(19) Europäisches Patentamt / European Patent Office / Office européen des brevets

(11) EP 2 595 694 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
01.06.2016 Bulletin 2016/22

(21) Application number: **11809359.0**

(22) Date of filing: **21.07.2011**

(51) Int Cl.:
A61N 1/375 (2006.01) *A61B 5/01* (2006.01)
A61B 5/0205 (2006.01) *A61B 5/0215* (2006.01)
A61B 5/042 (2006.01) *A61B 5/053* (2006.01)
A61B 5/145 (2006.01) *A61N 1/365* (2006.01)
A61N 1/37 (2006.01) *A61N 1/372* (2006.01)
A61B 5/00 (2006.01) *A61B 5/05* (2006.01)

(86) International application number:
PCT/IB2011/053244

(87) International publication number:
WO 2012/011065 (26.01.2012 Gazette 2012/04)

(54) **IMPLANTABLE RADIO-FREQUENCY SENSOR**
IMPLANTIERBARER FUNKFREQUENZSENSOR
CAPTEUR RADIOFRÉQUENCE IMPLANTABLE

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **21.07.2010 US 366173 P**

(43) Date of publication of application:
29.05.2013 Bulletin 2013/22

(73) Proprietor: **Kyma Medical Technologies Ltd**
67892 Tel Aviv (IL)

(72) Inventors:
- **WEINSTEIN, Uriel**
  76804 Mazkeret Batya (IL)
- **BERNSTEIN, Assaf**
  37825 Givat Nili (IL)
- **COHEN, Eyal**
  70700 Gedera (IL)
- **OPPENHEIM, Dov**
  96267 Jerusalem (IL)
- **MOSESKO, Moshe**
  60920 Kadima (IL)

(74) Representative: **Cooley (UK) LLP**
Dashwood
69 Old Broad Street
London EC2M 1QS (GB)

(56) References cited:
US-A- 4 825 880 **US-A- 5 404 877**
US-A- 6 061 589 **US-A1- 2004 261 721**
US-A1- 2007 100 385 **US-A1- 2008 129 511**
US-A1- 2008 183 247 **US-B1- 6 480 733**
US-B2- 6 592 518 **US-B2- 6 940 457**
US-B2- 7 747 302

EP 2 595 694 B1

Description

FIELD OF THE INVENTION

[0001] 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

[0002] 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 which is prior art under Art. 54(3) EPC describes diagnostic apparatus that includes an antenna, which directs RF electromagnetic waves into a living body and generates signals responsively 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.

[0003] As another example, U.S. Patent Application Publication 2011/0130800, which is assigned to the assignee of the present patent application describes diagnostic apparatus, which includes a plurality of antennas, 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.

[0004] 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 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.

[0005] US-A-5, 404, 877 discloses a diagnostic apparatus according to the first part of claim 1, comprising a leadless implantable cardiac arrhythmia alarm which continuously assesses a patient's heart function to discriminate between normal and abnormal heart functioning and, upon detecting an abnormal condition, generates a patient-warning signal.

[0006] US-A- 4,240,445 discloses a probe for coupling electromagnetic energy into tissue, the probe being fabricated from a printed circuit board.

[0007] The citation of certain references above is intended to provide a general overview of the state of the art.

SUMMARY

[0008] 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.

[0009] There is therefore provided, in accordance with an embodiment of the present invention, diagnostic apparatus as defined by claim 1.

[0010] 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.

[0011] 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.

[0012] 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.

[0013] 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.

[0014] In one embodiment, the indication includes a time trend of the characteristic of the target tissue.

[0015] 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.

[0016] 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.

[0017] In another embodiment, the at least one antenna is located partially outside the case and is connected to the processing circuitry via a sealed brazing to the case.

[0018] 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.

[0019] 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 at least one other implanted device.

[0020] 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.

[0021] 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.

[0022] 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 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.

[0023] There is additionally disclosed 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.

[0024] In a disclosed embodiment, implanting the device includes using an external antenna outside the body to identify an optimal location for implantation of the device.

[0025] 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

[0026]

Fig. 1 is a schematic pictorial illustration showing a monitoring system including an 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 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 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 a comparative example to the present invention;

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 comparative example to the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

OVERVIEW

[0027] 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. Similarly, monitoring accumulation of blood in the splanchnic system can be of medical benefit in assessing fluid status.

[0028] 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 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 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.

[0029] In a disclosed embodiment, the device is implanted in the thorax, adjacent to the lung. 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 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.

[0030] 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 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. 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

[0031] Reference is now made to Figs. 1 and 2, which schematically illustrate a RF-based 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 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.

[0032] 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, 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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, 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.

[0037] 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.

[0038] 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 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 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.

[0039] 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 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.

[0040] 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. 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.

[0041] A communication interface 48 transmits and receives data to and from telemetry station 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 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.

[0042] 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 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.

[0043] 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.

[0044] 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.

[0045] 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).

[0046] 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

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] Fig. 8 is a schematic, partly-exploded view of a RF_monitoring device 120, in accordance with a comparative example to the present invention.

