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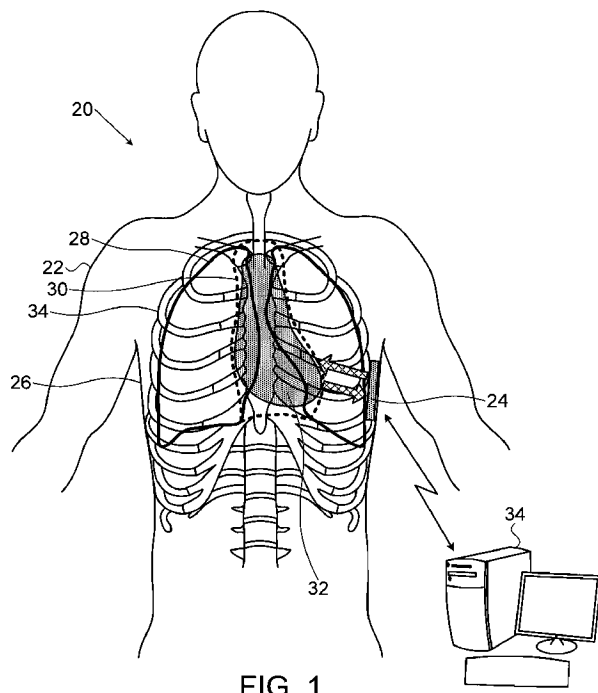
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(54) Title: IMPLANTABLE RADIO-FREQUENCY SENSOR



(57) Abstract: Diagnostic apparatus (24) includes a sealed case (40), including a biocompatible material and configured for implantation within a body of a human subject (22). At least one antenna (42) is configured to be implanted in the body in proximity to a target tissue (28) and to receive radio frequency (RF) electromagnetic waves propagated through the target tissue and to output a signal in response to the received waves. Processing circuitry (44, 46), which is contained within the case, is coupled to receive and process the signal from the antenna so as to derive and output an indication of a characteristic of the target tissue

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IMPLANTABLE RADIO-FREQUENCY SENSOR**CROSS-REFERENCE TO RELATED APPLICATION**

This application claims the benefit of U.S. Provisional Patent Application 61/366,173, filed July 21, 2010, which is incorporated herein by reference.

5 FIELD OF THE INVENTION

The present invention relates generally to methods and systems for medical diagnostic measurement and monitoring, and specifically to radio frequency (RF)-based measurement and monitoring of physiological conditions.

BACKGROUND OF THE INVENTION

10 Radio-frequency (RF) electromagnetic radiation has been used for diagnosis and imaging of body tissues. For example, PCT International Publication WO 2011/067623, which is assigned to the assignee of the present patent application and whose disclosure is incorporated herein by reference, describes diagnostic apparatus that includes an antenna, which directs RF electromagnetic waves into a living body and generates signals responsively
15 to the waves that are scattered from within the body. The signals are processed so as to locate a feature in a blood vessel in the body.

As another example, U.S. Patent Application Publication 2011/0130800, which is assigned to the assignee of the present patent application and whose disclosure is incorporated herein by reference, describes diagnostic apparatus, which includes a plurality of antennas,
20 which are configured to be disposed at different, respective locations on the thorax of a living body. The antennas direct radio frequency (RF) electromagnetic waves from different, respective directions toward the heart in the body and output RF signals responsively to the waves that are scattered from the heart. The RF signals are processed over time so as to provide a multi-dimensional measurement of a movement of the heart.

25 U.S. Patent Application Publication 2010/0256462 describes a method for monitoring thoracic tissue fluid content by intercepting reflections of electromagnetic (EM) radiation reflected from thoracic tissue of a patient in radiation sessions during a period of at least 24 hours. A change of a dielectric coefficient of the thoracic tissue is detected by analyzing the reflections. PCT International Publication WO 2009/031149 describes a wearable monitoring
30 apparatus comprising at least one transducer configured for delivering EM radiation to internal tissue and intercepting at least one reflection of the EM radiation therefrom. A housing for

containing the transducer, along with a reporting unit and a processing unit, is configured to be disposed on the body of an ambulatory user.

The citation of certain references above is intended to provide a general overview of the state of the art and does not constitute an admission that any of the references should be considered prior art against the present patent application.

SUMMARY

Embodiments of the present invention that are described hereinbelow provide implantable devices for measuring tissue characteristics using RF electromagnetic radiation and methods of measurement and monitoring using such devices.

There is therefore provided, in accordance with an embodiment of the present invention, diagnostic apparatus, including a sealed case, which includes a biocompatible material and configured for implantation within a body of a human subject. At least one antenna is configured to be implanted in the body in proximity to a target tissue and to receive radio frequency (RF) electromagnetic waves propagated through the target tissue and to output a signal in response to the received waves. Processing circuitry, which is contained within the case, is coupled to receive and process the signal from the antenna so as to derive and output an indication of a characteristic of the target tissue.

In some embodiments, the at least one antenna is configured to transmit the waves into the body and to receive the transmitted waves following propagation of the waves through the target tissue. In a disclosed embodiment, the at least one antenna is configured to receive the waves after reflection of the waves from a tissue in the body, and the processing circuitry is configured to detect a modulation of the reflection due to at least one of a heartbeat and a respiratory motion of the subject. The modulation may include a cyclical variation due to the heartbeat.

Additionally or alternatively, the apparatus may include a reflector configured for implantation in the body in a location across the target tissue from the case containing the at least one antenna, wherein the reflector serves as the structure for reflecting the waves toward the at least one antenna. The reflector may be a part of an implanted cardiac device (ICD) that is implanted in the body.

In another embodiment, the apparatus includes a transmitter, which is configured to be implanted in the body in a location across the target tissue from the case containing the at least one antenna and to transmit the waves through the target tissue.

In some embodiments, the processing circuitry is configured to process the signal so as to derive a measure of a fluid content of the target tissue. In a disclosed embodiment, the case is configured for implantation in a thorax, and the target tissue is lung tissue. In alternative embodiments, the target tissue is spleen, liver, tongue or palate tissue.

5 In one embodiment, the indication includes a time trend of the characteristic of the target tissue.

The at least one antenna may include a plurality of antennas. In one embodiment, the processing circuitry is configured to drive the antennas in a multi-static mode so as to spatially resolve the characteristic of the target tissue.

10 In some embodiments, the at least one antenna is contained inside the case. Typically, the at least one antenna includes a trace printed on a substrate, and wherein the case includes a window, and the antenna is configured to receive the waves through the window. The substrate may be sealed to the case by brazing.

In another embodiment, the at least one antenna is located partially outside the case and
15 is connected to the processing circuitry via a sealed brazing to the case.

In some embodiments, the at least one antenna includes a trace printed on a substrate and a backlobe suppression structure behind the trace. The backlobe suppression structure may be selected from a group of structures consisting of an air cavity and an electromagnetic bandgap (EBG) backing.

20 The at least one antenna may be selected from a group of antenna types consisting of a spiral antenna, a bowtie antenna, an elliptic bowtie antenna, and a slotted antenna.

In a disclosed embodiment, the processing circuitry is configured to convey the indication of the characteristic via a wireless link to a monitoring station outside the body. Additionally or alternatively, the processing circuitry may be configured to communicate with
25 at least one other implanted device.

The at least one antenna may also be configured to receive electrical energy to power the processing circuitry via an inductive link to a transmitter outside the body. Alternatively, the apparatus includes a power antenna, which is configured to receive electrical energy to power the processing circuitry via an inductive link to a transmitter outside the body.

30 In a disclosed embodiment, the apparatus includes one or more electrodes on the case for receiving electrical signals within the body. Additionally or alternatively, the apparatus may include a bio-impedance sensor. Further additionally or alternatively, the apparatus

includes an implanted cardiac device, which is configured to pace a heart of the subject responsively to the indication provided by the processing circuitry.

There is also provided, in accordance with an embodiment of the present invention, diagnostic apparatus including a radio frequency (RF) reflector, which is configured to be
5 implanted in a body of a human subject in proximity to a target tissue. A diagnostic device is configured to transmit RF electromagnetic waves toward the RF reflector and to receive the waves reflected by the RF reflector through the target tissue, and to process the received waves so as to derive and output an indication of a characteristic of the target tissue.

There is additionally provided, in accordance with an embodiment of the present
10 invention, a diagnostic method, which includes implanting a diagnostic device in proximity to a target tissue in a body of a human subject. The device receives radio frequency (RF) electromagnetic waves propagated through the target tissue and processes the received waves so as to derive an indication of a characteristic of the target tissue.

In a disclosed embodiment, implanting the device includes using an external antenna
15 outside the body to identify an optimal location for implantation of the device.

