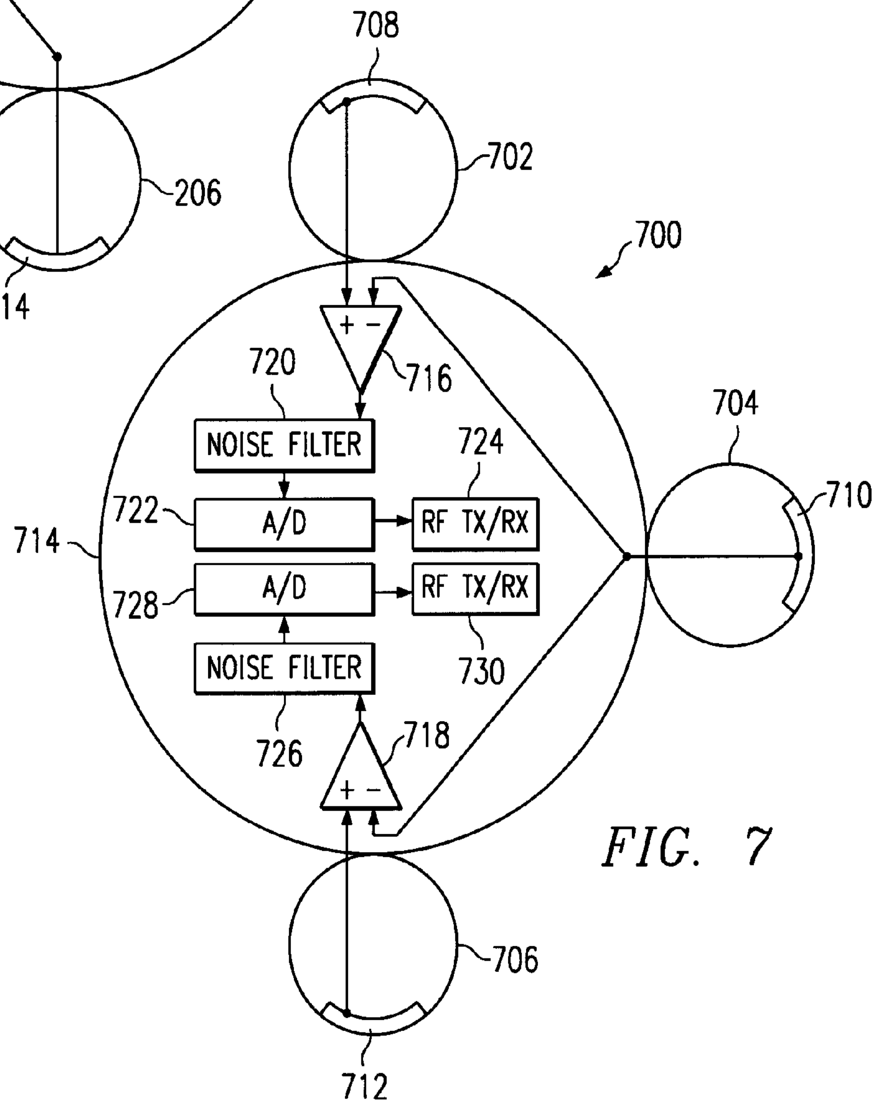

708
702
700
716
720
NOISE FILTER
724
704
722
A/D
RF TX/RX
710
714
728
A/D
RF TX/RX
730
NOISE FILTER
726
718
706
712

FIG. 7

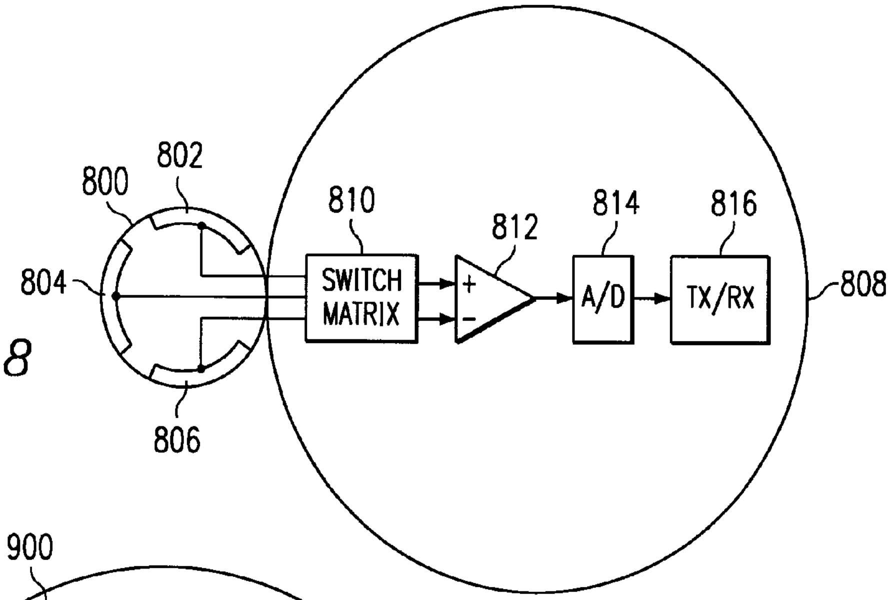


FIG. 8

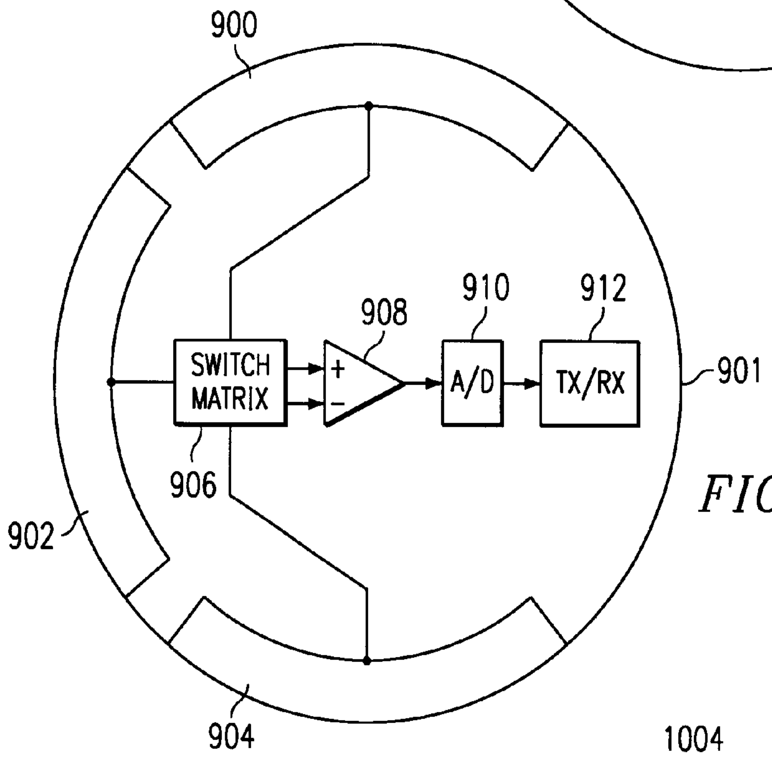


FIG. 9

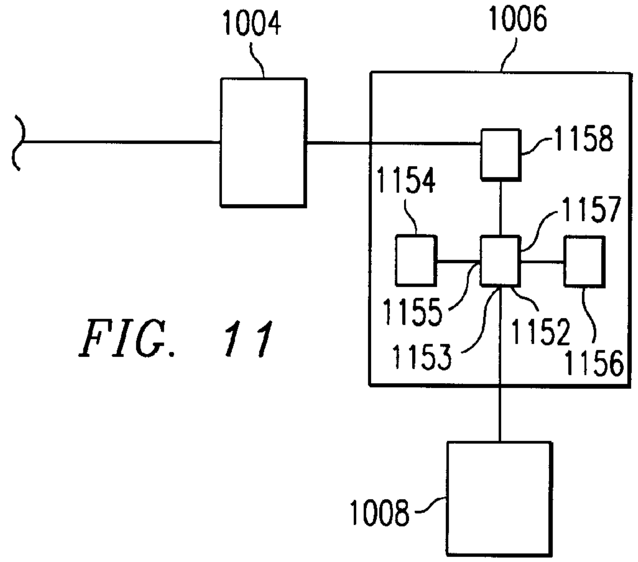


FIG. 11

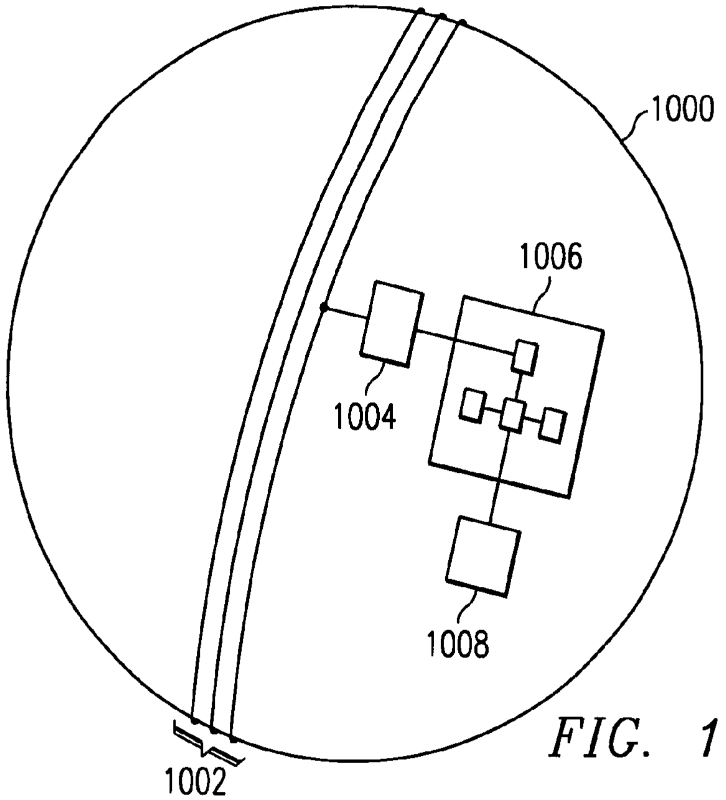

1000
1006
1004
1008
1002

FIG. 10

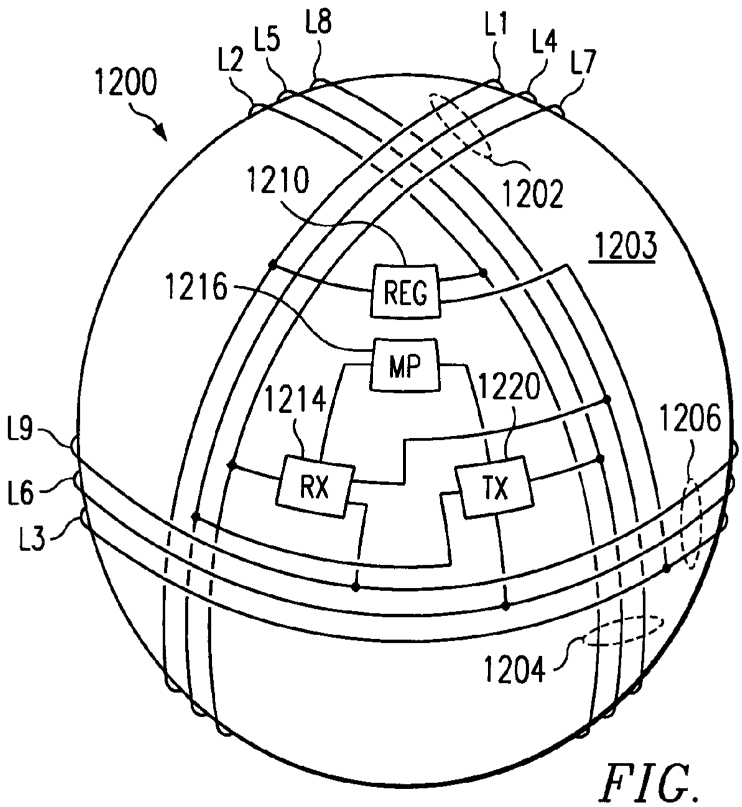

L8
L5
L2
L1
L4
L7
1200
1202
1210
1203
1216
REG
MP
1214
1220
1206
L9
L6
L3
RX
TX
1204

FIG. 12

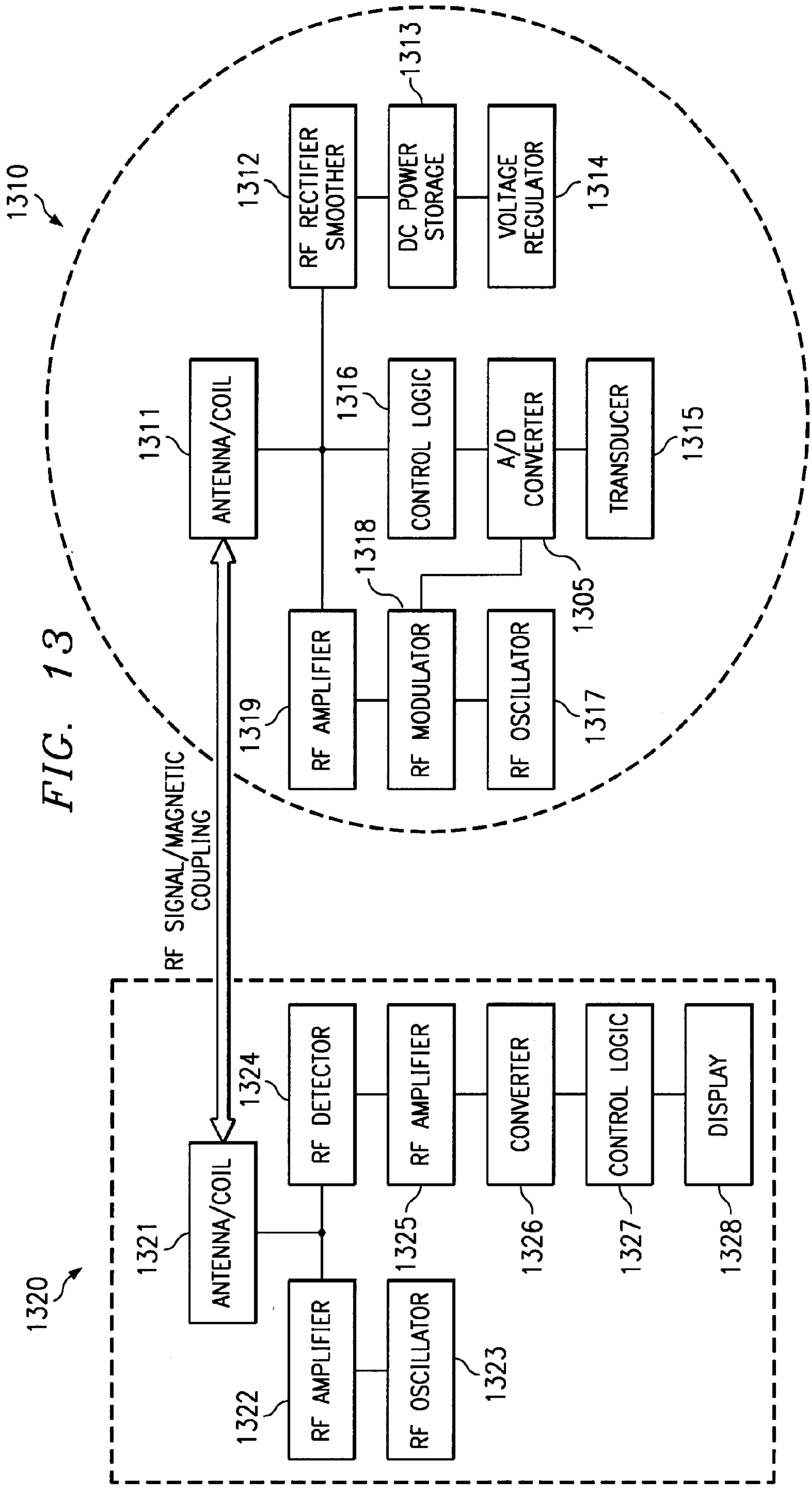
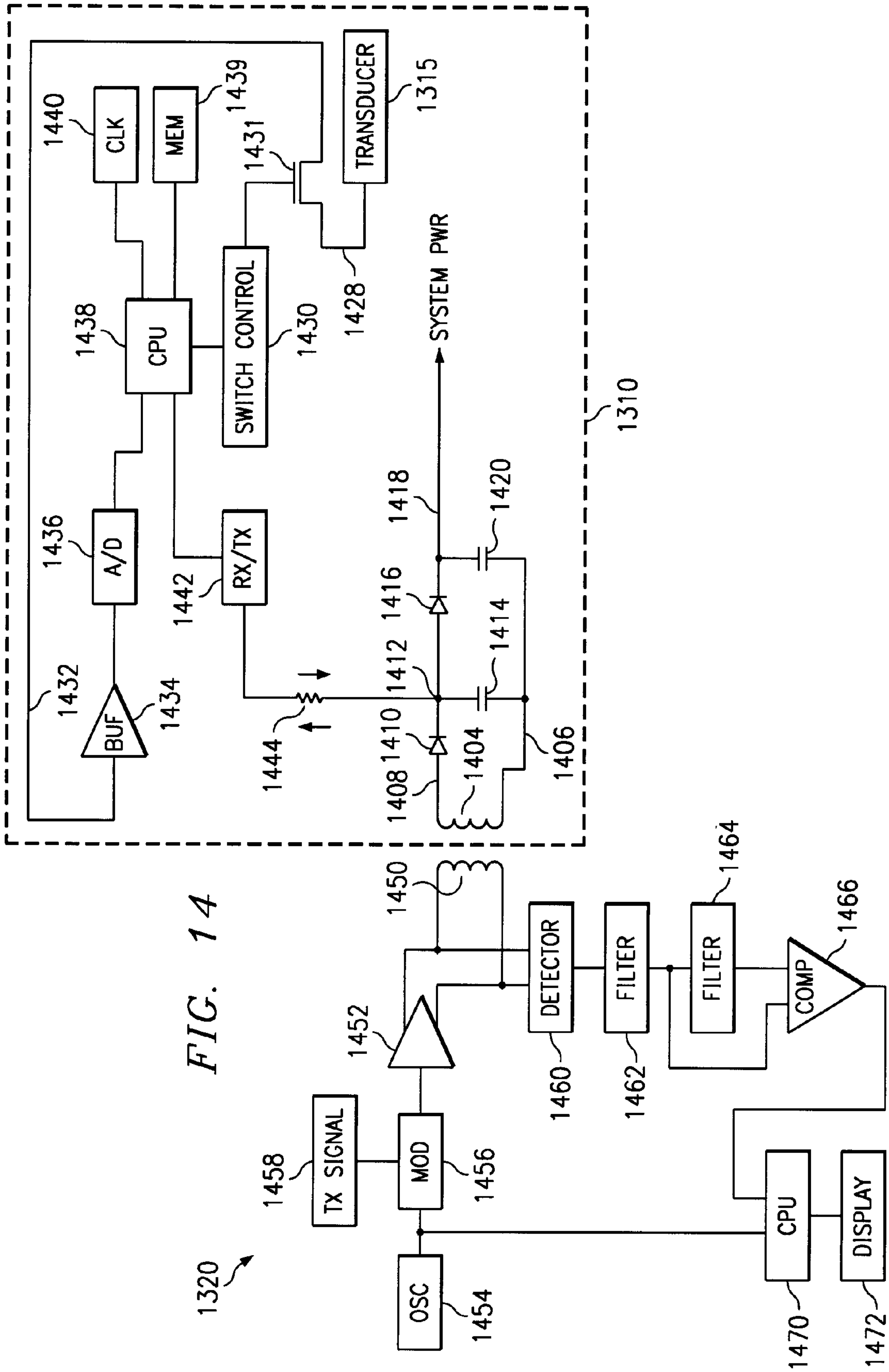

1310
1311
ANTENNA/COIL
1312
RF RECTIFIER SMOOTHER
1313
DC POWER STORAGE
VOLTAGE REGULATOR
1314
1316
CONTROL LOGIC
A/D CONVERTER
TRANSDUCER
1315
1318
1305
RF AMPLIFIER
RF MODULATOR
RF OSCILLATOR
1319
1317
RF SIGNAL/MAGNETIC COUPLING
1320
1321
ANTENNA/COIL
1324
RF DETECTOR
RF AMPLIFIER
CONVERTER
CONTROL LOGIC
DISPLAY
1325
1326
1327
1328
RF AMPLIFIER
RF OSCILLATOR
1322
1323

FIG. 13



CLK
MEM
TRANSDUCER
CPU
SWITCH CONTROL
SYSTEM PWR
A/D
RX/TX
BUF
DETECTOR
FILTER
FILTER
COMP
TX SIGNAL
MOD
OSC
CPU
DISPLAY
1310
1315
1320
1404
1406
1408
1410
1412
1414
1416
1418
1420
1428
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1439
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1466
1470
1472