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 in 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.

[0055] Fig. 9 is a schematic exploded view of antenna 124,

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 inside case 122. The two central vias provide the signals for exciting spiral 126.

[0056] Fig. 10 is a schematic pictorial illustration of a RF monitoring device 150, in accordance with an additional comparative example to 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. Device 150 in this embodiment also has a communication antenna 160, as described above.

[0057] 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 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.

Claims

1. A diagnostic apparatus, comprising:

a sealed case (40), comprising a biocompatible material and configured for implantation within a body of a human subject;

at least one antenna (42) configured to be implanted in the body in proximity to a target tissue, 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 (46) contained within the case and configured to receive and process the signal from the antenna so as to derive and output an indication of a characteristic of the target tissue,

characterised in that the at least one antenna (42) comprises a trace printed on a substrate and a backlobe suppression structure behind the trace.

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 (42) is configured to receive the waves after reflection of the waves from a tissue in the body, and wherein the processing circuitry (46) is further 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.

5. The apparatus according to claim 2, further comprising a reflector (84) configured for implantation in the body in a location across the target tissue from the case (40) 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 comprises part of an implanted cardiac device (ICD) (96) that is implanted in the body.

7. The apparatus according to claim 1, further comprising a transmitter (44) 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 (46) is further 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 any of claims 1-7, wherein the indication comprises a time trend of the characteristic of the target tissue.

11. The apparatus according to any of claims 1-7, wherein the at least one antenna (42) comprises a plurality of antennas.

12. The apparatus according to claim 11, wherein the processing circuitry (46) is configured to drive the antennas in a multi-static mode so as to spatially resolve the characteristic of the target tissue.

13. The apparatus according to any of claims 1-7, wherein the at least one antenna is contained inside the case, or is located partially outside the case and is connected to the processing circuitry (46) via a sealed brazing to the case.

14. The apparatus according to claim 13, wherein the at least one antenna (42) comprises a trace printed on a substrate, and wherein the case comprises a window (72), and the antenna is configured to receive the waves through the window.

15. The apparatus according to any of claims 1-7, further comprising a bio-impedance sensor (58).

16. The apparatus according to claim 1, wherein the backlobe suppression structure is selected from a group of structures consisting of an air cavity (68) and an electromagnetic bandgap (EBG) backing (136)

Patentansprüche

1. Diagnosevorrichtung, die umfasst:

ein abgedichtetes Gehäuse (40), das ein biokompatibles Material umfasst und zur Implantation in einen Körper eines menschlichen Patienten eingerichtet ist;
wenigstens eine Antenne (42), die so eingerichtet ist, dass sie in dem Körper in der Nähe eines Ziel-Gewebes implantiert wird, um elektromagnetische Funkfrequenz-Wellen zu empfangen, die sich durch das Ziel-Gewebe hindurch ausbreiten, und in Reaktion auf die empfangenen Wellen ein Signal ausgibt; und
eine Verarbeitungs-Schaltung (46), die im Inneren des Gehäuses aufgenommen und so eingerichtet ist, dass sie das Signal von der Antenne empfängt und verarbeitet, um eine Anzeige einer Eigenschaft des Ziel-Gewebes herzuleiten und auszugeben,

dadurch gekennzeichnet, dass

die wenigstens eine Antenne (42) eine auf ein Substrat aufgedruckte Leiterbahn und eine Hinterkeulenunterdrückungs-Struktur hinter der Leiterbahn umfasst.

2. Vorrichtung nach Anspruch 1, wobei die wenigstens eine Antenne so eingerichtet ist, dass sie die Wellen in den Körper hinein sendet und die gesendeten Wellen nach Ausbreitung der Wellen durch das Ziel-Gewebe hindurch empfängt.

3. Vorrichtung nach Anspruch 2, wobei die wenigstens eine Antenne (42) so eingerichtet ist, dass sie die Wellen nach Reflexion der Wellen von einem Gewebe in dem Körper empfängt, und die Verarbeitungs-Schaltung (46) des Weiteren so eingerichtet ist, dass sie eine Modulation der Reflexion aufgrund eines Herzschlags oder/und einer Atembewegung des Patienten erfasst.

4. Vorrichtung nach Anspruch 3, wobei die Modulation eine zyklische Änderung aufgrund des Herzschlags umfasst.

5. Vorrichtung nach Anspruch 2, die des Weiteren einen Reflektor (84) umfasst, der zur Implantation in den Körper an einer Position eingerichtet ist, die dem Gehäuse (40), das die wenigstens eine Antenne enthält, über das Ziel-Gewebe gegenüberliegt, wobei der Reflektor als die Struktur dient, mit der die Wellen auf die wenigstens eine Antenne zu reflektiert werden.

6. Vorrichtung nach Anspruch 5, wobei der Reflektor Teil einer implantierten Kardio-Vorrichtung (ICD) (96) ist, die in den Körper implantiert ist.