The present invention will be more fully understood from the following detailed description of the embodiments thereof, taken together with the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic pictorial illustration showing a monitoring system including an
20 implanted RF monitoring device, in accordance with an embodiment of the invention;

Fig. 2 is a schematic sectional view of a RF monitoring device implanted in a human body, in accordance with an embodiment of the invention;

Fig. 3 is a block diagram that schematically shows functional components of an implantable RF monitoring device, in accordance with an embodiment of the invention;

Fig. 4A is a schematic pictorial illustration of an implantable RF monitoring device, in
25 accordance with an embodiment of the invention;

Fig. 4B is a schematic exploded view of the device of Fig. 4A;

Fig. 5 is a schematic pictorial illustration showing a RF monitoring device implanted in a human body, in accordance with another embodiment of the invention;

Figs. 6A and 6B are schematic pictorial illustrations, in side and front views
30 respectively, showing a RF monitoring device implanted in a human body, in accordance with a further embodiment of the invention;

Fig. 7 is a schematic pictorial illustration of a part of a RF monitoring device, in accordance with another embodiment of the present invention;

Fig. 8 is a schematic, partly-exploded view of a RF monitoring device, in accordance with yet another embodiment of the present invention;

5 Fig. 9 is a schematic exploded view of an antenna used in the embodiment of Fig. 8; and

Fig. 10 is a schematic pictorial illustration of a RF monitoring device, in accordance with an additional embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

OVERVIEW

10 A number of chronic medical conditions lead to accumulation of fluid in and around body organs. For example, pulmonary edema is associated with chronic heart failure and other pathologies. As another example, conditions such as kidney failure and certain inflammatory disorders may lead to pericardial effusion. Monitoring such fluid levels in the patient's body over extended periods can be helpful in ongoing risk assessment and adjustment of treatment.
15 Similarly, monitoring accumulation of blood in the splanchnic system can be of medical benefit in assessing fluid status.

Embodiments of the present invention that are described hereinbelow provide implantable devices and methods that can be used for long-term measurement and monitoring of tissue characteristics, such as fluid accumulation in and around body organs. In these
20 embodiments, a diagnostic device comprises at least one antenna and associated processing circuitry, which are contained inside or connected to a sealed case made from a biocompatible material. The device is implanted within the body of a human subject in proximity to a target tissue, such as the lung. The antenna receives radio frequency (RF) electromagnetic waves transmitted through the target tissue. These waves may be transmitted by the antenna itself and
25 then reflected back through the target tissue to the device, or they may be transmitted from another source. The processing circuitry processes the signals that are output by the antenna in order to derive and output an indication of a characteristic of the target tissue, such as the tissue fluid content.

In a disclosed embodiment, the device is implanted in the thorax, adjacent to the lung.
30 The processing circuitry drives the antenna (or antennas) to transmit RF waves through the lung toward the heart, and to receive waves reflected from the heart and transmitted back through the lung. Alternatively, the waves may be reflected back from a dedicated reflector or another

reflective object. Further alternatively, the waves may be transmitted through the lung by a separate transmitter, which is implanted in the body in a location across the target tissue from the receiver. The processing circuitry processes the output signals from the antenna in order to derive a measure of the fluid content of the lung. The processing circuitry periodically reports
5 the fluid level by telemetric link to a monitor outside the patient's body, for use by a physician in tracking the patient's condition and making treatment changes as appropriate.

Although the embodiments described herein are directed specifically to monitoring of fluid levels in the lungs, the principles of the present invention may similarly be applied in other monitoring applications. For example, implanted devices of the types described herein
10 may be used, *mutatis mutandis*, in monitoring pericardial fluid levels. As another example, such a device may be used to monitor bladder fill level and/or muscle properties in patients suffering from urinary disorders, in order to provide an alert when the bladder should be emptied. In other embodiments, such devices may be used in long-term monitoring of fluid levels in the brain, tongue, palate or spleen, as well as in body extremities, such as the thighs.
15 More generally, the devices and methods described herein may be adapted for use in substantially any long-term diagnostic application in which tissue characteristics are evaluated using RF electromagnetic waves, including not only fluid monitoring but also imaging applications, as well.

SYSTEM DESCRIPTION

Reference is now made to Figs. 1 and 2, which schematically illustrate a RF-based
20 monitoring system 20, in accordance with an embodiment of the invention. Fig. 1 is a pictorial illustration, showing a RF monitoring device 24 implanted in a thorax 26 of a patient 22, while Fig. 2 is a sectional view taken through the body, showing the relation of device 24 to organs in the thorax. Device 24, which is typically similar in shape and size to a conventional implanted
25 cardiac device (ICD), such as a pacemaker, is implanted below the patient's skin adjacent to ribs 34 and transmits and receives RF electromagnetic waves through target tissue, such as a lung 28, as indicated by arrows in the figure.

In the pictured example, device 24 is implanted in the axillary region using a minimally-invasive procedure. The waves transmitted by device 24 pass through lung 28 and mediastinum
30 30, reflect back from heart 32 through lung 28, and are then received and detected by device 24. Alternatively, the device may be implanted in other suitable locations, such as the infra-mammary or dorsal regions of thorax 26. An external antenna may be used during implantation to choose an optimal antenna location, based upon which the surgeon implants device 24 and its

implanted antenna at the location giving the best signal. In some alternative embodiments, as shown in Figs. 5, 6A and 6B, for example, the monitoring device may be used in conjunction with an implanted reflector, instead of or in addition to sensing reflections from the heart.

RF monitoring device 24 processes the received RF waves to derive an indication of tissue characteristics, such as tissue fluid content. Device 24 collects these indications over time and periodically transmits the data to a telemetry station 34, typically via a suitable short-range wireless link. Station 34 typically comprises a general-purpose computer with suitable communication circuits and software, and may be located in a clinic or hospital or in the home or workplace of patient 22. Station 34 may also be configured to program device 24 over the wireless link, as well as to provide RF energy to recharge the battery in device 24, as described below.

Fig. 3 is a block diagram that schematically shows functional elements of RF monitoring device 24, in accordance with an embodiment of the invention. The elements of device 24 are contained in a sealed case 40, comprising a suitable biocompatible material, such as titanium or stainless steel. The case may be coated with a tissue-growth inducing material, as is known in the art. Case 40 contains, *inter alia*, processing circuitry including a RF front end 44 and a digital processing circuit 46. Front end 44 drives one or more antennas 42 to emit RF waves through lung 28. The front end receives and processes the signals that are output by antennas 42 in response to the reflected waves and outputs a digitized indication of the amplitude and phase of the signals to digital processing circuit 46. Typically, for high resolution in the presence of background noise, front end 44 and circuit 46 apply coherent methods of signal processing to correlate the reflected signals with the transmitted signals, but alternatively non-coherent processing methods may be used.

In one embodiment, front end 44 generates signals at multiple different frequencies for exciting the transmitting antennas. Device 24 may operate in an ultra-wide-band (UWB) mode, in which the signals are spread over a wide range of frequencies, such as from about 500 MHz to about 2.5 GHz (although higher and lower frequencies outside this range may also be used). UWB transmission and detection techniques of this sort are described, for example, in the above-mentioned PCT International Publication WO 2011/067623 and U.S. Patent Application Publication 2011/0130800. The UWB signal provides the frequency-domain equivalent of a very short pulse in the time domain and can thus be used for measuring the range of a reflecting spot in the body with high accuracy. The UWB signal can be transmitted as a short pulse or as a train of narrowband signals that together constitute a wideband signal, or other waveforms

used in radar pulse compression (such as chirped, stepped-frequency, or phase-coded pulses). Use of these sorts of waveforms in making measurements inside the body is described in the above-mentioned publications and may similarly be applied, *mutatis mutandis*, in system 20.

5 Digital processing circuit 46 measures the time delay for RF waves to travel from antenna 42 to heart 32 via lung 28 and back to the antenna. The waves reflected from the heart can be identified based on the modulation, typically comprising a cyclical change, of the resulting signal during a heartbeat. The short-term time cyclical variation of the delay from antenna to heart and back can also be used to measure heart movement, while long-term variation is indicative of changes in the pulmonary fluid level. Additionally or alternatively,
10 electrodes 56, which may be built into case 40 or mounted externally, may measure an electrocardiogram (ECG) signal for correlation with the actual heart movement. Further additionally or alternatively, circuit 46 may detect modulation of the waves due to respiratory motion.

15 Further additionally or alternatively, device may comprise other sensors 58, either in case 40 or connected to it externally. Sensors 58 may measure, for example, bio-impedance, fluid content, temperature, salinity, or motion (of the heart, lungs, or entire body) and may be useful in filling out the picture of fluid status that is provided by RF measurement.

As the RF waves pass through body tissue, such as lung 28, the group velocity of the waves will vary as a function of the fluid content of the tissue. Generally speaking, the higher
20 the fluid content, the greater will be the dielectric constant of the tissue, and hence the lower the velocity. Equivalently, fluid in the lungs can be considered to increase the RF path length of the waves, defined by the length of time required for the waves to pass through the tissue and back to device 24. The result of this decrease in velocity or increase in RF path length is that the delay of the reflected waves will increase as the fluid content of lungs 28 increases. Digital
25 processing circuit 46 measures this delay periodically and/or on command in order to compute an indication of the lung's fluid content. Typically, circuit 46 comprises a memory (not shown), which stores the computed values.

In addition to or alternatively to measuring the RF path length or delay, digital processing circuit may measure other signal characteristics, such as the amplitude of the
30 reflected signals from the transition layer between ribs 34 and lung 28. The amplitude of this reflection is typically stronger and differently shaped in patients suffering from pulmonary edema in comparison to healthier subjects. The signal amplitude and shape may also be fitted

parametrically to a stratified model of the various tissues traversed by the RF waves, wherein the fit parameters include the fluid content.