FIG. 14

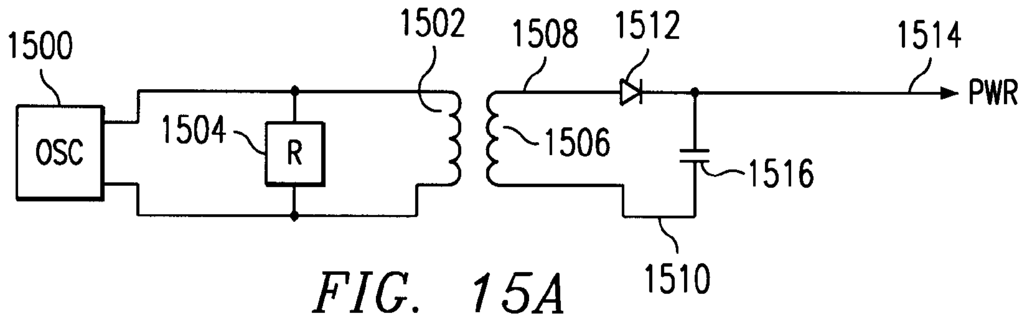


FIG. 15A

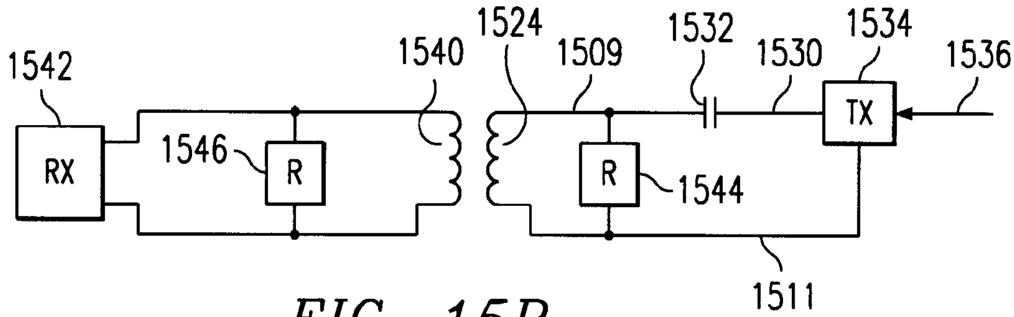


FIG. 15B

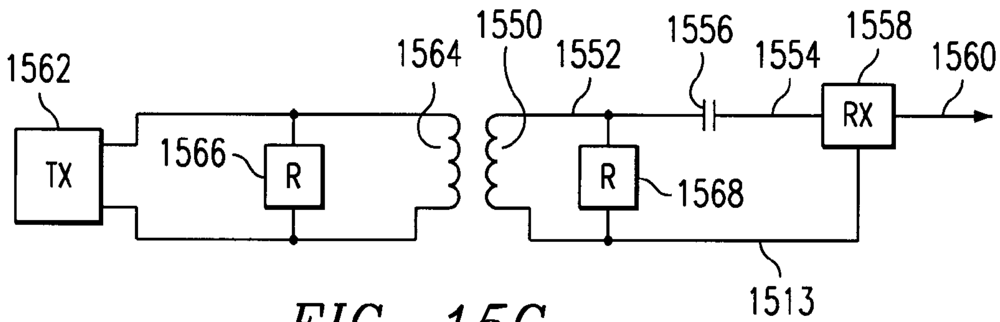


FIG. 15C

FIG. 16

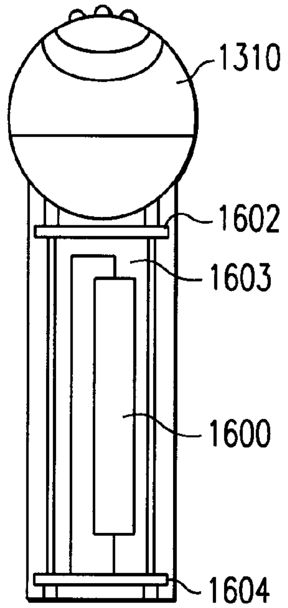


FIG. 17

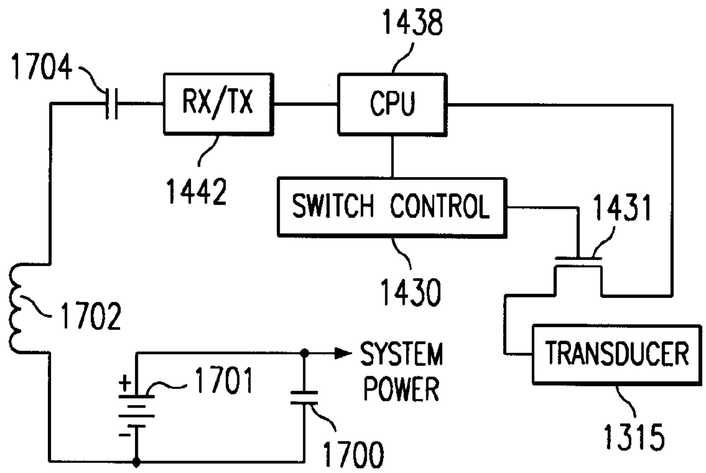


FIG. 18

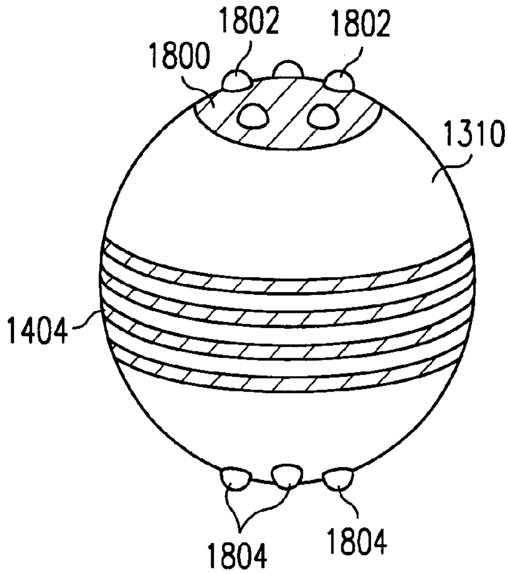
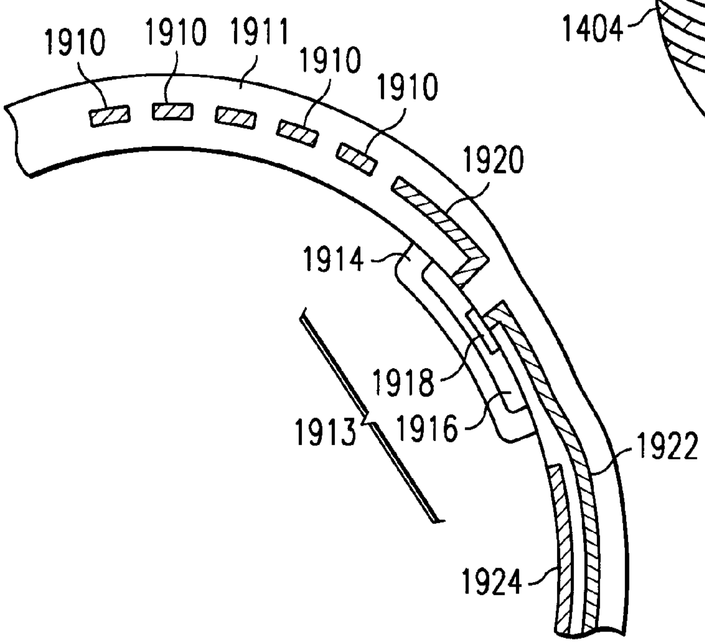


FIG. 19



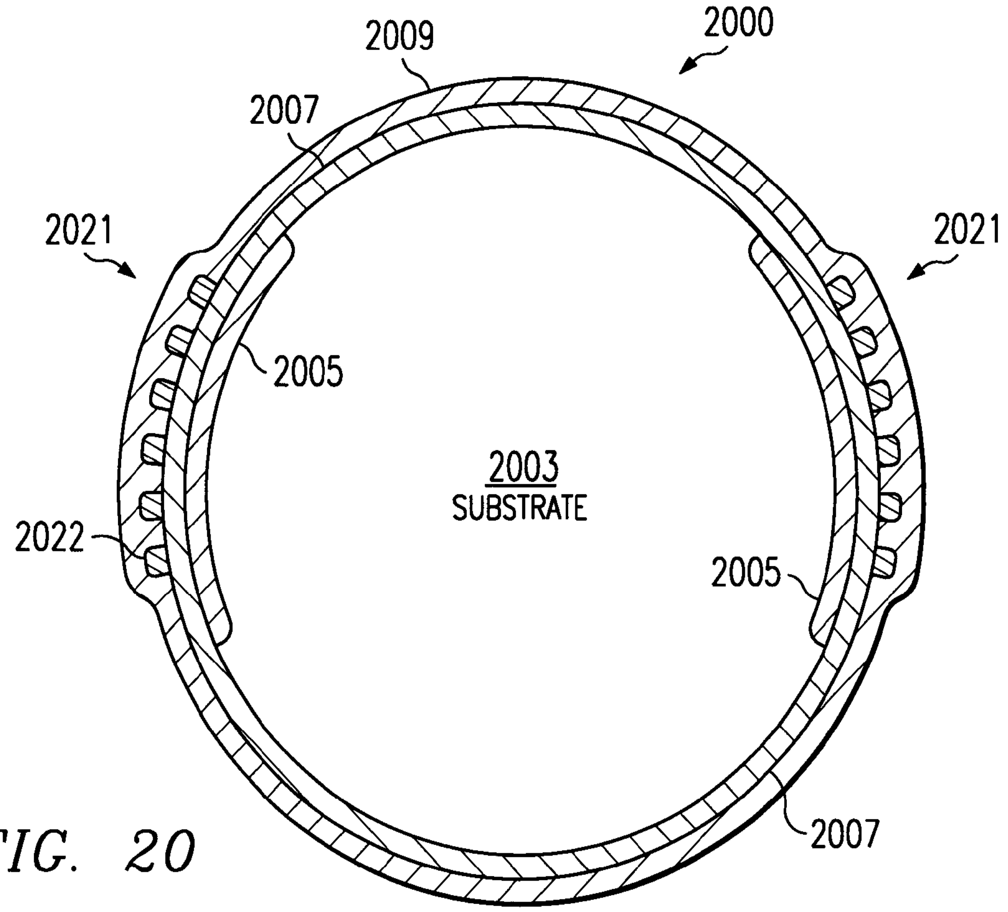

2009
2000
2007
2021
2021
2005
2003
SUBSTRATE
2022
2005
2007

FIG. 20

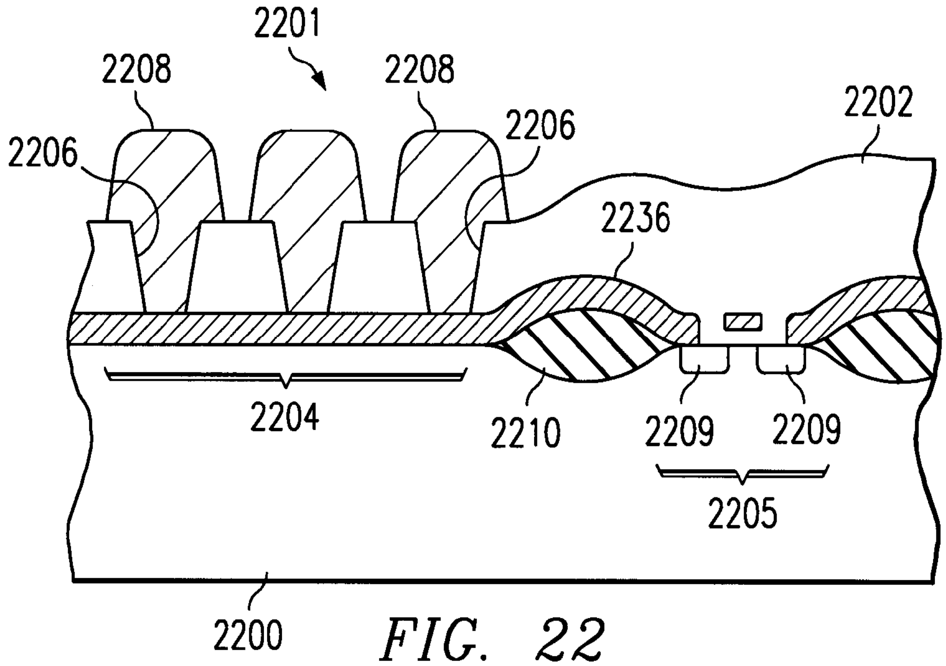

2201
2208
2208
2206
2206
2202
2236
2204
2210
2209
2209
2205
2200

FIG. 22

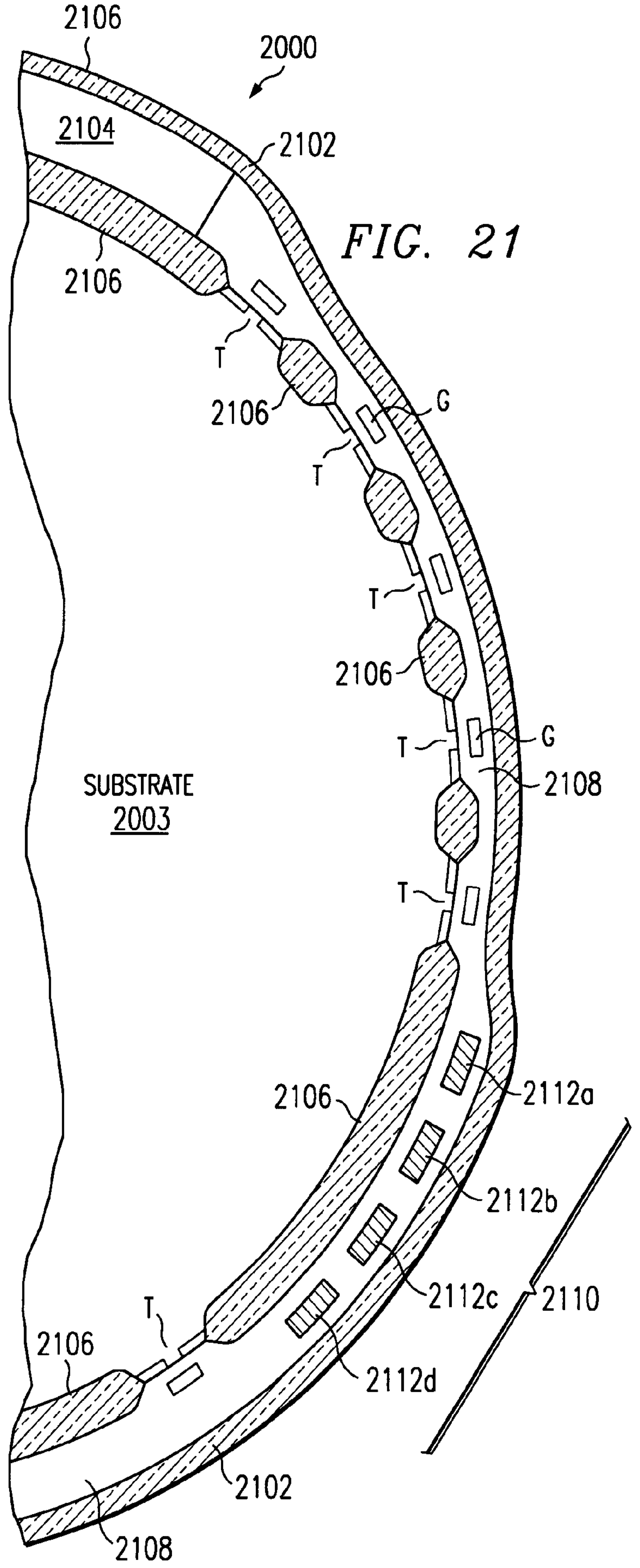

2106
2000
2104
2102
2106
T
2106
G
T
T
2106
T
G
2108
SUBSTRATE
2003
T
2106
2112a
2112b
2112c
2110
T
2106
2112d
2102
2108

FIG. 21

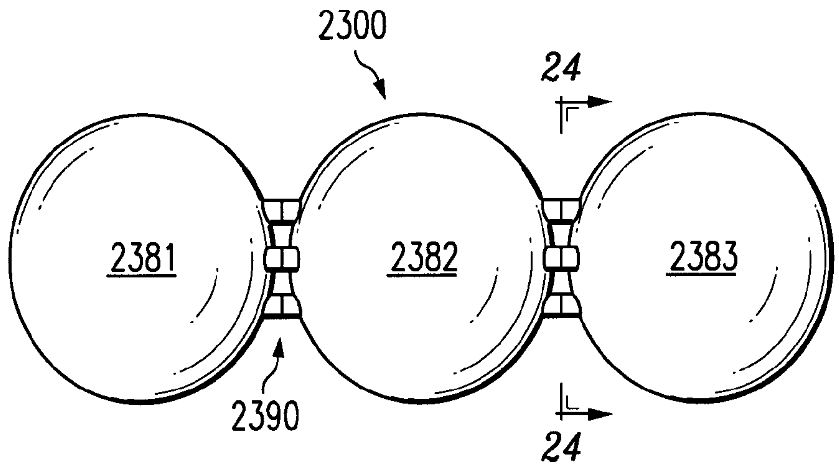


FIG. 23

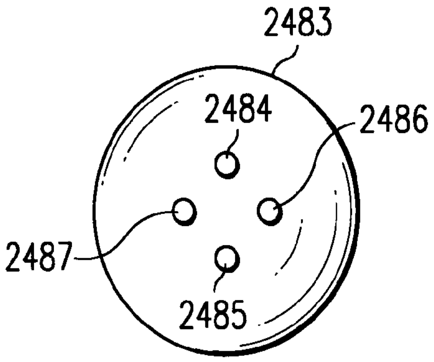


FIG. 24

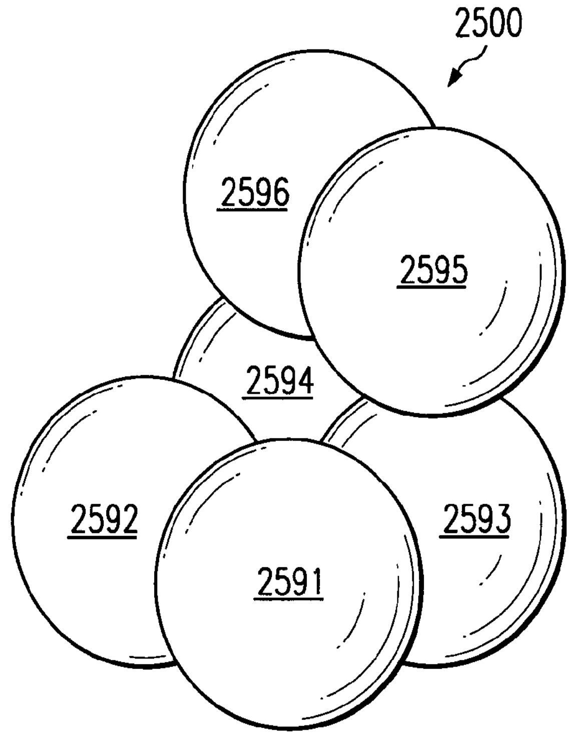


FIG. 25

WIRELESS EKG

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119(e) from U.S. Provisional patent application Ser. No. 60/115,193 filed on Jan. 6, 1999, having the same title as this application.