7. Vorrichtung nach Anspruch 1, die des Weiteren einen Sender (44) umfasst, der so eingerichtet ist, dass er in den Körper an einer Position implantiert wird, die dem Gehäuse, das die wenigstens eine Antenne enthält, über das Ziel-Gewebe gegenüberliegt, und der die Wellen durch das Ziel-Gewebe sendet.

8. Vorrichtung nach einem der Ansprüche 1-7, wobei die Verarbeitungs-Schaltung (46) des Weiteren so eingerichtet ist, dass sie das Signal verarbeitet, um ein Maß eines Fluidgehaltes des Ziel-Gewebes herzuleiten.

9. Vorrichtung nach Anspruch 8, wobei das Gehäuse zur Implantation in einen Thorax eingerichtet ist und das Ziel-Gewebe Lungengewebe ist.

10. Vorrichtung nach einem der Ansprüche 1-7, wobei die Anzeige einen Zeittrend der Eigenschaft des Ziel-Gewebes umfasst.

11. Vorrichtung nach einem der Ansprüche 1-7, wobei die wenigstens eine Antenne (42) eine Vielzahl von Antennen umfasst.

12. Vorrichtung nach Anspruch 11, wobei die Verarbeitungs-Schaltung (46) so eingerichtet ist, dass sie die Antennen in einem Multi-Static-Modus ansteuert, um so die Eigenschaft des Ziel-Gewebes räumlich aufzulösen.

13. Vorrichtung nach einem der Ansprüche 1-7, wobei die wenigstens eine Antenne im Inneren des Gehäuses aufgenommen ist oder teilweise außerhalb des Gehäuses angeordnet ist und über eine abgedichtete Verlötung an dem Gehäuse mit der Verarbeitungs-Schaltung (46) verbunden ist.

14. Vorrichtung nach Anspruch 13, wobei die wenigstens eine Antenne (42) eine auf ein Substrat gedruckte Leiterbahn umfasst und das Gehäuse ein Fenster (72) umfasst und die Antenne so eingerichtet ist, dass sie die Wellen über das Fenster empfängt.

15. Vorrichtung nach einem der Ansprüche 1-7, die des Weiteren einen Bioimpedanz-Sensor (58) umfasst.

16. Vorrichtung nach Anspruch 1, wobei die Hinterkeulenunterdrückungs-Struktur aus einer Gruppe von Strukturen ausgewählt wird, die aus einem Luftraum (68) und einem EBG-Träger (electromagnetic bandgap backing) (136) besteht.

Revendications

1. Appareil de diagnostic, comprenant :

un boîtier hermétique (40) comprenant un matériau biocompatible, et configuré en vue d'une implantation dans le corps d'un sujet humain ;
au moins une antenne (42) configurée de manière à être implantée dans le corps à proximité d'un tissu cible, en vue de recevoir des ondes électromagnétiques (RF) radiofréquence propagées à travers le tissu cible, et de générer en sortie un signal en réponse aux ondes reçues ; et
un montage de circuits de traitement (46) inclus dans le boîtier et configuré de manière à recevoir et à traiter le signal en provenance de l'antenne, de manière à dériver et à générer en sortie une indication d'une caractéristique du tissu cible ;

caractérisé en ce que ladite au moins une antenne (42) comprend une trace imprimée sur un substrat et une structure de suppression de lobe arrière derrière la trace.

2. Appareil selon la revendication 1, dans lequel ladite au moins une antenne est configurée de manière à transmettre les ondes dans le corps et à recevoir les ondes transmises suite à la propagation des ondes à travers le tissu cible.

3. Appareil selon la revendication 2, dans lequel ladite au moins une antenne (42) est configurée de manière à recevoir les ondes suite à une réflexion des ondes à partir d'un tissu dans le corps, et dans lequel le montage de circuits de traitement (46) est en outre configuré de manière à détecter une modulation de la réflexion sous l'effet d'au moins l'un parmi un battement de coeur et un mouvement respiratoire du sujet.

4. Appareil selon la revendication 3, dans lequel la modulation comprend une variation cyclique sous l'effet du battement de coeur.

5. Appareil selon la revendication 2, comprenant en outre un réflecteur (84) configuré en vue d'une implantation dans le corps, dans un emplacement à travers le tissu cible à partir du boîtier (40) contenant ladite au moins une antenne, dans lequel le réflecteur sert de structure pour réfléchir les ondes vers ladite au moins une antenne.

6. Appareil selon la revendication 5, dans lequel le réflecteur comprend une partie d'un défibrillateur implantable (ICD) (96) qui est implanté dans le corps.

7. Appareil selon la revendication 1, comprenant en outre un émetteur (44) configuré de manière à être implanté dans le corps, dans un emplacement à travers le tissu cible à partir du boîtier contenant ladite au moins une antenne, et à transmettre les ondes à travers le tissu cible.

8. Appareil selon l'une quelconque des revendications 1 à 7, dans lequel le montage de circuits de traitement (46) est en outre configuré de manière à traiter le signal de façon à dériver une mesure d'un contenu fluide du tissu cible.