5 Additionally or alternatively, circuit 46 may compute other parameters relating to tissue characteristics, such as the volume, shape, physical properties, locations and/or movement of structures in the path of the RF waves within the body. For example, the RF waves and signal processing carried out in front end 44 and circuit 46 may be adjusted to measure pericardial fluid content within mediastinum 30. As another example, antennas 42 can be driven in a multi-static configuration to measure the electromagnetic properties of different sub-volumes within thorax 26, and thus provide data that are spatially resolved in two or three dimensions. 10 Such multi-static techniques (using extracorporeal antennas) are described, for example, in the above-mentioned WO 2011/067623 and US 2011/0130800, which also describe digital signal processing methods that can be used to compute the complex dielectric constants for the individual sub-volumes.

A communication interface 48 transmits and receives data to and from telemetry station 15 34 (Fig. 1) via a communication antenna 50. The transmitted data typically comprise the indications of tissue characteristics that have been computed over time and stored by digital processing circuit 46. These indications may include statistical parameters computed by circuit 46 over the tissue measurement results, such as time trend parameters of the measured fluid level. Alternatively or additionally, the indications of tissue characteristics may include raw data collected from front end 44, and communication interface 48 may transmit data either 20 intermittently or continuously as they are measured. Further alternatively or additionally, interface 48 may communicate with other implanted diagnostic and/or therapeutic devices, such as an intravascular pressure sensor or an ICD, or with non-invasive monitoring devices, such as a bio-impedance measurement device.

25 A power source 52 supplies operating power to the circuits of device 24. Power source 52 typically comprises an energy storage component, such as a single-use or rechargeable battery. In the case of a rechargeable storage component, power source 52 may be coupled to a power antenna 54, which receives RF power from a suitable power transmission antenna (not shown) outside the body. Alternatively, one or more of antennas 42 may additionally receive 30 this RF power, instead of or in addition to power antenna 54. The power transmission antenna may comprise, for example, a coil, which is positioned outside thorax 26 in proximity to device 24 and provides power to antenna 54 by magnetic induction. The power transmission coil may be placed under a mattress on which the patient lies, or it may be worn as a vest, a bra or a

necklace, for example. Power source 52 rectifies the received power in order to charge its energy storage component.

Fig. 4A is a schematic pictorial illustration of RF monitoring device 24, in accordance with an embodiment of the invention, while Fig. 4B shows a schematic exploded view of the device of Fig. 4A. Case 40 comprises front and rear covers 62, 64, typically comprising titanium. Antennas 42 are printed, using hard gold or another suitable biocompatible conductor, on a main circuit board 66, which typically comprises a biocompatible ceramic substrate with brazing to enable it to be hermetically sealed against covers 62 and 64. Board 66 also has pads and conductors for mounting and connecting the components (not shown) of front end 44, processing circuit 46, and communication interface 48. These components are typically embodied in one or more integrated circuits, as are known in the art. Front cover 62 comprises windows 60 containing antennas 42, which are sealed by bonding the perimeters of the windows to brazing surrounding the antennas on board 66.

Antennas 42 in this example each comprise a pair of printed conductive loops with a center feed, in an elliptic bowtie configuration. For enhanced efficiency and directionality, antennas 42 are backed by conductive air-filled cavities 68 on the side of board 66 opposite windows 60. Cavity antennas of this sort (in an extracorporeal configuration) are described, for example, in the above-mentioned PCT International Publication WO 2011/067623. Alternatively, device 24 may comprise any other suitable type of antenna, such as a spiral, bowtie, or slotted antenna, with a cavity, electromagnetic bandgap (EBG) backing, or no backing.

Power antenna 54 comprises a coil 72 with a magnetic or ferritic core 74, covered by a non-conductive biocompatible cover 78. Coil 72 is connected via feed-throughs between covers 62 and 64 to power source 52. Cover 78 typically comprises a suitable biocompatible plastic or other dielectric material, such as silicone molded over coil 72 and core 74. Coil 72 may also serve as communication antenna 50. Alternatively, a separate communication antenna 70 may be connected to board 66 and positioned to transmit and receive communication signals through a window 72 in cover 64. As still another alternative, one or both of antennas 42 may serve as the communication antenna (although in this case it may be preferable that the antenna not have a cavity or other backing in order to strengthen the backlobe radiation transmitted by the antenna out of the body).

As noted earlier, device 24 comprises electrodes 56, which are shown in Figs. 4A and 4B as external elements on cover 62. The ECG signals sensed by these electrodes may be used

not only in synchronizing the measurements of RF reflections to the patient's heartbeat, but also as a diagnostic indicator in and of themselves, which is processed and stored by circuit 46. This diagnostic indicator can then be used, for example, to detect cardiac arrhythmias, in a manner similar to a Holter monitor. Alternatively or additionally, device 24 can comprise sensors for other sorts of intra-body clinical measurements, such as temperature, blood pressure, and/or blood oxidation, thereby broadening the usefulness and improving the diagnostic accuracy of system 20.

ALTERNATIVE EMBODIMENTS

Fig. 5 is a schematic pictorial illustration of a monitoring system 80 comprising a RF monitoring device 82 implanted in a human body, in accordance with another embodiment of the invention. Device 82 is similar in structure and function to device 24, as described above, but in this embodiment, device 82 operates in conjunction with an internally-placed reflector 84 on the opposite side of the patient's lung, as shown in the figure, rather than relying on reflections from the heart. The use of a dedicated reflector strengthens the reflected waves that are received by device 82 and provides a constant physical path length to which the measured RF path length can be compared. Alternative placements of the monitoring device and reflector are shown in Figs. 6A and 6B. As yet another alternative, the RF reflector may be positioned outside the patient's body.

Reflector 84 may be a passive structure made of biocompatible conducting material, or it may comprise one or more active components, which can be modulated to enhance signal extraction by device 82. The modulation of this reflector can be triggered and powered externally by means of a magnetic pulse source or a low-frequency electromagnetic wave. As another alternative, an internal active or passive reflector of this sort can be used in conjunction with an external RF transmitter/receiver, in place of device 82.

In an alternative embodiment, reflector 84 may be replaced by a RF transmitter, which transmits RF waves through the lung to device 82. In this case, device 82 may comprise only a RF receiver (together with the processing circuitry and other components shown in Fig. 3). As still another alternative, transmit/receive devices on opposite sides of the heart may each transmit RF waves and receive the RF waves transmitted by the counterpart device.

Figs. 6A and 6B are schematic pictorial illustrations, in side and front views respectively, showing a system 90 in which a RF monitoring device 92 is implanted in a human body, in accordance with a further embodiment of the invention. In this embodiment, device 92 is similar in structure and function to device 24, but is implanted in an infra-mammary location

and operates in conjunction with a reflector 94 in a dorsal location, between the fourth and sixth ribs, for example. Alternatively, the locations of device 92 and reflector 94 may be reversed.

Fig. 6B also shows an ICD 96, which may be used in conjunction with device 92 or integrated with device 92. For example, device 92 and pacemaker 96 may share a power source and/or communication circuits for communicating with station 34 outside the body. Device 92 and ICD 96 may even be contained in the same case, which may be implanted, for example, in the infra-mammary region. The measurements provided by device 92, particularly with regard to the level of pulmonary fluid accumulation, may be used as an input in controlling the pacing of the heart by ICD 96.

ICD 96 may alternatively serve as the reflector for device 92, in place of reflector 94. In this case, the ICD may simply be configured as a passive reflector, or it may comprise a modulated reflector, as described above.

Fig. 7 is a schematic pictorial illustration of a part of a RF monitoring device 100, in accordance with another embodiment of the present invention. This figure shows the internal side of case 102 of device 100, to which a cylindrical antenna support 104 is attached, by laser welding along a seam 106, for example. A substrate 108 of the antenna is mounted on support 104. Substrate 108 typically comprises a ceramic material, such as a low-temperature co-fired ceramic (LTCC), for example, Dupont 951LTCC. Substrate 108 comprises a metal coating around its perimeter, and is brazed to support 104 (as well as to the overlying front side of case 102, which is not shown in this figure) using a titanium ring 110 and a suitable filler material. The brazing serves the dual purposes of electromagnetically sealing the antenna to its backing and mechanically sealing the substrate to the case.

Fig. 8 is a schematic, partly-exploded view of a RF monitoring device 120, in accordance with yet another embodiment of the present invention. In this embodiment, an antenna 124 is attached externally to a sealed case 122 of device 120. Antenna 124 in this example comprises a conductive spiral 126, but this sort of external configuration is equally applicable to other antenna types. Antenna 124 is inserted into a slot 128 in case 122, and an edge 130 of the antenna is then sealed to case 122 by brazing, for example. The antenna is thus partially inside and partially outside the case, with sealed RF connections from the circuits inside the case to the outer antenna using printed electrical traces.