This application is related to co-pending U.S. patent application Ser. No. 09/321,862 entitled "X-RAY IMAGING APPARATUS USING SPHERICAL SEMICONDUCTOR DETECTORS," filed May 28, 1999; U.S. patent application Ser. No. 09/323,585 entitled "IMPLANTABLE EPICARDIAL ELECTRODE," filed Jun. 2, 1999; U.S. Provisional patent application Ser. No. 60/137,100 entitled "METHOD AND APPARATUS FOR ATTACHING TAGS TO MEDICAL DEVICES," filed Jun. 2, 1999; U.S. patent application Ser. No. 09/448,641 entitled "INTRALUMINAL MONITORING SYSTEM," filed Nov. 24, 1999; U.S. patent application Ser. No. 09/448,781 entitled "SPHERICALLY-SHAPED BIOMEDICAL IC," filed Nov. 24, 1999; U.S. patent application Ser. No. 09/448,642 entitled "MINIATURE SPHERICAL-SHAPED SEMICONDUCTOR WITH TRANSDUCER," filed Nov. 24, 1999; and U.S. Provisional patent application Ser. No. 06/163,656 entitled "MEDICALLY IMPLANTED ACCELEROMETER," filed Nov. 3, 1999, each of which is herein incorporated by reference.

TECHNICAL FIELD OF THE INVENTION

This invention is related to a cutaneous medical sensing device and more particularly to a miniature ball-shaped electrode sensing device with wireless communication capabilities.

BACKGROUND OF THE INVENTION

The cardiac cycle can be described as the activation of certain specialized heart conduction cells in a predictable sequence which leads to a coordinated and sequential contraction of the atrial and ventricular muscle fibers. This sequence of events, culminating in a cardiac contraction, leads to effective circulation of blood to vital parts of the body. Normally, heart activation is an ordered sequence of electrical depolarization and repolarization from the sinoatrial node to the ventricular fibers. Effective cardiac contraction is thus dependent upon the anatomical distribution and electrical properties of these specialized fibers. Voltage variations are generated from the depolarization and repolarization of the specialized cardiac fibers which creates electrical fields that reach the body surface. A surface electrocardiogram is a graph of these voltage variations plotted over time.

Cardiac monitoring is a critical component of all emergency rooms, critical care units, and telemetry beds. Abnormalities of cardiac rhythm may be the first sign of an impending cardiopulmonary arrest and can be prevented with early detection and treatment. The monitors in current use utilize surface electrodes located on the body connected by wires to an electrocardiographic machine which allows the detected heart signal to be displayed on a paper strip or a monitor screen. Alternatively, these wires can be connected to a small but cumbersome relay box hung around the patient's neck. Often these relay boxes or monitors cannot be used during critical tests such as with imaging studies using magnetic resonance.

The normal electrocardiogram is obtained from one of three types of electrical connections. These connections are known as limb leads, augmented limb leads, and precordial leads. Limb leads are bipolar leads in which two electrodes are used to detect electrical variations at two points and the difference between these signals is what is displayed. Augmented limb leads are unipolar in that one electrode is used to detect electrical variations in potential at one site on the body and then compared to an electrode located at a site where electrical activity does not vary much with the cardiac cycle. For instance, one electrode could be connected to either a right arm, left arm, or leg and the generated signal can be compared to a signal from an electrode located at a point which does not vary significantly in electrical activity during cardiac contraction. The precordial leads are also unipolar, but unlike the augmented limb leads, one or more precordial electrodes are connected to the chest wall. The generated signal(s) is compared to a signal generated by an electrode located at a point which again does not vary significantly with the cardiac cycle. The current state of the art requires wire connections between these surface electrodes to generate the resultant electrocardiogram.

In an ideal lead system for monitoring electrical activity of the heart, the electrodes should be perpendicular to each other, the amplitude detected by each electrode should be roughly equal, and each electrode should have the same signal strength and direction for all points in the heart where electrical forces are generated. These ideal electrodes have been termed corrected "orthogonal leads." Orthogonal lead systems have recently been constructed on implantable subcutaneous cardiac monitors for detecting and recording episodes of cardiac syncope. A disadvantage of these implantable monitors is the need for surgical placement and the limited usefulness for short term cardiac monitoring situations which occur in emergency or operating rooms and in the critical care facility or elsewhere.

SUMMARY OF THE INVENTION

The present invention disclosed and claimed herein, in one aspect thereof, comprises a surface cardiac monitor system for monitoring electrical activity of the heart. The system comprises one or more semiconductor electrode balls having respective electrode sensors for sensing electrical heart activity, a central processing semiconductor ball having each of the one or more semiconductor electrode balls connected electrically thereto for receiving respective heart signals from the sensors of the electrode balls, and processing the heart signals for transmission via wireless communication; and a remote control system for receiving the transmitted heart signals and extracting heart information from the transmitted heart signal about the electrical activity of the heart.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention and the advantages thereof, reference is now made to the following description taken in conjunction with the accompanying Drawings in which:

FIG. **1** illustrates a frontal view of a human body having a torso marked with one or more locations for the placement of the disclosed ball semiconductor surface mount EKG monitors;

FIGS. **2**A and **2**B illustrate side and front views of a surface mount cardiac monitor utilizing four semiconductor ball ICs, according to a disclosed embodiment;

FIG. **3** illustrates a general system block diagram of a remote control system and the monitor;

FIG. **4** illustrates a more detailed block diagram of the monitor processor for processing the sensed cardiac electrical signal;

FIG. **5** illustrates the surface cardiac monitor system further comprising a display for displaying the interpreted digitized electrical signal;

FIG. **6** illustrates an enlargement of a central semiconductor ball having a schematic representation of the circuitry required for processing electrical signals received from each of the electrodes;

FIG. **7** illustrates a 4-ball surface monitor having signals which are processed in a parallel non-linear fashion;

FIG. **8** illustrates an alternative 2-ball embodiment where a single ball semiconductor is fabricated with three electrodes oriented in three different directions;

FIG. **9** illustrates a 1-ball alternative embodiment having three electrodes and the processing circuitry all positioned on one semiconductor ball;

FIG. **10** illustrates a central processing ball having a single transmit/receive coil;

FIG. **11** illustrates a more detailed block diagram of the RF transmitter/receiver circuit of the central processing ball;

FIG. **12** illustrates an alternative embodiment of a central processor ball having three orthogonal coil structures;

FIG. **13** illustrates a more detailed block diagram of an alternative embodiment having basic circuit functions of an external control system and a ball IC;

FIG. **14** illustrates a schematic block diagram of the control system and the ball IC for the powering/detection operation;

FIG. **15**A illustrates an oscillator which drives an external inductive element;

FIG. **15**B illustrates the receive operation which utilizes a separate inductive element or antenna in the ball IC;

FIG. **15**C illustrates a simplified schematic diagram of the receive portion;

FIG. **16** illustrates a side view of an alternative embodiment utilizing additional circuitry or structure attached to the ball IC for providing a local power source;

FIG. **17** illustrates a schematic block diagram of the ball IC using a battery as the local power supply system;

FIG. **18** illustrates a perspective view of the ball IC, wherein an inductive element is illustrated as being strips of conductive material wrapped around the exterior of the ball IC;

FIG. **19** illustrates a cross-sectional diagram of the surface of the ball IC illustrating the conductive strips forming the inductive element;

FIG. **20** illustrates a schematic block diagram of the ball IC in an actuator function and the remote control system for the powering/detection operation;

FIG. **21** illustrates additional semiconductor details of a semiconductor processor ball;

FIG. **22** illustrates a cross-sectional view of an electrode sensor pad;

FIG. **23** illustrates a side elevation of a cluster of three semiconductor balls interconnected in a cooperative function;

FIG. **24** illustrates a cross section of the ball interconnections taken through the line **24**—**24** of FIG. **23**; and

FIG. **25** illustrates a 3-D ball cluster in a cooperative orientation.

DETAILED DESCRIPTION OF THE INVENTION

The disclosed architecture provides a surface mount cardiac monitor system and the circuitry required for selectively detecting and comparing electrical signals received by any combination of electrode (cathode-anode) pairs present on the surface cardiac monitor used in the system and the processing, integration, conversion, and transmission of said signals to an offsite central processing unit for storage or viewing.

Referring now to FIG. **1**, there is illustrated a frontal view of a human body having a torso marked with one or more locations for the placement of the disclosed ball semiconductor surface mount EKG monitors. In this particular embodiment, the monitor(s) may be placed over the precordium anywhere from the sternum **100** to the anterior axillary line in the 5th intercostal space **102**. There is provided a control center **104** for wirelessly interfacing with the monitor(s), as will be described in greater detail hereinbelow.

Referring now to FIGS. **2**A and **2**B, there are illustrated side and front views of a surface mount cardiac monitor **200** utilizing four semiconductor ball ICs, according to a disclosed embodiment. In FIG. **2**A, a side view of the surface cardiac monitor system **200** shows three semiconductor electrode ball ICs **202**, **204**, and **206** contacting a central communication ball **208** for electrical communication therebetween. Each of the electrode balls **202**, **204**, and **206** have fabricated thereon a respective electrode **210**, **212**, and **214** for receiving electrical signals from the heart. These electrodes would be arranged in an orthogonal relationship to each other as displayed in FIG. **2**A. The frontal view of FIG. **2**B further illustrates the orthogonal relationship of the electrode balls **202** and **206** to the central communication ball **208**. This redundant orthogonal arrangement is intended to obtain an electrocardiogram not only with information concerning the rhythm of the heart, but also to supply information with regards to cardiac ischemia, injury, or presence of necrosis. As these electrodes are in close proximity, they will be electrically isolated from each other by a suitable insulating material. A more detailed discussion of the contact interconnections between the balls is discussed hereinbelow.

Referring now to FIG. **3**, there is illustrated a general system block diagram of a remote control system and the monitor **200**. A surface cardiac monitor system **300** is illustrated for monitoring electrical activity of the heart, and comprises a remote control system **302** for interacting with and receiving data from the monitor system **200** attached to the skin of the human body, the dashed line **305** indicating the human body having the monitor system **200** attached thereon and the control system **302** located remoter thereto. (Note that where necessary, the disclosed monitor system **200** may also be inserted under the skin to obtain the same results.) The monitor system **200** contains a detector **320** for detecting the electrical activity of the heart from three orthogonal points and generating a signal indicative of the detected electrical heart activity; a processor **330** for processing the generated electrical signal for transmission from the surface cardiac monitor **200** using wireless communication; a transmitter **340** for wirelessly transmitting the generated electrical signal to the remote location **302**; a receiver/transmitter **310** at the remote location **302** for receiving the electrical signal; and a processor **312** at the remote location **302** for processing the received electrical signal for the purpose of extracting therefrom the information about the detected electrical activity of the heart.

Referring now to FIG. **4**, there is illustrated a more detailed block diagram of the monitor processor **330** for processing the sensed cardiac electrical signal. The processor **330** comprises a comparator amplifier **432**, a noise filter

434, and an analog-to-digital (A/D) converter **436**. The comparator amplifier **432** receives the electrical signals generated by each of the three electrodes **210**, **212**, **214**, and generates an analog signal indicative of the comparison of the signals of one of the three electrode pairs (**210**/**212**, **210**/**214**, or **212**/**214**). The noise filter **434** removes noise signals generated by and picked up from skeletal muscle contractions, and the A/D converter **436** converts the analog signal into a digital representative of the detected electrical heart activity for transmission to the remote location **302** using wireless communication. Preferably, the wireless transmission mechanism (which comprises transmitter/receiver devices **340** and **310**) for transmitting the digitized electrical signal is a telemetry transmitter device operating at radio frequency (RF). Any wireless transmission technique may be used. In addition, the remote location **302** receives the digitized transmitted electrical signal using a compatible RF telemetry receiver device or some other wireless receiver that is compatible with the transmitted signal.