9. Appareil selon la revendication 8, dans lequel le boîtier est configuré en vue d'une implantation dans un thorax, et dans lequel le tissu cible est un tissu pulmonaire.

10. Appareil selon l'une quelconque des revendications 1 à 7, dans lequel l'indication comprend une tendance temporelle de la caractéristique du tissu cible.

11. Appareil selon l'une quelconque des revendications 1 à 7, dans lequel ladite au moins une antenne (42) comprend une pluralité d'antennes.

12. Appareil selon la revendication 11, dans lequel le montage de circuits de traitement (46) est configuré de manière à commander l'antenne dans un mode multistatique de façon à résoudre spatialement la caractéristique du tissu cible.

13. Appareil selon l'une quelconque des revendications 1 à 7, dans lequel ladite au moins une antenne est incluse à l'intérieur du boîtier, ou est située partiellement en dehors du boîtier et est connectée au montage de circuits de traitement (46) par l'intermédiaire d'un brasage étanche au boîtier.

14. Appareil selon la revendication 13, dans lequel ladite au moins une antenne (42) comprend une trace imprimée sur un substrat, et dans lequel le boîtier comprend une fenêtre (72), et l'antenne est configurée de manière à recevoir les ondes à travers la fenêtre.

15. Appareil selon l'une quelconque des revendications 1 à 7, comprenant en outre un capteur d'impédance biométrique (58).

16. Appareil selon la revendication 1, dans lequel la structure de suppression de lobe arrière est sélectionnée parmi un groupe de structures comportant une cavité d'air (68) et un support à bande interdite électromagnétique (EBG) (136).