Fig. 9 is a schematic exploded view of antenna 124, in accordance with an embodiment of the present invention. Antenna 124 comprises a stack of three layers, each on a respective ceramic substrate 132, 134, 138. Spiral 126 is printed on the upper layer. An EBG structure

136 is printed on the middle layer, serving as a backing for spiral 126, with EBG elements of different sizes corresponding to the different frequencies radiated by different areas of the spiral. The lower layer serves as a ground plane, with vias 140 passing through all the layers of antenna 124. The vias are connected via leads (not shown) on substrate 138 to the circuits
5 inside case 122. The two central vias provide the signals for exciting spiral 126.

Fig. 10 is a schematic pictorial illustration of a RF monitoring device 150, in accordance with an additional embodiment of the present invention. Here a bowtie antenna 154 is connected by a coaxial cable 156 to circuits inside a case 152. The cable and case are sealed by a feedthrough in a header 158, which may comprise a suitable epoxy and/or polyurethane.
10 Device 150 in this embodiment also has a communication antenna 160, as described above.

As noted earlier, although the embodiments shown in the figures relate specifically to measurement of the fluid content of the lungs, the principles of the present invention may similarly be applied in monitoring of other organs, such as the heart, bladder, tongue, palate, spleen, brain, or body extremities. It will thus be appreciated that the embodiments described
15 above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

20

CLAIMS

1. Diagnostic apparatus, comprising:
 - a sealed case, comprising a biocompatible material and configured for implantation within a body of a human subject;
 - 5 at least one antenna, which is configured to be implanted in the body in proximity to a target tissue and to receive radio frequency (RF) electromagnetic waves propagated through the target tissue and to output a signal in response to the received waves; and
 - processing circuitry, which is contained within the case and is coupled to receive and process the signal from the antenna so as to derive and output an indication of a characteristic
 - 10 of the target tissue.
2. The apparatus according to claim 1, wherein the at least one antenna is configured to transmit the waves into the body and to receive the transmitted waves following propagation of the waves through the target tissue.
3. The apparatus according to claim 2, wherein the at least one antenna is configured to
- 15 receive the waves after reflection of the waves from a tissue in the body, and wherein the processing circuitry is configured to detect a modulation of the reflection due to at least one of a heartbeat and a respiratory motion of the subject.
4. The apparatus according to claim 3, wherein the modulation comprises a cyclical variation due to the heartbeat.
- 20 5. The apparatus according to claim 2, and comprising a reflector configured for implantation in the body in a location across the target tissue from the case containing the at least one antenna, wherein the reflector serves as the structure for reflecting the waves toward the at least one antenna.
6. The apparatus according to claim 5, wherein the reflector is a part of an implanted
- 25 cardiac device (ICD) that is implanted in the body.
7. The apparatus according to claim 1, and comprising a transmitter, which is configured to be implanted in the body in a location across the target tissue from the case containing the at least one antenna and to transmit the waves through the target tissue.
8. The apparatus according to any of claims 1-7, wherein the processing circuitry is
- 30 configured to process the signal so as to derive a measure of a fluid content of the target tissue.

9. The apparatus according to claim 8, wherein the case is configured for implantation in a thorax, and wherein the target tissue is lung tissue.
10. The apparatus according to claim 8, wherein the target tissue is spleen, liver, tongue or palate tissue.
- 5 11. The apparatus according to any of claims 1-7, wherein the indication comprises a time trend of the characteristic of the target tissue.
12. The apparatus according to any of claims 1-7, wherein the at least one antenna comprises a plurality of antennas.
13. The apparatus according to claim 12, wherein the processing circuitry is configured to
10 drive the antennas in a multi-static mode so as to spatially resolve the characteristic of the target tissue.
14. The apparatus according to any of claims 1-7, wherein the at least one antenna is contained inside the case.
15. The apparatus according to claim 14, wherein the at least one antenna comprises a trace
15 printed on a substrate, and wherein the case comprises a window, and the antenna is configured to receive the waves through the window.
16. The apparatus according to claim 15, wherein the substrate is sealed to the case by brazing.
17. The apparatus according to any of claims 1-7, wherein the at least one antenna is located
20 partially outside the case and is connected to the processing circuitry via a sealed brazing to the case.
18. The apparatus according to any of claims 1-7, wherein the at least one antenna comprises a trace printed on a substrate and a backlobe suppression structure behind the trace.
19. The apparatus according to claim 18, wherein the backlobe suppression structure is
25 selected from a group of structures consisting of an air cavity and an electromagnetic bandgap (EBG) backing.
20. The apparatus according to any of claims 1-7, wherein the at least one antenna is selected from a group of antenna types consisting of a spiral antenna, a bowtie antenna, an elliptic bowtie antenna, and a slotted antenna.

21. The apparatus according to any of claims 1-7, wherein the processing circuitry is configured to convey the indication of the characteristic via a wireless link to a monitoring station outside the body.
22. The apparatus according to any of claims 1-7, wherein the processing circuitry is
5 configured to communicate with at least one other implanted device.
23. The apparatus according to any of claims 1-7, wherein the at least one antenna is also configured to receive electrical energy to power the processing circuitry via an inductive link to a transmitter outside the body.
24. The apparatus according to any of claims 1-7, and comprising a power antenna, which is
10 configured to receive electrical energy to power the processing circuitry via an inductive link to a transmitter outside the body.
25. The apparatus according to any of claims 1-7, and comprising one or more electrodes on the case for receiving electrical signals within the body.
26. The apparatus according to any of claims 1-7, and comprising a bio-impedance sensor.
- 15 27. The apparatus according to any of claims 1-7, and comprising an implanted cardiac device, which is configured to pace a heart of the subject responsively to the indication provided by the processing circuitry.
28. Diagnostic apparatus comprising:
a radio frequency (RF) reflector, which is configured to be implanted in a body of a
20 human subject in proximity to a target tissue; and
a diagnostic device, which is configured to transmit RF electromagnetic waves toward the RF reflector and to receive the waves reflected by the RF reflector through the target tissue, and to process the received waves so as to derive and output an indication of a characteristic of the target tissue.
- 25 29. A diagnostic method, comprising:
implanting a diagnostic device in proximity to a target tissue in a body of a human subject;
receiving in the device radio frequency (RF) electromagnetic waves propagated through
the target tissue; and
30 processing the received waves in the device so as to derive an indication of a characteristic of the target tissue.

30. The method according to claim 29, and comprising transmitting the waves from the device into the body, so that the device receives the transmitted waves following propagation of the waves through the target tissue.
31. The method according to claim 30, wherein the waves are received by the device after reflection of the waves from a tissue in the body, and wherein processing the received waves comprises detecting a modulation of the reflection due to at least one of a heartbeat and a respiratory motion of the subject.
32. The method according to claim 31, wherein the modulation comprises a cyclical variation due to the heartbeat.
33. The method according to claim 30, and comprising implanting a reflector in the body in a location across the target tissue from the case containing the at least one antenna, wherein the reflector serves as the structure for reflecting the waves toward the device.
34. The method according to claim 33, wherein the reflector is a part of an implanted cardiac device (ICD) that is implanted in the body.
35. The method according to claim 29, and comprising implanting a transmitter in the body in a location across the target tissue from the device, and transmitting the waves through the target tissue from the transmitter to the device.
36. The method according to any of claims 29-35, wherein processing the received waves comprises deriving a measure of a fluid content of the target tissue.
37. The method according to claim 36, wherein the diagnostic device is implanted in a thorax, and wherein the target tissue comprises a lung of the subject.
38. The method according to claim 34, wherein the target tissue is spleen, liver, tongue or palate tissue.
39. The method according to any of claims 29-35, wherein processing the received waves comprises computing a time trend of the characteristic of the target tissue.
40. The method according to any of claims 29-35, wherein the device comprises a plurality of antennas.
41. The method according to claim 40, wherein receiving the RF electromagnetic waves comprises driving the antennas in a multi-static mode so as to spatially resolve the characteristic of the target tissue.

42. The method according to any of claims 29-35, and comprising conveying the indication of the characteristic from the implanted device via a wireless link to a monitoring station outside the body.
43. The method according to any of claims 29-35, and comprising communicating between
5 the implanted device and at least one other implanted device.
44. The method according to any of claims 29-35, and comprising receiving electrical energy to power the device via an inductive link to a transmitter outside the body.
45. The method according to any of claims 29-35, and comprising receiving electrical signals within the body using one or more electrodes on the device.
- 10 46. The method according to any of claims 29-35, and comprising measuring a bio-impedance using a sensor associated with the device.
47. The method according to any of claims 29-35, and comprising pacing a heart of the subject responsively to the indication provided by the device.
48. The method according to any of claims 29-35, wherein implanting the device comprises
15 using an external antenna outside the body to identify an optimal location for implantation of the device.