Referring now to FIG. **5**, there is illustrated the surface cardiac monitor system **200** further comprising a display **500** for displaying the interpreted digitized electrical signal. On the monitor system **200**, the detector **320** is illustrated having two electrodes **502** and **504** which can detect electrical activity of the heart. The output of the electrodes **502** and **504** is input to the processor **330** for conditioning of the detected heart signal prior to transmission by the transmitter/receiver unit **340** from the monitor system **200** to the remoter control station **302**. The measured electrical signal can then be presented to the technician via the display **500**.

As seen from the foregoing drawings, the surface monitor **200** thus contains the capability of comparing and processing electrical signals from any of the three orthogonal electrodes (**210**, **212**, and **214**) of the monitor **200** by a series of switching circuits and signal processors. These signals are then amplified and filtered, and converted from an analog to a digital signal using the processor **330**. The digital signal is then wirelessly transmitted to the remote location **302** via RF transmission techniques for further processing.

Referring now to FIG. **6**, there is illustrated an enlargement of a central semiconductor ball having a schematic representation of the circuitry required for processing electrical signals received from each of the electrodes **210**, **212**, and **214**. Pairs of electrode signals can be compared using switching circuitry which allows these signals to be separately processed through parallel linear and nonlinear combinational processing circuitry and separately transmitted to the remote location **302** for off-site comparison. Signals detected from electrodes **210**, **212**, and **214** (only **210** and **214** are shown coupled in this frontal view) to a central switching device (or matrix) **600** which allows an electrocardiogram signal to be developed across pairs of electrodes (**210**/**212** and **212**/**214**). The switching matrix **600** is operable to input selected pairs of electrode outputs into a comparator **602** (similar to comparator/amplifier **432**) under control of the onboard processor (not shown) of the monitor system **200**. For example, in a first mode, the switching matrix **600** passes the outputs of electrodes **210** and **214** into the comparator **602**. In a second mode, the outputs of electrodes **210** and **212** are passed into the comparator **602**, and a third mode selects the outputs of electrodes **212** and **214** to be fed into the comparator **600**. This signal is then amplified and routed to an analog/digital converter **604** to derive a signal for RF transmission using a transmit/receive circuit **606** to a central processing unit (CPU) (not shown) external to the monitor **200**.

The surface cardiac monitor **200** would generate a signal of a specific radio frequency which is transmitted to the CPU. Within the CPU, signals are compared from each surface cardiac monitor **200** and the maximal signal is selected for conversion back to an analog signal (electrocardiogram) for display on the viewing device **500**, or for storage. In a busy emergency room where multiple patients are to be monitored, specific identification tags will be tied to each RF signal to allow for proper orientation of each signal, i.e., radio frequency signals from bed X will be received and processed only by the CPU for bed X, and not the CPU for bed Y. In this way, two or more signals taken from the surface cardiac monitors **200** would be always available to the remote location processor **312**. Thus, if one of the signals were weaker due to the orientation of the monitor **200**, the other electrodes which are not so oriented would not be so influenced and could provide a continuous generated signal on the heart activity irrespective of monitor orientation.

Referring now to FIG. **7**, there is illustrated a 4-ball surface monitor **700** (similar to monitor **200**) having signals which are processed in a parallel non-linear fashion. The central processor ball **714** has been enlarged to include the block diagram when in practice, the central processor ball **714** is substantially the same size as the electrode balls **702**, **704**, and **706**. Each of three electrode balls **702**, **704**, and **706** have respective electrodes **708**, **710**, and **712**. Signals from each of the electrodes **708**, **710**, and **712** passed from the electrode balls **702**, **704**, and **706** to a central processing ball **714**, where they are amplified and filtered prior to digital conversion and transmission to a remote CPU (not shown). The disclosed embodiment shows two independent processing circuits, each having a comparator, a noise filter, and A/D, and a transmit/receive circuit.

In operation, the signal from electrode **710** is compared to both the signal of electrode **708** and the signal of electrode **712**, resulting in two independent signal transmissions being sent from the central processing ball **714** to the remote control system **302**. The transmission frequencies would need to be different to allow reception by the remote control system **302** of the independent signals, and of course, the remote control system will also need the discrimination capabilities to process each signal independently. For example, the output signal of the electrode **710** of ball **704** is received onto the central processing ball **714** where it is split to the input of two independent comparators, a comparator **716** and a comparator **718**. Comparator **716** also receives the output of electrode **708** of ball **702**, the resulting output of the comparator **716** being passed to a noise filter **720** to filter unwanted noise. The filtered analog signal is then converted to a digital signal using an A/D converter **722**, and then transmitted from the monitor **700** at a first frequency f_1 of a transmission circuit **724** to the remote control station **302**. Similarly, the other comparator **718** receives the output of electrode **712** of ball **706** and compares it to the output of electrode **710**, the resulting output of the comparator **718** being passed to a noise filter **726** to filter unwanted noise. The filtered analog signal is then converted to a digital signal using an A/D converter **728**, and then transmitted from the monitor **700** at a second frequency f_2 of a transmission circuit **730** to the remote control station **302**. Within the CPU **312** of the remote control system **302**, signals are mathematically processed using standard vector mathematics to determine vector magnitude allowing for an orientation-insensitive signal to be generated. This signal can be used to overcome any rotational bias created by the placement of the surface cardiac monitor **700** in a particular position on a patient.

Referring now to FIG. **8**, there is illustrated an alternative 2-ball embodiment where a single ball semiconductor is fabricated with three electrodes oriented in three differing directions. An electrode ball **800** contains three electrodes **802**, **804**, and **806** oriented substantially orthogonally with one another. The electrode ball **800** connects to a processing ball **808** to facilitate signal processing of the signals from the three electrodes **802, 804**, and **806**. The outputs from each of the three electrodes **802**, **804**, and **806** are passed through interconnecting contacts (discussed in greater detail hereinbelow) to a switching matrix **810** on the processing ball **808**. The switching matrix **810** operates to switch pairs of electrode outputs to the input of a comparator **812** (i.e., **802/804, 802/806**, and **804/806**). The comparator **812** output is then digitized using an A/D converter **814**, and ultimately transmitted from the processor ball **808** using a transmit/receive circuit **816**.

Referring now to FIG. **9**, there is illustrated a 1-ball alternative embodiment having three electrodes and the processing circuitry all positioned on one semiconductor ball **901**. Three electrodes **900, 902**, and **904** are fabricated substantially orthogonal to one another on a substrate of the ball **901** and whose outputs connect to a switch matrix **906** to switch any pair of electrode outputs to a comparator **908**. The composite analog electrocardiogram output signal of the comparator **908** is then digitized using an A/D converter **910** and transmitted from the ball **901** to a remote control station **302** using a transmit/receive circuit **912**. The signals from each electrode would be compared, processed, amplified, and digitalized all on one semiconductor ball in this embodiment. Software within the CPU **312** of the remote control station **302** will compare signals derived from each surface cardiac monitor to elicit any vectorial change in the electrocardiogram signal obtained from one surface cardiac monitor versus another surface cardiac monitor allowing the CPU **312** to detect dynamic changes in orientation and magnitude of electrical fields which occur under conditions of ischemic changes within cardiac muscle.

The distinct advantages of this surface cardiac monitor are the wireless nature of recording and transmission which frees the patient from wires and relay boxes. These wires and relay boxes may not be compatible with certain diagnostic imaging equipment. Current surface electrodes connected by wires to a relay box are constantly detached from the body, or disconnected from one another, because of the constant pull exerted by the wires attached to the box leading to malfunction.

Referring now to FIG. **10**, there is illustrated a central processing ball **1000** (similar to ball **208**) having a single transmit/receive coil **1002**. The antenna coil **1002** comprises several windings the number of which is determined according to the particular application. A greater number of windings increases the coupling of a received signal. The antenna coil **1002** connects to a power regulator circuit **1004** to provide stable power for any onboard circuitry. In this embodiment, the power regulator connects to receive/transmit circuitry **1106**. In transmit mode, the output signal passes through the power regulator circuit **1004** to the antenna coil **1002**. In receive mode, power and signal are coupled into the antenna coil **1002** where the power portion is stripped off by the regulator circuit **1004** to supply onboard power. The signal portion is passed through the regulator circuit **1004** to the transmit/receive circuit **1006** where it is demodulated from an RF carrier and passed to a processor section **1008**. When the central processing ball **1000** receives electrode information from electrode balls (not shown), that electrode information is passed into the processor section **1008** for comparison, filtering, and digital conversion prior to being transmitted to the remote control station **302**. Digitized data from processor section **1008** is applied to the RF transmit/receive section **1006** for modulation of the digitized data on an RF signal using, for example, Frequency-Shift Keying (FSK) techniques.

Referring now to FIG. **11**, there is illustrated a more detailed block diagram of the RF transmitter/receiver circuit of the central processing ball **1000**. The RF transmitter **1006** comprises a mixing circuit **1152**, first and second RF oscillators **1154**, **1156**, and an amplifier **1158**. In particular, the signal from an electrode corresponding to the level of current present during cardiac activity is digitized by the processor **1008** and applied to one input **1153** of mixing circuit **1152**. A first high frequency signal from RF oscillator **1154** is applied to a second input **1155** of mixing circuit **1152**, and a second low frequency signal from RF oscillator **1156** is applied to a third input **1157** of mixing circuit **1152**. The mixing circuit **1152** modulates the incoming packet of digital information between a high frequency signal from RF oscillator **1154** for use in generating each logic "high" bit of data in the information packet; and a low frequency signal from RF oscillator **1156** for use in transmitting each logic "low" bit of data in the information packet. The resulting FSK signal is amplified by amplifier **1158** and applied to the coil **1002** for transmission to the RF receiver **310** (shown in FIG. **3**) of the remotely located control station **302**.

Fabrication of these kind of sensors can be readily adapted to a ball IC using the fabrication techniques described in commonly-assigned U.S. Pat. No. 5,955,776 entitled "Miniature Spherical-Shaped Semiconductor With Transducer," issued Sep. 21, 1999, and which is herein incorporated by reference. The performance of the monitor **200** can be protected from body tissues, or other of the body's defensive mechanisms by encapsulation of the device within a polymeric or gel coating albumin, or a "bio-coating." Examples of such encapsulation are described in the following U.S. Pat. No. 4,530,974 by Munro et al., entitled "Nonthrombogenic Articles Having Enhanced Albumin Affinity," issued Jul. 23, 1985; and 5,017,670 by Frautchi et al., entitled "Methods And Compositions For Providing Articles Having Improved Biocompatibility Characteristics," issued May 21, 1991, both of which are incorporated herein by reference.

Notably, the electrode sensor **210** is readily replaceable by other suitable sensors for sensing other physiological parameters such as pH, chemical parameters, and physical parameters such as pressure, movement, temperature and the like. For example, in applications where information regarding ionic activity or concentration is sought, one embodiment of a sensor utilizes an ion-sensitive field effect transistor ISFET which is essentially an insulated gate field effect transistor (IGFET) without its metal gate. The operation of the ISFET is similar to that of IGFET if one considers the reference electrode and the electrolyte into which the semiconductor ball is placed as the modified gate. In operation, the interfacial potential of the electrolyte-insulator interface produced by the net surface charge due to the ionization and complexation with the ions in a solution will affect the channel conductance of the ISFET in the same way as the external gate voltage applied to the reference electrode. The drain current of the ISFET is therefore a function of the electrolytes in solution for a constant drain-source voltage. Various materials can be used for the gate insulators, such as SiO_2, Si_3N_4 and Al_2O_3. For pH sensors, Si_3N_4 and Al_2O_3 provide satisfactory performance. ISFET's for other ions such as K^+, Na^+, and Ca_2^+may have a layer coated over the gate insulator of valinomysin in PVC, aluminosilicate, and dedecyl phosphonate, respectively. Thus, the disclosed architecture is intended to be illustrative and not limited to only electrode applications.

Referring now to FIG. **12**, there is illustrated an alternative embodiment of a central processor ball having three orthogonal coil structures. The processor ball **1200** (similar to processor ball **302**) is fabricated on a substantially spherical substrate **1203**, and includes nine coils L_1–L_9 in three sets **1202**, **1204**, and **1206** of three coils, each set **1202**, **1204**, and **1206** preferably orthogonal to each other so that power and signal communication requirements can be optimized according to the orientation of each processor ball **1200**. Each coil set **1202**, **1204**, and **1206** comprises three coils; one transmit coil, one receive coil, and a power coupling coil. Therefore, in this embodiment, there are three power coils L_1, L_2, and L_3; three transmit coils L_4, L_5, and L_6; and three receive coils L_7, L_8, and L_9. The coils sets are grouped in this fashion to ensure that at least one coil set is orientated to provide potentially optimum power coupling and signal communication therewith. Onboard circuitry comprises a processor circuit **1216** for controlling all aspects of the processor ball **1200**. The processor circuit **1216** can be a digital signal processor or other conventional processor. Power for the processor **1200** is provided via a regulator circuit **1210** which regulates power coupled into any of the power coils L_1, L_2, and L_3. Communications are provided by a transmit circuit **1220** and a receive circuit **1214**. The transmit circuit **1220** connects to the three transmit coils L_4, L_5, and L_6 in order to provide transmit communications which are capable of outputting signals in any orientation of the processor **1200**, and only one of which is included in one of the three sets of coils **1202**, **1204**, and **1206**. Similarly, the receive circuit **1214** connects to each of the receive coils L_7, L_8, and L_9, in order to provide receive communications which are capable of receiving signals in any orientation of the processor ball **1200**, and only one of which is included in each one of the three sets of coils **1202**, **1204**, and **1206**. The coils L_1–L_9 can have any number of windings (not shown) in order to achieve the desired results.