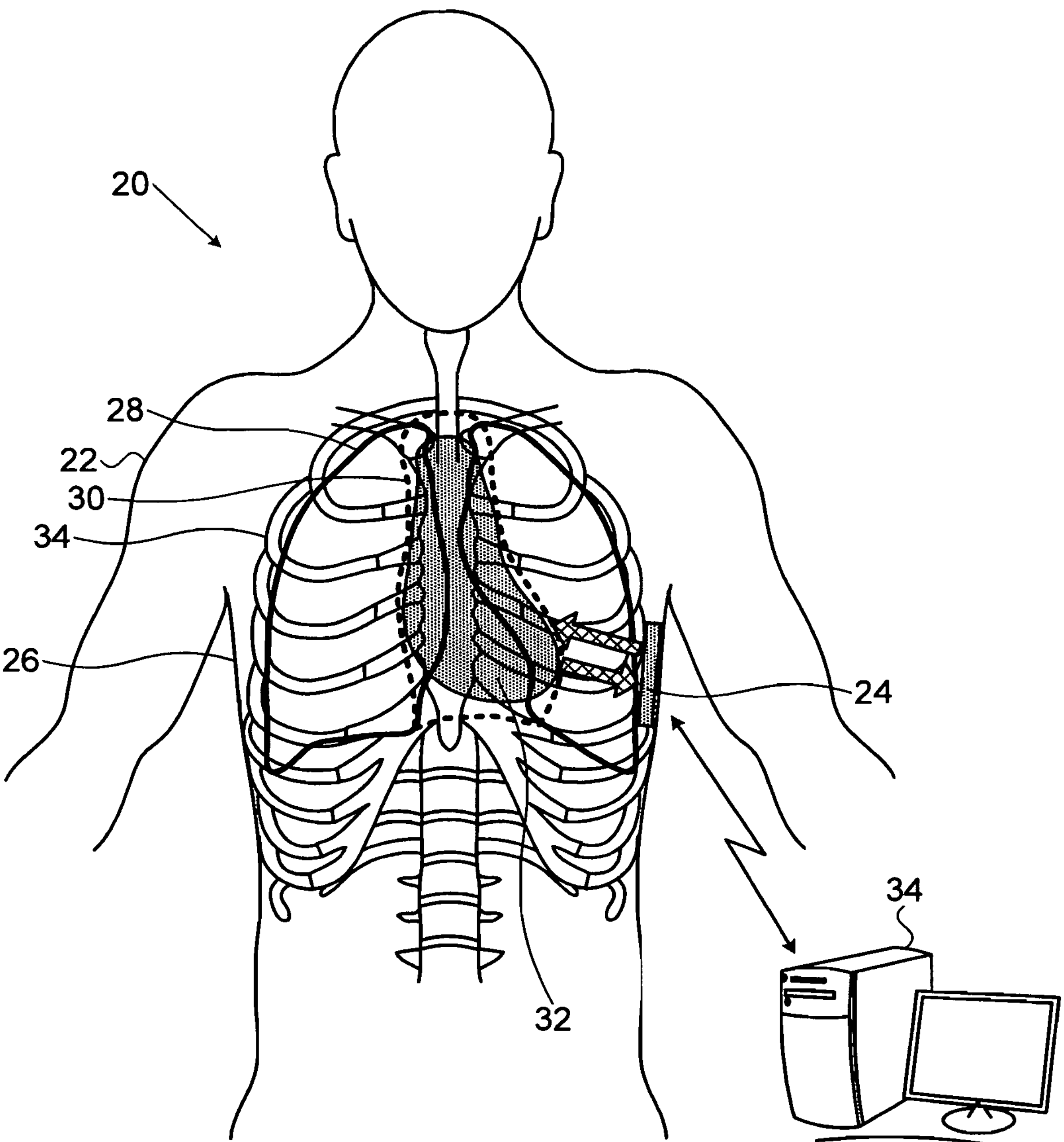

FIG. 1

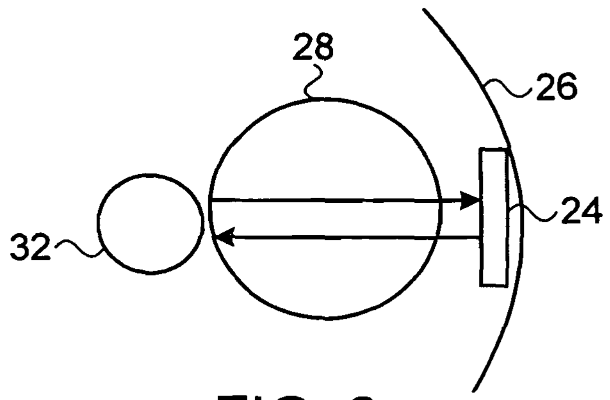
28
26
24
32

FIG. 2

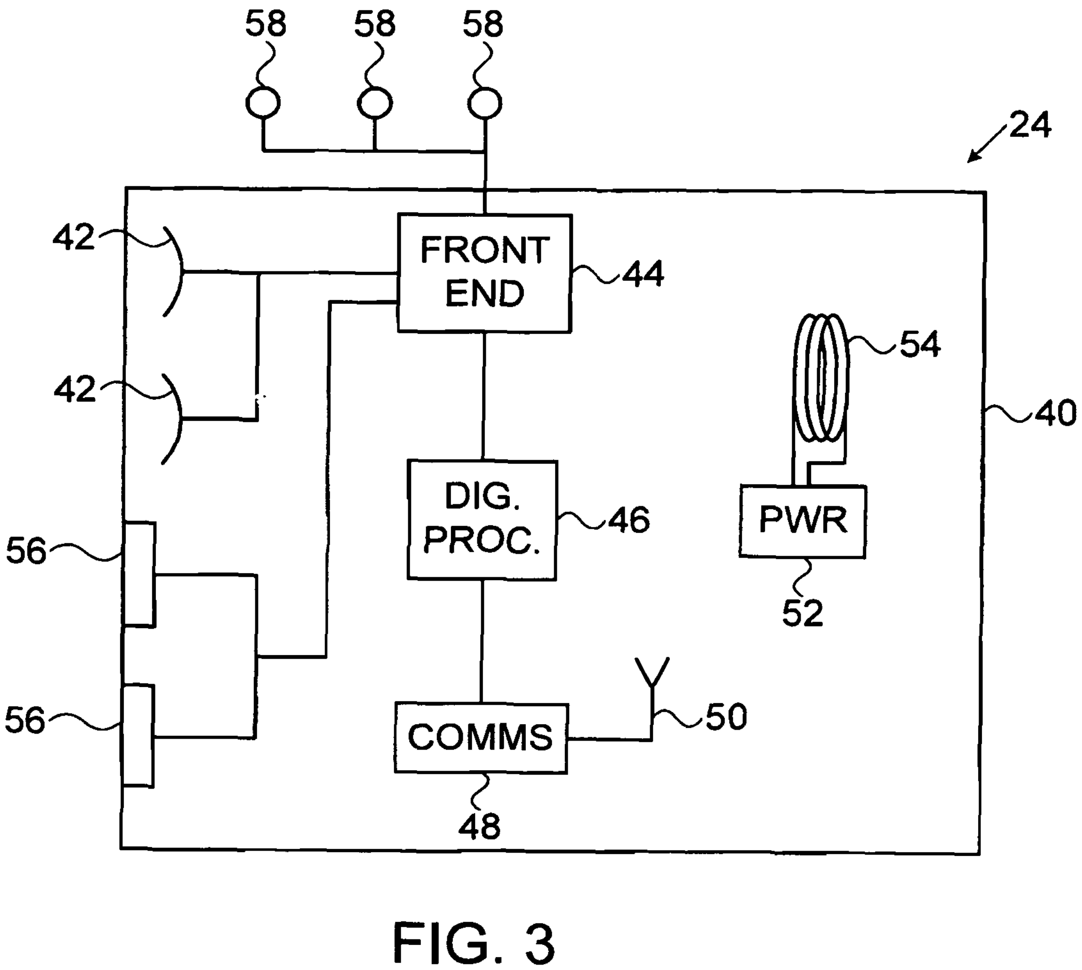
58
58
58
24
42
FRONT END
44
42
54
40
56
DIG. PROC.
46
PWR
52
56
COMMS
50
48