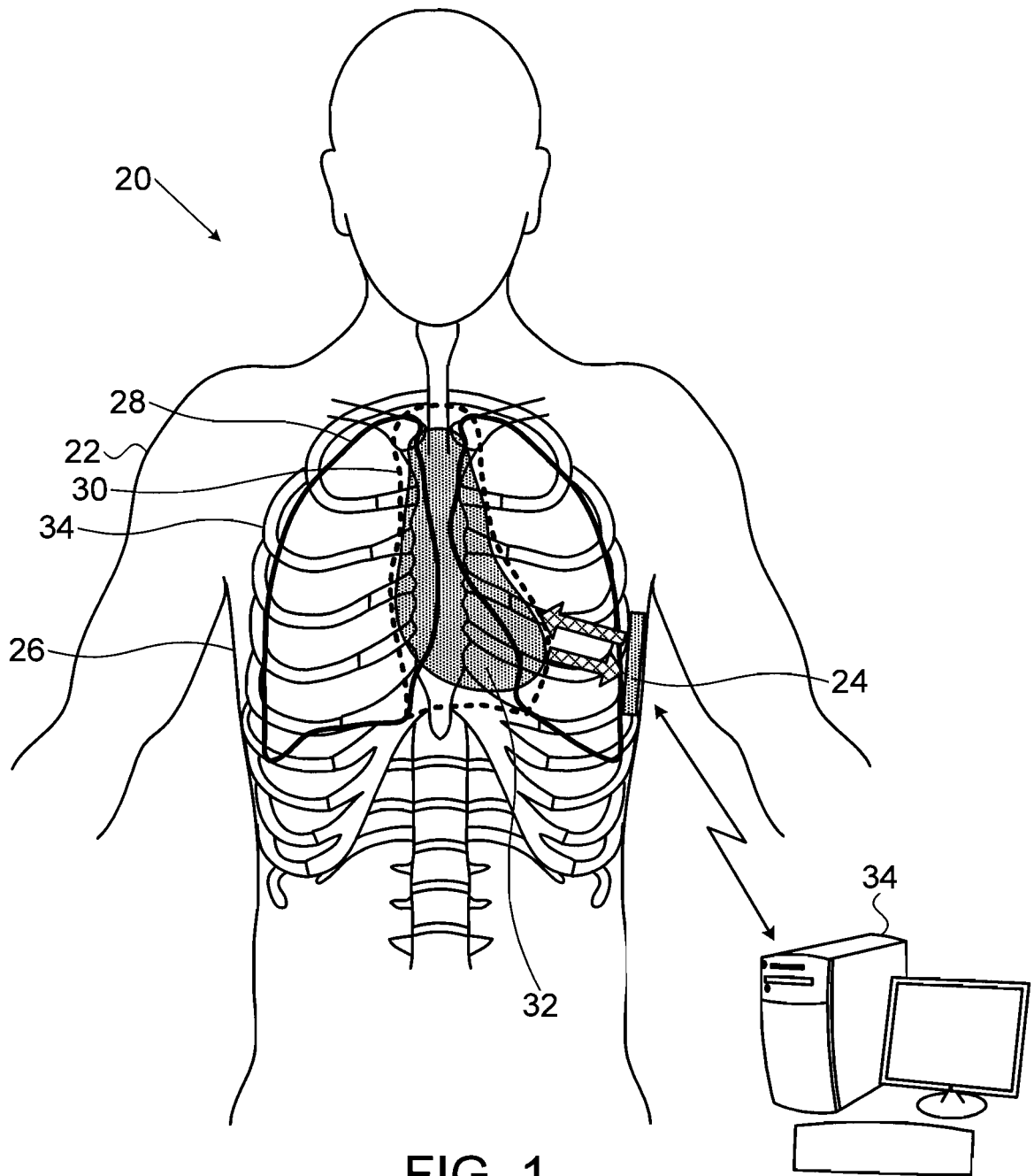


FIG. 1

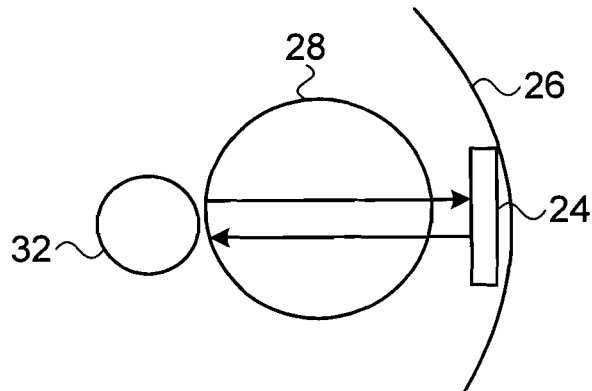


FIG. 2

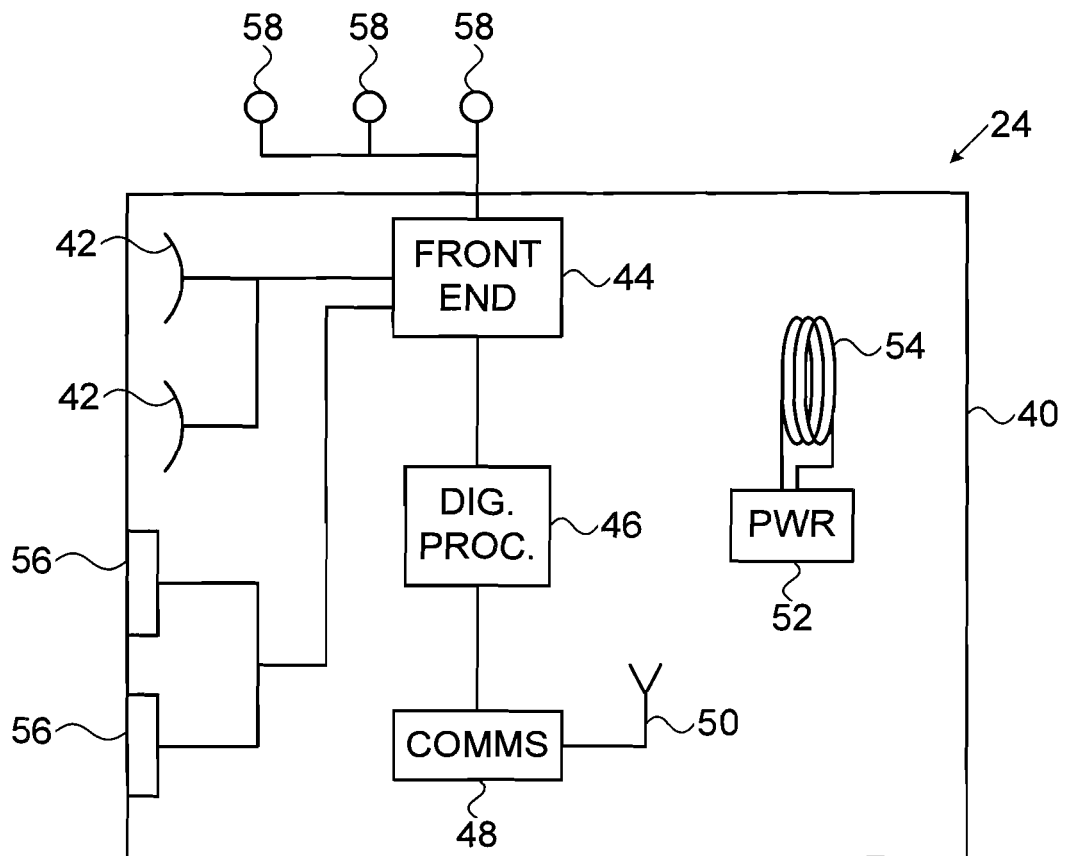


FIG. 3

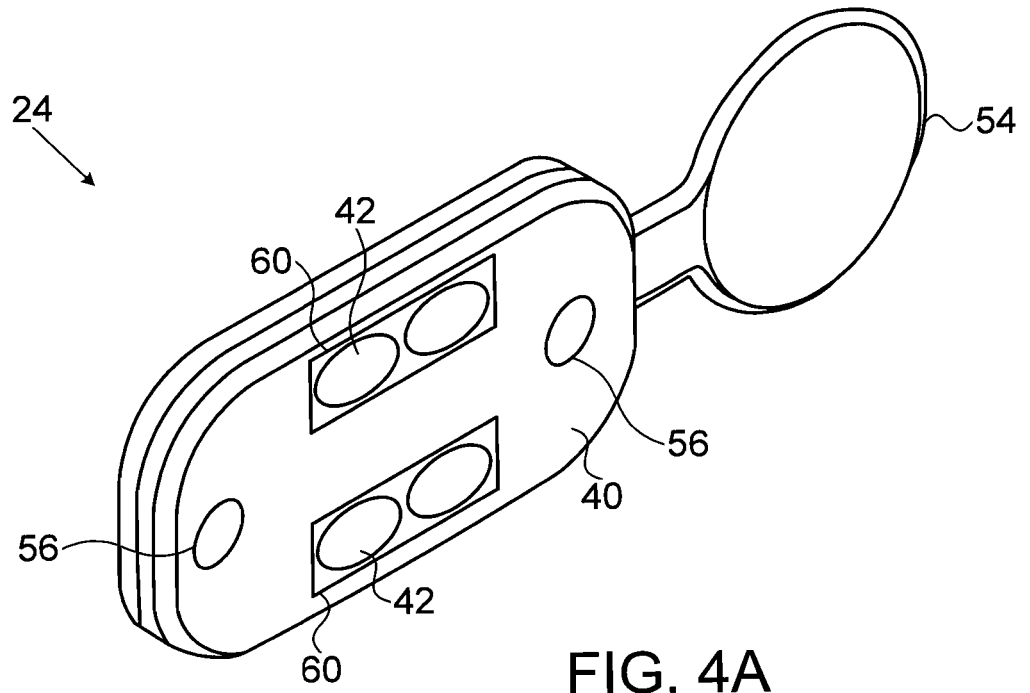


FIG. 4A