The coils L_1–L_9 are connected by subsurface conductors (not shown) to the other circuit elements on the processor ball **1200**. The processor **1216** provides an output to the transmitter **1220** that preferably radiates an RF signal to the external antenna **310** for processing by the CPU **312**. The power regulator **1210** provides a relatively constant DC voltage of about 3.0 volts to the circuits on the processor ball **1200**. A disclosed power source for the processor ball **1200** is provided externally by operation of the remote control system **302** utilizing the CPU **312** in conjunction with the antenna **310** which couples power to the power coils L_1, L_2, and L_3 in the form of a varying magnetic field. Alternatively, the processor ball **1200** can be powered by a miniature battery connected to the processor ball **1200** (which is discussed in greater detail hereinbelow). The miniature battery can also be in the shape of a ball (battery ball) configured to accommodate a common connection scheme for use between adjacent balls. Preferably, battery balls can be fashioned as electrical double-layer condensers from such materials as manganese dioxide, lithium or lithium ion, samarium-cobalt, carbon, etc. Since such a battery ball is a greater capacity energy source than an RF energy receiving coil, longer communication distances can be achieved by this means. Both the external magnetic field generator (CPU system **312**) and receiver antenna **310** can be included in the same computer-controlled apparatus or remote CPU station **302** within proximity of the processor ball **1200**, at least, but not limited to periods when its operation is required.

Referring now to FIG. **13**, there is illustrated a more detailed block diagram of a disclosed monitor and control system. Processor ball **1310** (similar to processor balls **1200** and **208**) includes an antenna/coil **1311**, which serves the dual purpose of receiving signal energy from a remote control station **1320** (similar to control station **302**) and transmitting signal energy thereto. The signal energy may be received by the antenna/coil **1311** by inductive coupling if the control station **1320** is sufficiently close to the processor ball **1310**. Alternatively, electromagnetic waves can be used to transmit power from the control station **1320** to the processor ball **1310**, whereby the magnetic field component of the electromagnetic wave induces a current in the coil **1311** in accordance with known techniques. The power signal received by the antenna/coil **1311** is rectified and smoothed by a RF rectifier/smoother block **1312**. The output of the rectifier block **1312** is connected to a DC power storage block **1313**, such as a capacitor. Such capacitor might also perform a waveform smoothing function. A voltage regulator **1314** is used to make the DC voltage stable regardless of the distance between the control station **1320** and the processor ball **1310**.

The processor ball **1310** includes a transducer block **1315** which represents both the function of sensing quantitative conditions, and the function of an actuator, such as an impulse generator, having anode and cathode portions of an electrode, and flanking electrodes. Such semiconductor electrical sensors and impulse generators are known in the art, and can be adapted to fabrication on a spherical semiconductor substrate, as described hereinabove. An A/D converter **1305** is connected to the transducer **1315** to convert the electrical signal sensed by the transducer **1315** to a signal that can be transmitted out to the control station **1320**. Notably, the converter **1305** can be part of the transducer **1315**, such as a variable capacitor for generating a signal depending upon the variations in capacitance. Control logic **1316**, which can be part of an onboard processor that controls not only the converter **1305** but also circuitry on the ball **1310**, is provided in accordance with known techniques. An RF oscillator **1317** generates an RF signal at a predetermined frequency in the RF band. An RF modulator **1318** modulates the output of the converter **1315** onto the carrier frequency signal. The resulting modulated signal is amplified by an RF amplifier **1319**, and then transmitted to the antenna/coil **1311**. The technique for transmitting data from the ball **1310** to the main control station **1320** using the carrier frequency generated by the RF oscillator **1317** can be in the form using any suitable modulation and protocol. For example, the modulation can be AM, FM, PM, FSK or any other suitable modulation technique. Further details of the preferred coil are described in the aforementioned commonly-assigned U.S. patent application Ser. No. 09/448,642 entitled "Miniature Spherical-Shaped Semiconductor With Transducer," and filed Nov. 24, 1999.

The external control station **1320** includes an antenna/coil **1321** that serves the dual purpose of generating the electromagnetic wave for transmitting power to the ball **1310**, and receiving the RF data signal transmitted by the ball **1310**. It is preferred that the frequency of the electromagnetic wave that is output by the antenna/coil **1321** is different from the carrier frequency generated by the RF oscillator **1317**. An RF amplifier **1322** is used to couple the electromagnetic wave for power transmission to the antenna/coil **1321**. An RF oscillator **1323** determines the frequency of the electromagnetic wave that is emitted by the control station **1320**. The data received by the antenna/coil **1321** is detected by an RF detector **1324**, and then amplified by an RF amplifier **1325**. Preferably, the converter **1326** converts the signal from the RF amplifier **1325** to a digital signal, which in turn is input to a control logic block **1327**. The control logic **1327** may be a smaller processor unit to interface with the main control station **1320**. The control logic **1327** extracts the data from the signal received by the control station **1320** from the ball **1310**, and displays that information on a suitable display **1328**, such as a CRT screen.

Referring now to FIG. **14**, there is illustrated a schematic block diagram of the control system and the ball IC for the powering/detection operation. The ball IC **1310**, as described hereinabove, is operable to provide the transducer **1315** for interfacing with the desired quantitative condition. The illustrated embodiment of FIG. **14** is that associated with a "passive" system, which term refers to a system having no battery associated therewith. In order to operate the system, there is provided an inductive coupling element **1404** in the form of an inductor, which is operable to pick up an alternating wave or impulse via inductive coupling, and extract the energy therein for storage in the inductive element **1404**. This will create a voltage across the inductive element **1404** between a node **1406** and a node **1408**. A diode **1410** is connected between the node **1408** and the node **1412**, with the anode of diode **1410** connected to node **1408** and the cathode of diode **1410** connected to a node **1412**. Typically, the diode **1410** will be fabricated as a Schottky diode, but can be a simple PN semiconductor diode. For the purposes of this embodiment, the PN diode will be described, although it should be understood that a Schottky diode could easily be fabricated to replace this diode. The reason for utilizing a Schottky diode is that the Schottky diode has a lower voltage drop in the forward conducting direction.

The diode **1410** is operable to rectify the voltage across the inductive element **1404** onto the node **1412**, which has a capacitor **1414** disposed between node **1412** and node **1406**. Node **1412** is also connected through a diode **1416** having the anode thereof connected to node **1412** and the cathode thereof connected to a node **1418** to charge up a capacitor **1420** disposed between node **1418** and **1406**. The capacitor **1420** is the power supply capacitor for providing power to the ball IC **1310**. The capacitor **1414**, as will be described hereinbelow, is operable to be discharged during operation of the system and, therefore, a separate capacitor, the capacitor **1420**, is required for storing power to power the system of the ball IC **1310**.

There is also provided a switching transistor **1431** which has one side of the gate/source path thereof connected to a node **1428** which is the output of the transducer **1315** and the other side thereof connected to a node **1432**. The gate of transistor **1431** is connected to the output of the switch control **1430**. Node **1432** is connected to the input of a buffer **1434** to generate an analog signal output thereof which is then converted with an A/D converter **1436** to a digital value for input to a CPU **1438**. The CPU **1438** is operable to receive and process this digital input voltage. A clock circuit **1440** is provided for providing timing to the system. A memory **1439** is provided in communication with the CPU **1438** to allow the CPU **1438** to store data therein for later transmittal back to the remote location or for even storing received instructions. This memory **1439** can be volatile or it can be non-volatile, such as a ROM. For the volatile configuration, of course, this will lose all information when the power is removed. The CPU **1438** is operable to provide control signals to the switch control **1430** for turning on the transistor **1431** at the appropriate time. In addition to the transistor **1431** being toggled to read the transducer **1315**, transistor **1431** could be a pass-through circuit such that the CPU **1438** can continually monitor the voltage at the output of the transducer **1315**. System power to all power-consuming elements of the ball IC **1310** is provided at the SYSTEM PWR output node.

In order to communicate with the CPU **1438** for transferring data thereto and for allowing the CPU **1438** to transfer data therefrom, a receive/transmit circuit **1442** is provided for interfacing to node **1412** through a resistive element **1444**. This allows RF energy to be transmitted to node **1412**. It is important to note that the semiconductor junction across diode **1410** is a capacitive junction. Therefore, this will allow coupling from node **1412** to node **1408**. Although not illustrated, this could actually be a tuned circuit, by selecting the value of the capacitance inherent in the design of the diode **1410**. In any event, this allows an RF connection to be provided across diode **1410** while allowing sufficient energy to be input across conductive element **1404** to provide a voltage thereacross for rectification by the diode **1410** and capacitor **1414**. Typically, the frequency of this connection will be in the MHz range, depending upon the design. However, many designs could be utilized. Some of these are illustrated in Beigel, U.S. Pat. No. 4,333,072, entitled "Identification Device," issued Jun. 1, 1982, and Mogi et. al., U.S. Pat. No. 3,944,982, entitled "Remote Control System For Electric Apparatus," issued Mar. 16, 1976, which are incorporated herein by reference. With these types of systems, power can continually be provided to the node **1412** and subsequently to capacitor **1420** to allow power to be constantly applied to the ball IC **1310**.

The remote control system **1320** which is disposed outside of the body or away from the prosthesis and proximate to the ball IC **1310** includes an inductive element **1450** which is operable to be disposed in an area proximate to the skin, yet exterior to the body, in the proximity of the ball IC **1310**, as close thereto as possible. The inductive element **1450** is driven by a driving circuit **1452** which provides a differential output that is driven by an oscillator **1454**. This will be at a predetermined frequency and power level necessary to couple energy from inductive element **1450** to inductive element **1404**. Since this is an external system, the power of the oscillator can be set to a level to account for any losses through the body tissues. To allow information to be transmitted, a modulation circuit **1456** is provided which is modulated by a transmitter signal in a block **1458** that allows information to be modulated onto the oscillator signal of the oscillator **1454**, which oscillator signal is essentially a "carrier" signal. However, it should be understood that the information that is transmitted to the ball IC **1310** could merely be date information, whereas the CPU **1438** could operate independent of any transmitted information to provide the correct timing for the output pulses and the correct waveshape therefor. Alternatively, entire control of the system could be provided by the transmit signal **1458** and the information carried thereon, since power must be delivered to the illustrated embodiment due to the lack of any independent power in the ball IC **1310**. In the present disclosure, the information transmitted to the ball **1310** is frequency selective or it is ID dependent. In the frequency selective mode, the transmit signal **1458** operates at a select frequency for a particular ball when multiple balls **1310** are imbedded. Each ball **1310** will be tuned to its associated frequency. This can be for both power and command information. In the ID mode, each ball **1310** has a particular ID associated therewith and stored in memory **1439**, and will only create the stimulus when its ID is transmitted by the transmitter **1458**. In this mode, all balls **1310** are powered at the same time. Additionally, the power levels can be reduced, such that a separate transmit circuit can be provided for each ball **1310** and disposed on the skin proximate to the associated ball **1310** with the central control system **1320** controlling the plurality of separate transmit circuits.

When the information is received from the ball IC **1310**, it is superimposed upon the oscillator signal driving the inductive element **1450**. This is extracted therefrom via a detector **1460** which has the output thereof input to a first low pass filter **1462**, and then to a second low pass filter **1464**. The output of low pass filters **1462** and **1464** are compared using a comparator **1466** to provide the data. The filter **1462** provides an average voltage output, whereas the filter **1464** provides the actual digital voltage output. The output of the comparator **1466** is then input to a CPU **1470** which also is powered by the oscillator **1454** to process the data received therefrom. This can then be input to a display **1472**.

Referring now to FIGS. **15A–15C**, there are illustrated alternate embodiments for the transmit/receive operation. In FIG. **15A**, there is provided an oscillator **1500** which drives an external inductive element **1502**. Typically, there is some type of load **1504** disposed across the inductive element **1502**. This is the primary power that is provided to the system. A separate inductive element **1506** is provided on the ball IC **1310**, for being inductively coupled to the inductive element **1502**. Thereafter, a voltage is generated across the inductive element **1506**, the inductive element **1506** being connected between nodes **1508** and **1510**. A diode **1512** is connected between node **1508** and a power node **1514**, and a power supply capacitor **1516** is disposed across node **1514** and a node **1510**. This allows the voltage on node **1508** to be rectified with diode **1512**.

In FIG. **15B**, the receive operation, in this alternative embodiment, utilizes a separate inductive element or antenna **1524** in the ball IC **1310**, which is operable to be connected between nodes **1509** and **1511**. Node **1509** is capacitively coupled to a transmit node **1530** with a capacitor **1532**, the capacitor **1532** being a coupling capacitor. A transmitter **1534** is provided for transmitting received data from a line **1536** to the node **1530**, which is then coupled to the node **1509** to impress the RF signal across the inductive element **1524**.