FIG. 3

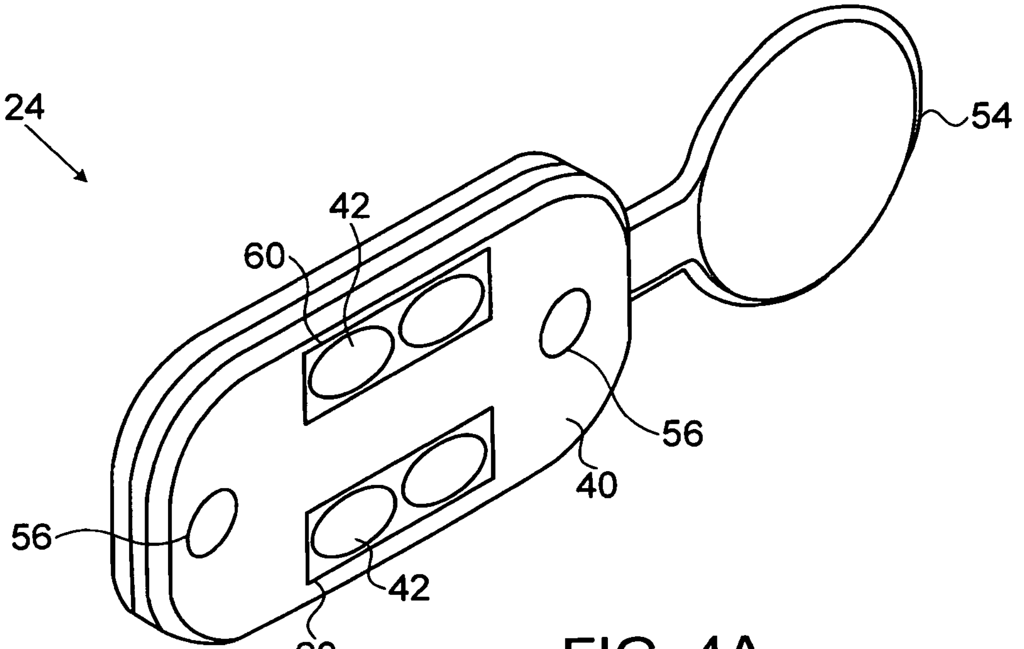
24
54
42
60
56
40
56
42
60

FIG. 4A

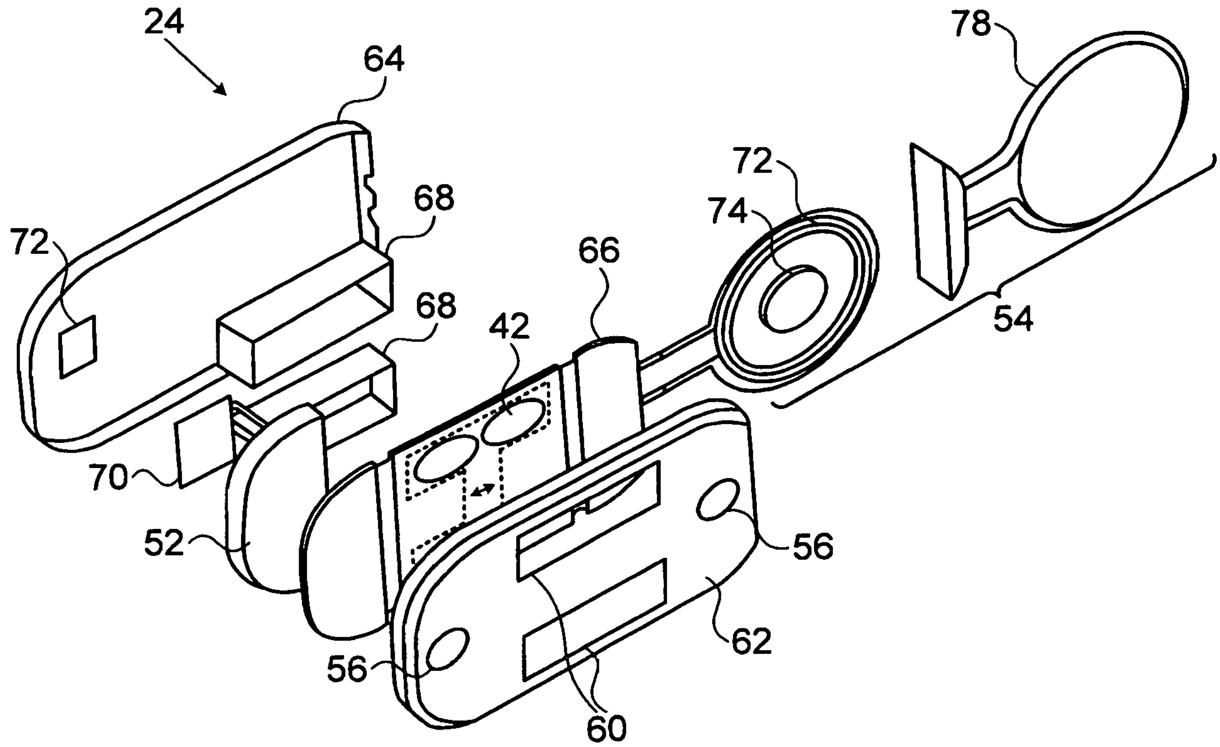
24
64
78
72
68
72
74
68
66
54
42
70
52
56
62
56
60