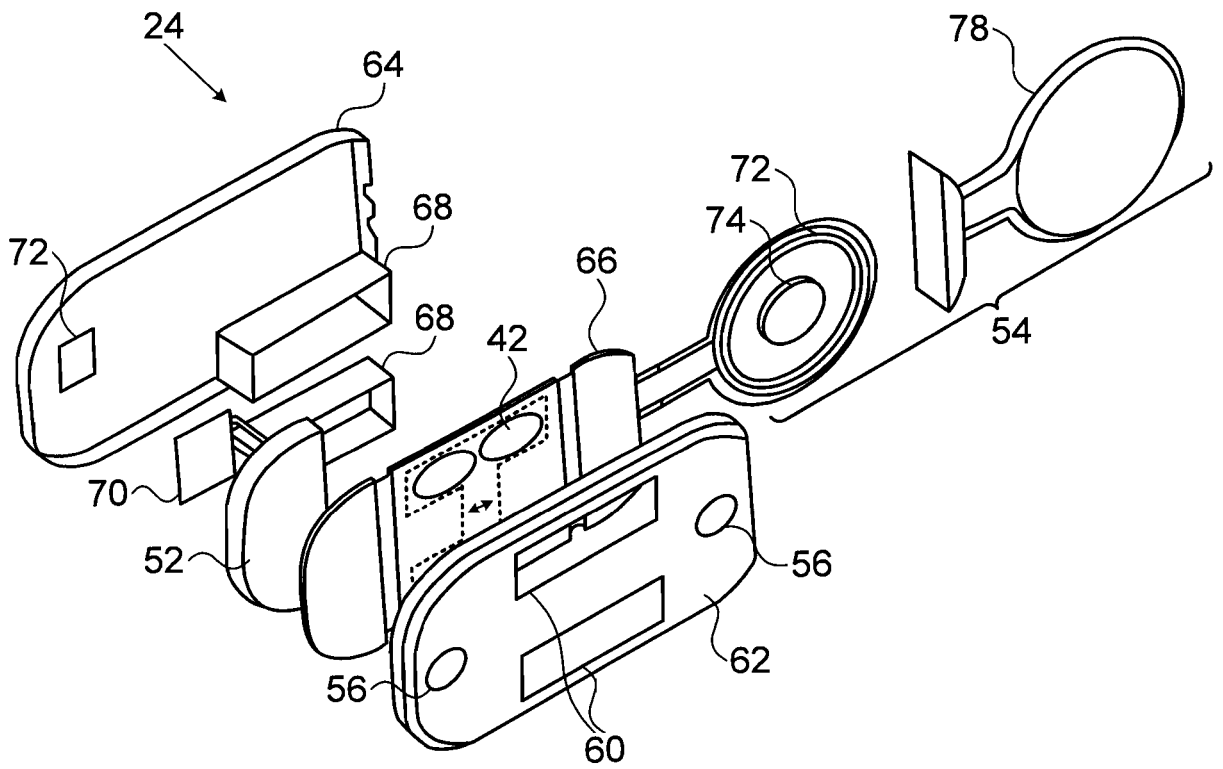


FIG. 4B

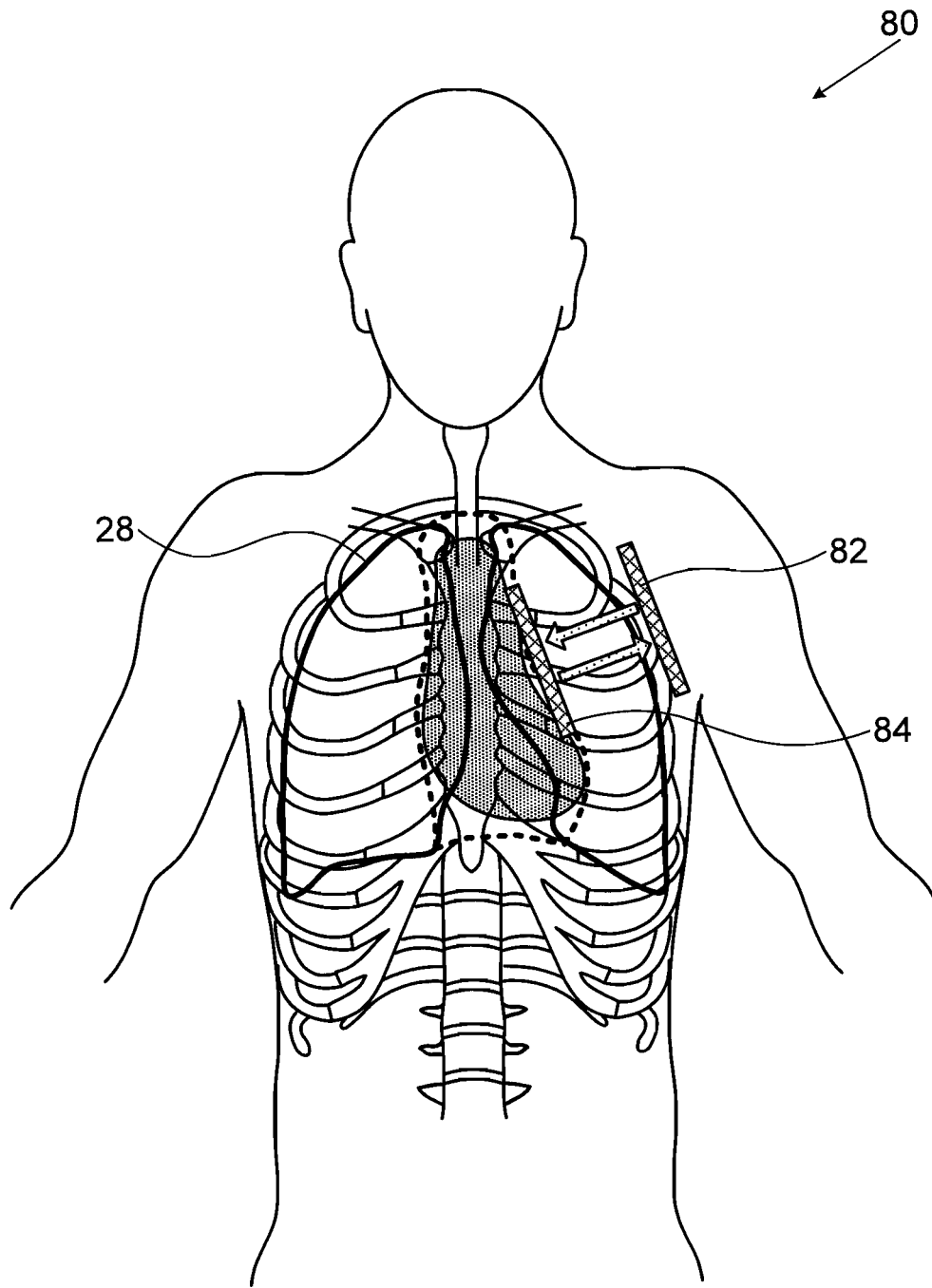


FIG. 5

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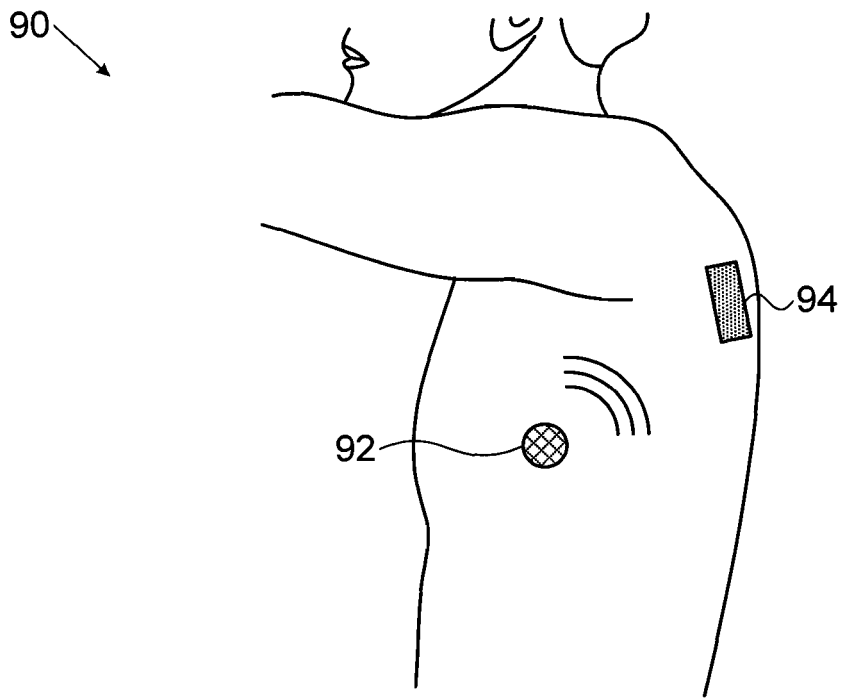