A corresponding inductive element **1540** is disposed on the external remote controller of control system **1320**, which inductive element **1540** is operable to be disposed proximate to the inductive element **1524**, but external to the human body. The inductive element **1540** is basically a "pick-up" element which is operable to receive information and function as an antenna, and provide the received signal to a receiver **1542**. The structure of FIG. **15B** is a separate structure, such that node **1509** is isolated from node **1508**, the power receiving node. However, it should be understood that any harmonics of the oscillator **1500** would, of course, leak over into the inductive element **1524**. This can be tuned out with the use of some type of tuning element **1544** on the ball IC **1310** disposed across inductive element **1524**, and also a tuning element **1546** disposed across the inductive element **1540**, i.e., the antenna.

Referring now to FIG. **15C**, there is illustrated a simplified schematic diagram of the receive portion. The ball IC **1310** has associated therewith a separate receive antenna or inductive element **1550** disposed between node **1513** and a node **1552**. Node **1552** is capacitively coupled to a receive node **1554** with a coupling capacitor **1556**. A receiver **1558** is provided for receiving the information transmitted thereto and providing on the output thereof data on a data line **1560**. The receiver **1558** is operable to receive the RF signal, demodulate the data therefrom, and provide digital data on the output **1560**. External to the human body and the ball IC **1310** is a transmitter **1562** which is operable to impress a signal across an external inductive element **1564**. The inductive element **1564** basically provides the RF energy and is essentially tuned with a tuning element **1566**. A corresponding tuning element **1568** is provided on the ball IC **1310** and disposed across inductive element **1550**, the inductive element **1550** acting as an antenna, as well as the inductive element **1564**.

Note that in circumstances where the signals of ball IC **1310** cannot be adequately received therefrom and/or power coupled thereto, the external location system **1320** may need to be inserted into the body proximate to the ball IC **1310** in order to couple the transmit/receive signals and power. Furthermore, where more than one ball **1310** is used, communication of power and data signals between the various ball ICs **1310** may need to employ distinct time periods (i.e., time multiplexing) when communication occurs using a single common frequency, or discrimination circuits may need to be used where communication occurs simultaneously with the plurality of implanted ball ICs **1310** having different oscillator frequencies. Referring now to FIG. **16**, there is illustrated a side view of an alternative embodiment utilizing additional circuitry or structure attached to the ball IC **1310** for providing a local power source. As described hereinabove, the ball IC **1310** requires a power-generating structure for storing a power supply voltage such that diodes must be provided for receiving and rectifying a large amount of power and charging up a power supply capacitor. Alternatively, the ball IC **1310** could be configured to interface to an attached power supply system **1600** comprising either a battery or a capacitor. The local power supply system **1600** is illustrated as disposed on a circuit board **1603** defined by supporting structures **1602** and **1604**. The circuit board **1603** contains electronics for interfacing the local power supply system **1600** to the ball IC **1310**.

Referring now to FIG. **17**, there is illustrated a schematic block diagram of the ball IC **1310** using a battery as the local power supply system **1600**. A battery **1701** is provided as a source of self-contained power and is connected across a capacitor **1700** to provide smoothing of any power output to the system power-consuming elements of the ball IC **1310**. Power for all onboard components is obtained from the SYSTEM POWER output by providing sufficient charge to the capacitor **1700**. The capacitor **1700** could be formed on the surface of the ball IC **1310** or it could actually be part of the battery structure **1701**. Additionally, the capacitance **1700** could actually be the capacitance of the battery **1701**. Additional structure could be provided for powering the CPU **1438** and the other circuitry on the ball IC **1310** from the battery **1701**. As such, there would only be required a smaller inductive element **1702** and a capacitor **1704** to allow the receive/transmit block **1442** to receive/transmit information from and to the remote exterior control station **1320**. The switch control **1430** controls the gate of the switching transistor **1431** to switch output of the transducer **1315** through the switching transistor **1431** source/drain path to the CPU **1438**.

Referring now to FIG. **18**, there is illustrated a perspective view of the ball IC **1310**, wherein the inductive element **1404** (similar to inductive element **120**) is illustrated as being strips of conductive material wrapped around the exterior of the ball IC **1310**. The inductive element **1404** is formed of a conductive strip wrapped many times around the ball IC **1310**. The length of inductive element **1404** depends upon the receive characteristics that are required. As described hereinabove with reference to FIGS. **15A–15C**, there could be multiple conductive strips, one associated with a receive function, another for a transmit function, and another for a power function, or they could all share one single conductive element or strip. Notably, the inductive strips would be disposed on one side of the ball IC **1310** for communication purposes.

On one end of the ball IC **1310** there is provided a transducer interface **1800** of the transducer **1315** having, optionally, one or more interface balls **1802** (or partial balls, called nodules) associated therewith extending from the transducer interface surface to provide enhanced engagement of the measuring surface or physical entity. (Note that only a single sensor area is illustrated, although there could be more.) The interface balls **1802** can be made of non-reactive material, e.g., gold to prevent degradation while in the body. Note that in some applications, the interface nodules **1802** are not required for obtaining the desired quantitative data. On the other end of the ball IC **1310** are provided interconnect balls **1804** (or nodules) for interconnecting to one or more other spherical balls, as described hereinabove, which may provide similar functions such as monitoring of quantitative data, or unique functions such as supplying only power or data buffering and storage.

Referring now to FIG. **19**, there is illustrated a cross-sectional diagram of the surface of the ball IC **1310** illustrating the conductive strips forming the inductive element **1404**. The conductive strips are referred to by reference numeral **1910** which are spaced above the surface of the integrated circuit of the ball IC **1310** by a predetermined distance, and separated therefrom by a layer of silicon dioxide. A passivation layer **1911** is then disposed over the upper surface of the conductive strips **1910**. The conductive strips **1910** can be fabricated from polycrystalline silicon but, it would be preferable to form them from the upper metal layer to result in a higher conductivity strip. This will allow the strips **1910** to be narrower and separated from each other by a larger distance. This separation would reduce the amount of capacitance therebetween.

One end of the strips **1910** is connected to a diode structure **1913**. The diode structure **1913** is formed of an N-well implant region **1914** into which a P-well implant region **1916** is disposed, and an N-well implant region **1918** disposed within the P-well implant region **1916**. This forms a PN diode where one end of the conductive strips **1910**, a conductive connection **1920**, is connected to the P-well **1916** implant region, and a conductive layer **1922** is connected at one end to the N-well implant region **1918**. This conductive layer or strip **1922** extends outward to other circuitry on the integrated circuit and can actually form the capacitor. Since it needs to go to a capacitor directly, a lower plate **1924** formed of a layer of polycrystalline silicon or metal in a double-metal process, could be provided separated therefrom by a layer of oxide.

In another application, the sensor ball is used to stimulate excitable tissue. The semiconductor ball can function as a TENS (Transcutaneous Electrical Nerve Stimulator) unit. This is very important in treating chronic pain syndromes. The unit can also be used to stimulate both nerve and muscles in paralyzed or injured limbs to help prevent the development of atrophy or as a means to reduce the inflammatory response. Multiple balls which function as both receivers of electrical signal and also as transmitters of signal could function as a bridge between an amputated limb and a moveable prosthetic "hand."

Referring now to FIG. **20**, there is illustrated a cross section of a processor ball comprising a spherical-shaped semiconductor device on which an integrated circuit has been formed. Such a spherical-shaped integrated circuit semiconductor device is described in commonly assigned U.S. Pat. No. 5,955,776, issued Sep. 21,1999, and entitled "Spherical Shaped Semiconductor Integrated Circuit," the disclosure of which is referenced hereinabove. Processor ball **2000** (similar to processor balls **208, 1200, 1310**, is built on the substantially spherical semiconductor substrate **2003**, which may be doped P-type or N-type in accordance with the particular requirements of the fabrication process. Semiconductor circuitry indicated generally at **2005** resides on the substrate **2003**. Circuitry **2005** includes the power regulator **1210**, the transmit and receive circuits **1214** and **1220**, the processor **1216**, as well as other circuitry. The substrate **2003** and circuitry **2005** are covered with an insulating layer **2007** which is preferably formed of silicon dioxide or phosphosilicate glass. A power coil **2021** (one of L_1, L_2, and L_3), described with respect to FIG. **12**, is formed of helically wrapped windings over the insulating shell **2007**. The power coil **2021** may be fabricated from a deposited layer of aluminum (or copper, gold, etc.) that is patterned and etched using conventional semiconductor fabrication techniques. The actual number of individual windings **2022** of power coil **2021** may be more or less than the six shown in FIG. **20**.

The processor ball **2000** is coated with or encapsulated in a coating layer **2009** of a biological inert material such as phosphosilicate glass. The coating **2009** is inert and can withstand potential chemical degradation into which it contacts, for example, the acidity of the stomach, to a very low pH level, and it is not subject to the enzymatic actions of the digestive tract. Processor ball **2000** is substantially spherical and preferably about one millimeter in diameter. The very small size of processor ball **2000** enables it to be embedded in surgical or medical tools and apparatus.

Referring now to FIG. **21**, there are illustrated additional semiconductor details of a semiconductor processor ball. The processor ball **2000** is hermetically protected by a thin exterior glass passivation layer **2102**, which may be phosphosilicate glass. The interior of the processor ball **2000** comprises a semiconductor substrate **2003**, which may be doped p-type or n-type in accordance with the particular requirements of the fabrication process. Optionally, the substrate **2003** may be connected to, for example, a metallic intraluminal or a prosthetic device to serve as a ground potential for the processor ball **2000**. In an embodiment where an electrode sensor **2104** is on the processor ball **2000**, sensor **2104** has an outer surface **2106** that is exposed to the desired medium. The sensor **2104** preferably is formed atop a thick dielectric layer **2106**, which may be a field oxide layer grown on the substrate **2003**.

A large number of transistors T make up the circuitry of the voltage regulator **1210**, processor **1216** and RF transmitter **1220**, described above in connection with FIG. **12**. Although these transistors T are depicted schematically as field-effect transistors, the integrated circuitry of the processor ball **2000** could also use bipolar transistors. The individual transistors T are shown separated by portions of the field oxide **2106**. Transistor gates G and circuit interconnections (not shown) are embedded in an inter-level dielectric layer **2108** and are made using conventional semiconductor fabrication techniques adapted to the spherical surface of the processor ball **2000**.

A power coil **2110** (as described in connection with antenna/coil **1002** of FIG. **10**, or coils **1202, 1204**, and **1206** of FIG. **12**), is shown as having a plurality of separate windings **2112***a*, **2112***b*, **2112***c* and **2112***d*, which may be fabricated from a deposited layer of aluminum that is patterned and etched using conventional semiconductor fabrication techniques adapted to the spherical shape of the processor ball **2000**. The windings **2112***a*, **2112***b*, **2112***c* and **2112***d* are insulated from each other by portions of the inter-level dielectric layer **2108**. The actual number of individual windings of the coil may be far greater than the four specific windings **2112***a*, **2112***b*, **2112***c* and **2112***d*, shown. The ends of the coil **2110** are connected by additional conductors (not shown) to other circuit elements of the processor ball **2000**.

Referring now to FIG. **22**, there is illustrated a cross-sectional view of an electrode sensor pad **2201**. In general, the pad **2201** is required to provide a conductive interface between the transistor **2205** and the desired medium. This therefore requires some type of metallic interface that is non-reactive. Such an interface would require a metal such as gold, platinum and the like. In the disclosed embodiment, gold would be provided. After the formation of the upper metal layer **2236** on a substrate **2200** via a deposition technique with metal such as aluminum or copper, a passivation layer of oxide **2202** is deposited to basically prevent oxidation of the metal layer **2236**, and protect the semiconductor circuits, in general. The metal contact layer **2236** extends beyond the active region **2205** to a pad region **2204**, and is separated from the active region **2205** by a layer of field oxide **2210** or some type of isolation oxide. There may be some type of channel stop implant disposed below the field oxide layer **2210**. The metal contact layer **2236** extends from the source/drain implant **2209** to the region **2204**. This metal contact layer **2236** is required to be fairly conductive. Typically, polycrystalline silicon is not of sufficient conductivity to meet this requirement. Therefore, some type of polysilicide process may be required, wherein the upper surface is converted to some type of silicide such as titanium disilicide to lower the surface resistivity thereof. Alternatively, a metal layer could be provided which is connected to the metal contact region **2236**.

Once the contact region **2236** is formed, and the passivation layer **2202** is disposed over the entire structure, vias **2206** are formed therein. These vias **2206** are then filled with metallic plugs **2208** by forming a layer of metal over the oxide passivation layer **2202** and then etching the passivation layer **2202** to remove the undesired portions. The metal plugs **2208** may be formed of metal such as aluminum or gold. If they were formed of gold, this would allow for soldering if they were to be used as contacts. However, in this context, these plugs **2208** are utilized for conductivity purposes. Therefore, an aluminum plug would be sufficient if it were covered with a thin layer of gold to render the aluminum non-reactive and prevent oxidation thereof. Alternatively, in the disclosed embodiment, the plug may, of course, be gold. However, it should be understood that any type of non-reactive metal could be utilized as long as the surface thereof is sufficiently non-reactive and the conductance of the plug **2208** is sufficiently high to result in a low resistance path between the exterior of the spherical ball IC and a capacitive plate of the capacitor **2026**. The reason for this is that the stored charge must be discharged into a resistance as low as 500 Ohms, and any significant resistance disposed between the upper plate of the capacitor **2026** and the exterior must be minimized.