FIG. 4B

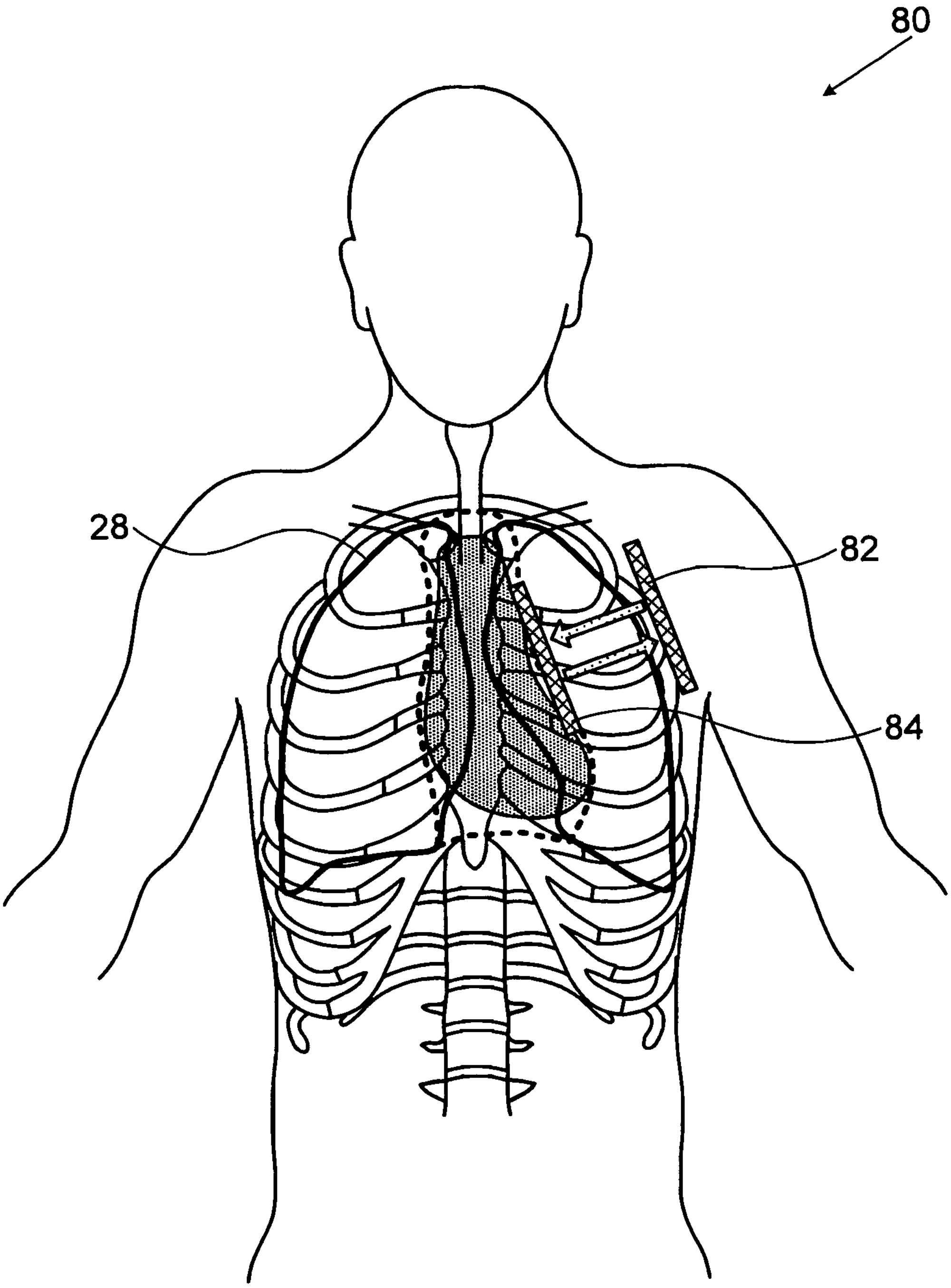

FIG. 5

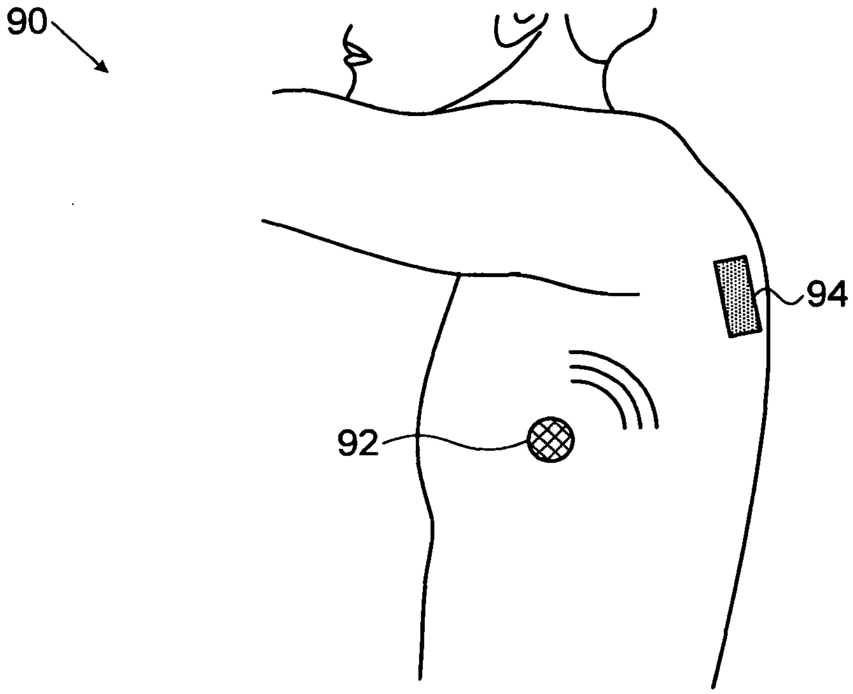