FIG. 6A

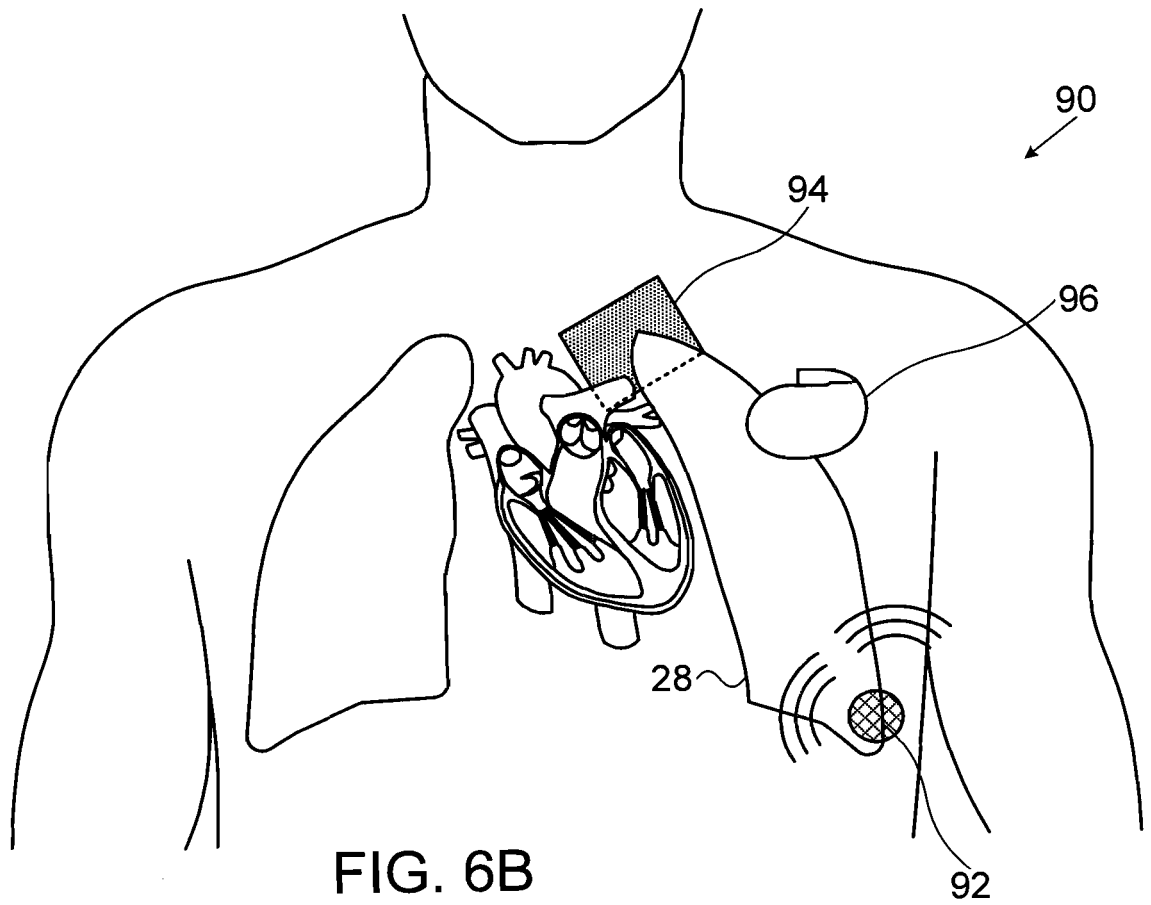


FIG. 6B

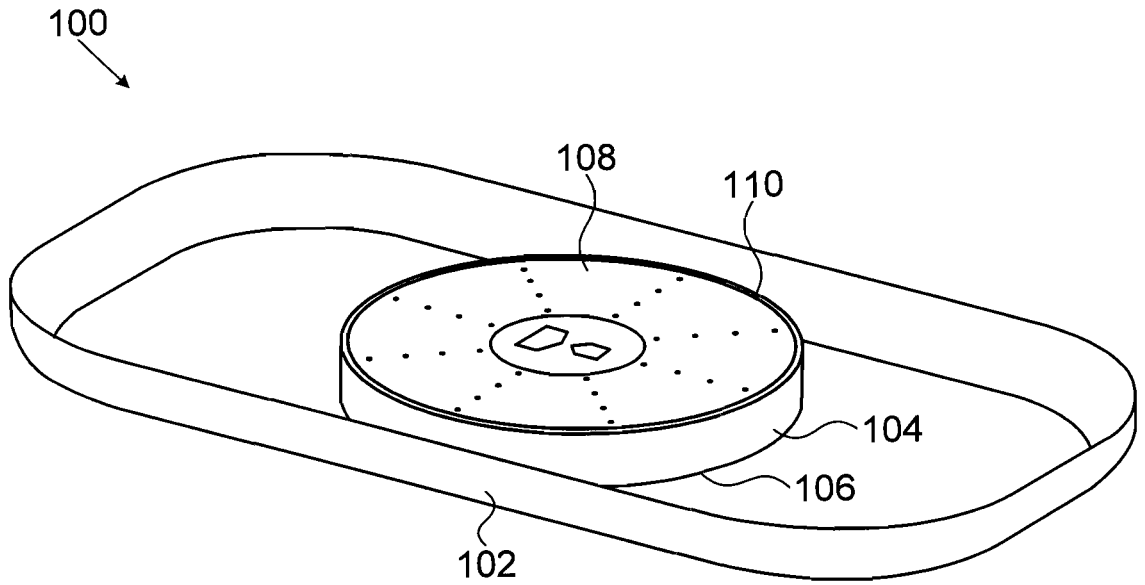


FIG. 7

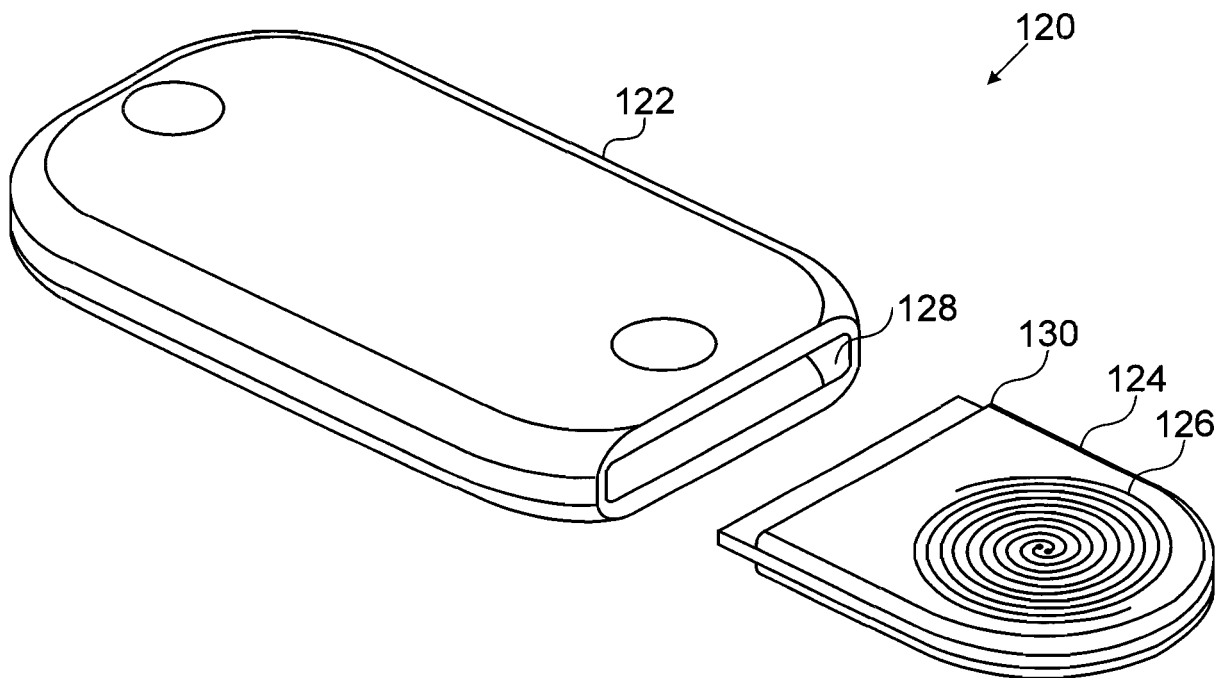


FIG. 8

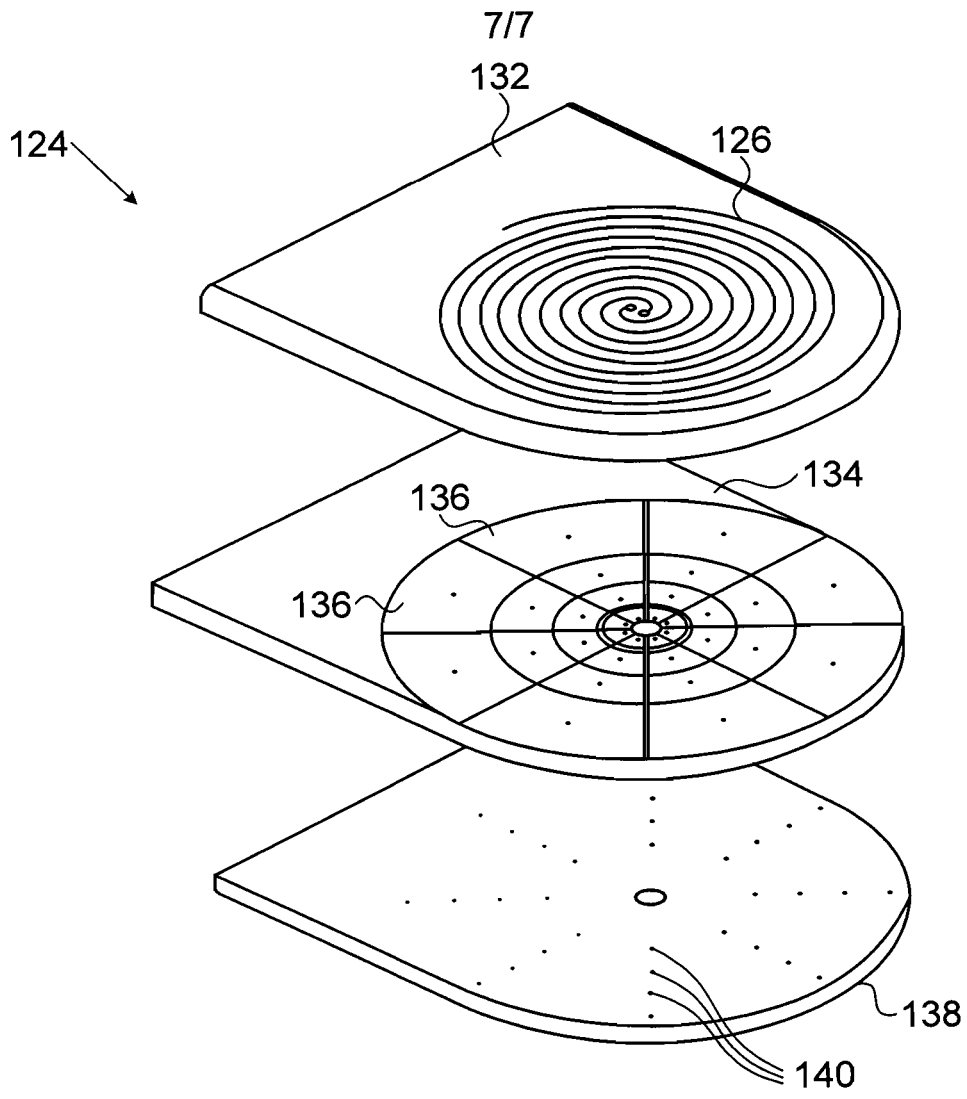


FIG. 9

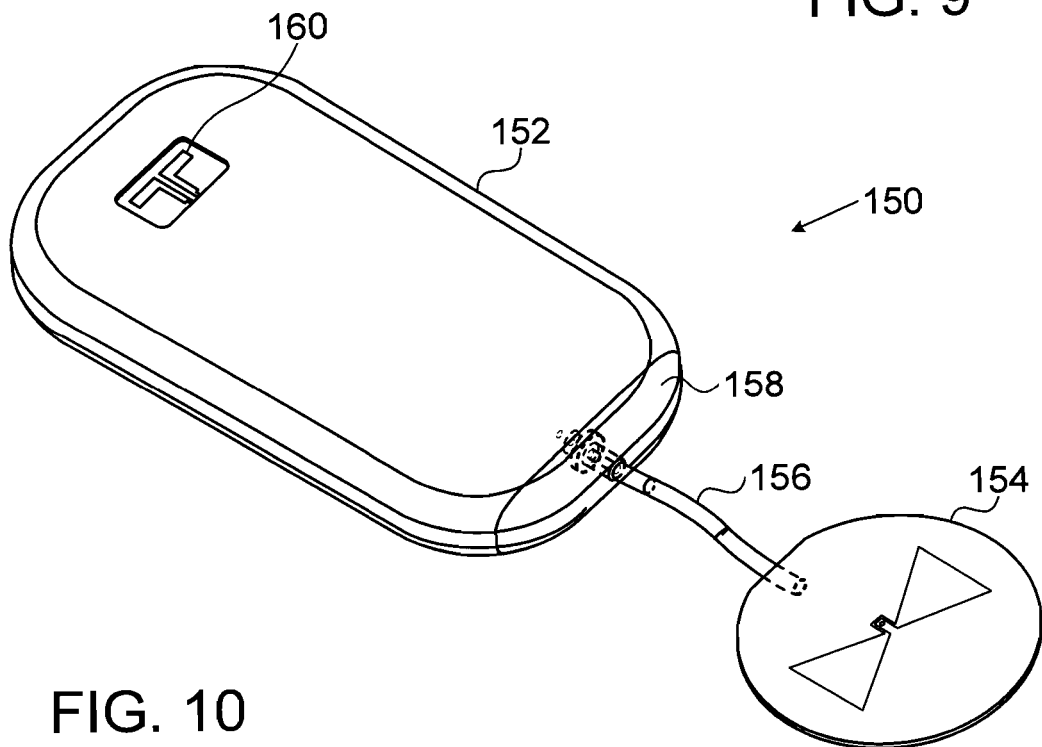


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 11/53244

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(8) - A61N 1/00 (2011.01); A61N 2/00 (2011.01)
 USPC - 607/2

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 USPC: 607/2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 USPC: 607/1,2,36,59-62; 128/903,905; 600/9,12 (see terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 PubWEST(PGPB,USPT,USOC,EPAB,JPAB), GOOGLE SCHOLAR, terms: implant, medical, cardiac device, radio frequency, RF, antenna, seal, case, housing, enclosure, reflect, brazing, pacemaker, thorax, electromagnetic bandgap, EBG, electrode, optimize, location, position, bio-compatible, heart beat, transmit, bio-impedance, bowtie, fluid, tissue, backlobe sup

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,592,518 B2 (Denker et al.) 15 July 2003 (15.07.2003), claim 1, fig. 1, 5-7, col 1, ln 22 - col 5, ln 64.	1-12, 14, 20-27, 29-40, 42-47 ----- 13, 15-19, 41, 48
X	US 7,747,302 B2 (Milledge et al.) 29 June 2010 (29.06.2010), fig. 1-2, col 2, ln 28 - col 4, ln 12.	28
Y	US 2009/0299175 A1 (Bernstein et al.) 03 December 2009 (03.12.2009), fig. 1, para [0042]-[0043], [0058].	13, 41
Y	US 2004/0261721 A1 (Steger) 30 December 2004 (30.12.2004), fig. 1, 4, para [0023]-[0025], [0033].	15-17