Referring now to FIG. **23**, there is illustrated a side elevation of a cluster **2300** of three semiconductor balls interconnected in a cooperative function. For example, ball **2381** (similar to ball **202**) can include a single electrode for sensing heart electrical activity. Ball **2382** can include the processing functions of a processor ball (similar to ball **208**), and ball **2383** can include a second electrode function. Connections between the balls are made through metal contacts **2390**, which may be solder bumps, and as described in greater detail hereinbelow, the metal contacts **2390** may be used for a variety interface functions, such as power, data, and a signal bypass path.

Referring now to FIG. **24**, there is illustrated a cross section of the ball interconnections taken through the line **24**—**24** of FIG. **23**. As mentioned hereinabove, the contacts **2390** may be employed to interface a variety of functions. For example, the contacts **2484** and **2486** may be power contacts, such as a positive 3.0 volts and ground, which can be passed from ball **2381** (if ball **2381** were to provide the power function for the set **2300**) to ball **2382**, and then around ball **2382** to ball **2383** by conductors on the surface of ball **2382** using two of a group of similar contacts of contacts **2390** to power ball **2383**. The contacts **2485** and **2487** may be data and control contacts for communications between balls of the set **2300**. Similar data and control contacts may exist among contact group **2390** between ball **2382** and ball **2383** to the extent needed.

Referring now to FIG. **25**, there is illustrated a 3-D ball cluster in a cooperative orientation. As an example of the versatility of such ball systems is illustrated where the cluster **2500** specifically shows six balls **2591**, **2592**, **2593**, **2594**, **2595** and **2596**, arranged in a three-dimensional configuration. It will be appreciated that various other cluster arrangements are possible which have fewer balls, and are limited only by the constraints of the end-use application. Each of the balls **2591**, **2592**, **2593**, **2594**, **2595** and **2596**, of the cluster **2500** can perform different electronic functions, and communicate with each other through contacts (not shown here, but discussed in detail in FIGS. **23** and **24**). Such cluster arrangements can provide a mix of, for example, three battery balls **2591**, **2592**, and **2593**, which provide ample power for the remaining energy-consuming balls, according to the functions provided. Such a mix may be necessary where a heating application is required for, for example, tumor ablation, or for more precise heating applications related to cartilage or ligament treatment.

Although the preferred embodiment has been described in detail, it should be understood that various changes, substitutions and alterations can be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A surface cardiac monitor system for monitoring electrical activity of the heart, comprising:

one or more semiconductor electrode balls adaptable to be embedded in organic tissue, and/or dispersed adjacent thereto having respective electrode sensors for sensing electrical heart activity;

a central processing semiconductor ball having each of said one or more semiconductor electrode balls connected electrically thereto for receiving respective heart signals from said sensors of said electrode balls, and processing said heart signals for transmission via a wireless communication link external to said organic tissue in which it is embedded; and

a remote control system for receiving said transmitted heart signals and extracting heart information from said transmitted heart signal about the electrical activity of the heart.

2. The system of claim **1**, wherein each of said one or more electrode balls is uniquely selectable by a respective unique frequency in a frequency mode, and by a unique ID stored therein in an ID mode, wherein in said frequency mode, one or more independent frequencies are transmitted to cause respective said one or more electrode balls to respond independently with said heart signals, and in said ID mode, one or more respective said unique IDs are transmitted to cause respective said one or more electrode balls to respond independently with said heart signals.

3. The system of claim **1**, wherein said one or more semiconductor electrode balls are oriented substantially orthogonally from each other.

4. The system of claim **1**, wherein said one or more semiconductor electrode balls and said central processing ball are substantially spherical.

5. The system of claim **1**, wherein said one or more semiconductor electrode balls and said central processing ball are placed on the skin over the precordium anywhere from the sternum to the anterior axillary line in the 5^{th} intercostal space.

6. The system of claim **1**, wherein said remote control system has a display for displaying said heart information.

7. The system of claim **1**, wherein said one or more electrode balls is a single semiconductor electrode ball having three electrode sensors fabricated thereon in an orthogonal orientation, and said single electrode ball connects electrically to said central processing ball for processing of said heart signals.

8. The system of claim **1**, wherein said electrode sensors are fabricated on the central processing ball such that the capabilities of sensing the heart activity and processing the heart in formation occurs on said central processing ball.

9. The system of claim **1**, wherein said central processing ball comprises a comparator amplifier, a noise filter, and an analog-to-digital converter, said comparator amplifier receiving pairs of said electrode signals generated by pairs of said electrodes and generating an analog signal indicative of the comparison of said electrode signals; said noise filter removes noise signals from said generated analog signal; and said analog-to-digital signal converts said analog signal into a digital representative of the sensed electrical heart activity for transmission to said remote control system using said wireless communication.

10. The system of claim **9**, wherein said central processing ball contains a matrix switch for switching pairs of said electrode signals into said comparator amplifier.

11. The system of claim **1**, wherein said wireless communication for transmitting said heart signal is a telemetry transmitter device operating at radio frequency.

12. The system of claim **1**, wherein said remote location receives said digitized transmitted heart signal is a telemetry receiver device operating at radio frequency.

13. The system of claim **1**, wherein said central processing ball comprises first and second processing circuits which process electrode signals of said electrodes in a parallel, but non-linear fashion, by processing with said first processing circuit an electrode signal of a second electrode and an electrode signal of a first electrode, and by processing with said second processing circuit an electrode signal of said second electrode and an electrode signal of a third electrode.

14. A method of monitoring electrical activity of the heart with surface cardiac monitor system, comprising the steps of:

providing one or more semiconductor electrode balls having respective electrode sensors for sensing electrical heart activity;

disposing the one or more semiconductor balls proximate to the surface of the skin of an individual in such a manner as to selectively monitor electrical activity of the heart;

electrically connecting a central processing semiconductor ball to each of the one or more semiconductor electrode balls for receiving respective heart signals from the sensors of the electrode balls, and processing the heart signals for transmission via a wireless communication link; and

receiving the transmitted heart signals at a remote control system heart information from the transmitted heart signal corresponding to the electrical activity of the heart.

15. The method of claim **14**, wherein each of the one or more electrode balls in the step of providing are uniquely selectable by a respective unique frequency in a frequency mode, and by a unique ID stored therein in an ID mode, wherein in the frequency mode, one or more independent frequencies are transmitted to cause respective the one or more electrode balls to respond independently with the heart signals, and in the ID mode, one or more respective the unique IDs are transmitted to cause respective the one or more electrode balls to respond independently with the heart signals.

16. The method of claim **14**, wherein the one or more semiconductor electrode balls in the step of providing are oriented substantially orthogonally from each other.

17. The method of claim **14**, wherein the one or more semiconductor electrode balls and the central processing ball are substantially spherical.

18. The method of claim **14**, wherein the one or more semiconductor electrode balls and the central processing ball are placed on the skin over the precordium anywhere from the sternum to the anterior axillary line in the 5^{th} intercostal space.

19. The method of claim **14**, wherein the remote control system in the step of receiving has a display for displaying the heart information.

20. The method of claim **14**, wherein the one or more electrode balls in the step of providing is a single semiconductor electrode ball having three electrode sensors fabricated thereon in an orthogonal orientation, and the single electrode ball connects electrically to the central processing ball for processing of the heart signals.

21. The method of claim **14**, wherein the electrode sensors in the step of providing are fabricated on the central processing ball such that the capabilities of sensing the heart activity and processing the heart in formation occurs on the central processing ball.

22. The method of claim **14**, wherein the central processing ball in the step of connecting comprises a comparator amplifier, a noise filter, and an analog-to-digital converter, the comparator amplifier receiving pairs of the electrode signals generated by pairs of the electrodes and generating an analog signal indicative of the comparison of the electrode signals; the noise filter removes noise signals from the generated analog signal; and the analog-to-digital signal converts the analog signal into a digital representative of the sensed electrical heart activity for transmission to the remote control system using the wireless communication.

23. The method of claim **22**, wherein the central processing ball in the step of connecting contains a matrix switch for switching pairs of the electrode signals into the comparator amplifier.

24. The method of claim **14**, wherein the wireless communication for transmitting the heart signal in the step of connecting is a telemetry transmitter device operating at radio frequency.

25. The method of claim **14**, wherein the remote location in the step of receiving receives the digitized transmitted heart signal is a telemetry receiver device operating at radio frequency.

26. The method of claim 14, wherein the central processing ball in the step of connecting comprises first and second processing circuits which process electrode signals of the electrodes in a parallel, but non-linear fashion, by processing with the first processing circuit an electrode signal of a second electrode and an electrode signal of a first electrode, and by processing with the second processing circuit an electrode signal of the second electrode and an electrode signal of a third electrode.

27. A wireless EKG monitor, comprising:

one or more semiconductor electrode balls adaptable to be embedded on organic tissue, and/or dispersed adjacent thereto, having respective electrode sensors for sensing electrical heart activity; and

a central processing semiconductor ball having each of said one or more semiconductor electrode balls connected electrically thereto for receiving respective heart signals from said sensors of said electrode balls, and processing said heart signals for transmission via a wireless communication link external to said organic tissue in which it is embedded.

28. The system of claim 27, wherein said one or more semiconductor electrode balls are oriented substantially orthogonally from each other.

29. The system of claim 27, wherein said one or more semiconductor electrode balls and said central processing ball are substantially spherical.

30. The system of claim 27, wherein said one or more semiconductor electrode balls and said central processing ball are placed on the skin over the precordium anywhere from the sternum to the anterior axillary line in the 5^{th} intercostal space.

31. The system of claim 27, wherein said one or more electrode balls is a single semiconductor electrode ball having three electrode sensors fabricated thereon in an orthogonal orientation, and said single electrode ball connects electrically to said central processing ball for processing of said heart signals.

32. The system of claim 27, wherein said electrode sensors are fabricated on the central processing ball such that the capabilities of sensing the heart activity and processing the heart in formation occurs on said central processing ball.

33. The system of claim 27, wherein said central processing ball comprises a comparator amplifier, a noise filter, and an analog-to-digital converter, said comparator amplifier receiving pairs of said electrode signals generated by pairs of said electrodes and generating an analog signal indicative of the comparison of said electrode signals; said noise filter removes noise signals from said generated analog signal; and said analog-to-digital signal converts said analog signal into a digital representative of the sensed electrical heart activity for transmission to said remote control system using said wireless communication.

34. The system of claim 33, wherein said central processing ball contains a matrix switch for switching pairs of said electrode signals into said comparator amplifier.

35. A method of monitoring using a wireless EKG monitor, comprising:

providing one or more semiconductor electrode balls which are adaptable to be embedded in organic tissue, and/or dispersed adjacent thereto, having respective electrode sensors for sensing electrical heart activity; and

electrically connecting a central processing semiconductor ball having each of the one or more semiconductor electrode balls connected electrically thereto for receiving respective heart signals from the sensors of the electrode balls, and processing the heart signals for transmission via a wireless communication link external to the organic tissue in which it is embedded.

36. The method of claim 35, wherein the one or more semiconductor electrode balls in the step of providing are oriented substantially orthogonally from each other.

37. The method of claim 35, wherein the one or more semiconductor electrode balls and the central processing ball are substantially spherical.

38. The method of claim 35, wherein the one or more semiconductor electrode balls and the central processing ball are placed on the skin over the precordium anywhere from the sternum to the anterior axillary line in the 5^{th} intercostal space.

39. The method of claim 35, wherein the one or more electrode balls in the step of providing is a single semiconductor electrode ball having three electrode sensors fabricated thereon in an orthogonal orientation, and the single electrode ball connects electrically to the central processing ball for processing of the heart signals.

40. The method of claim 35, wherein the electrode sensors are fabricated on the central processing ball such that the capabilities of sensing the heart activity and processing the heart in formation occurs on the central processing ball.

41. The method of claim 35, wherein the central processing ball in the step of connecting comprises a comparator amplifier, a noise filter, and an analog-to-digital converter, the comparator amplifier receiving pairs of the electrode signals generated by pairs of the electrodes and generating an analog signal indicative of the comparison of the electrode signals; the noise filter removes noise signals from the generated analog signal; and the analog-to-digital signal converts the analog signal into a digital representative of the sensed electrical heart activity for transmission to the remote control system using the wireless communication.

42. The method of claim 41, wherein the central processing ball in the step of connecting contains a matrix switch for switching pairs of the electrode signals into the comparator amplifier.

* * * * *

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摘要(译)

一种利用微型半导体球的协作关联的无线心电图监视器。表面安装心脏监测系统（200）的侧视图示出了三个半导体电极球（202），（204）和（206）接触中心通信球（208）以在它们之间进行电连通。每个电极球（202），（204）和（206）在其上制造有相应的电极（210），（212）和（214），用于接收来自心脏的电信号。电极信号被传递到中央通信球（208），用于处理，过滤，数字转换和从其传输到由医疗技术人员操作的遥控系统。然后可以将数据显示给医务人员。