Y	US 6,940,457 B2 (Lee et al.) 06 September 2005 (06.09.2005), fig. 1-2, col 2, ln 3 - col 6, ln 37.	18-19
Y	US 4,825,880 A (Stauffer et al.) 02 May 1989 (02.05.1989), col 6, ln 28-66.	48

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 20 November 2011 (20.11.2011)	Date of mailing of the international search report 02 DEC 2011
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

专利名称(译)	植入式射频传感器		
公开(公告)号	EP2595694A1	公开(公告)日	2013-05-29
申请号	EP2011809359	申请日	2011-07-21
[标]申请(专利权)人(译)	基马医疗科技有限公司		
申请(专利权)人(译)	Kyma酒店MEDICAL TECHNOLOGIES LTD		
当前申请(专利权)人(译)	Kyma酒店MEDICAL TECHNOLOGIES LTD		
[标]发明人	WEINSTEIN URIEL BERNSTEIN ASSAF COHEN EYAL OPPENHEIM DOV MOSESKO MOSHE		
发明人	WEINSTEIN, URIEL BERNSTEIN, ASSAF COHEN, EYAL OPPENHEIM, DOV MOSESKO, MOSHE		
IPC分类号	A61N1/00 A61N2/00 A61N1/375 A61B5/00 A61B5/01 A61B5/0205 A61B5/0215 A61B5/042 A61B5/05 A61B5/053 A61B5/145 A61N1/365 A61N1/37 A61N1/372		
CPC分类号	A61B5/0538 A61B1/313 A61B5/0028 A61B5/0031 A61B5/0059 A61B5/01 A61B5/0205 A61B5/0215 A61B5/0422 A61B5/05 A61B5/0537 A61B5/076 A61B5/0809 A61B5/14542 A61B5/416 A61B5/4244 A61B5/4552 A61B5/4875 A61B5/6833 A61B5/686 A61B5/72 A61B17/3468 A61B2560/0219 A61B2562 /0214 A61B2562/164 A61N1/36521 A61N1/3702 A61N1/37229 A61N1/3756		
优先权	61/366173 2010-07-21 US		
其他公开文献	EP2595694A4 EP2595694B1		
外部链接	Espacenet		

摘要(译)

诊断设备 (24) 包括密封壳体 (40) , 其包括生物相容性材料并且被配置用于植入人体 (22) 的体内。至少一个天线 (42) 被配置为在身体中植入接近目标组织 (28) 并接收通过目标组织传播的射频 (RF) 电磁波并响应于接收到的波输出信号。包含在壳体内的处理电路 (44,46) 被耦合以接收和处理来自天线的信号 , 以便导出并输出目标组织的特征的指示。