FIG. 6A

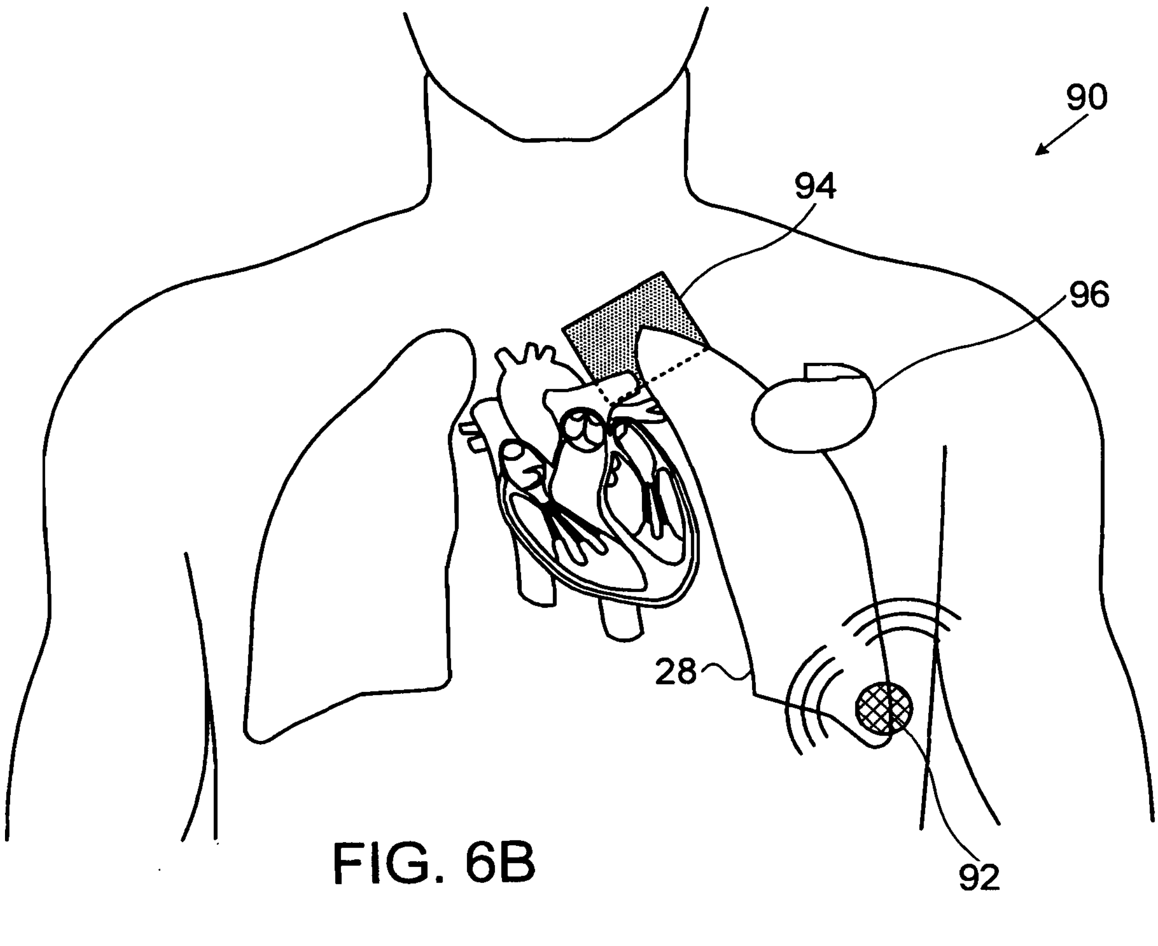

FIG. 6B

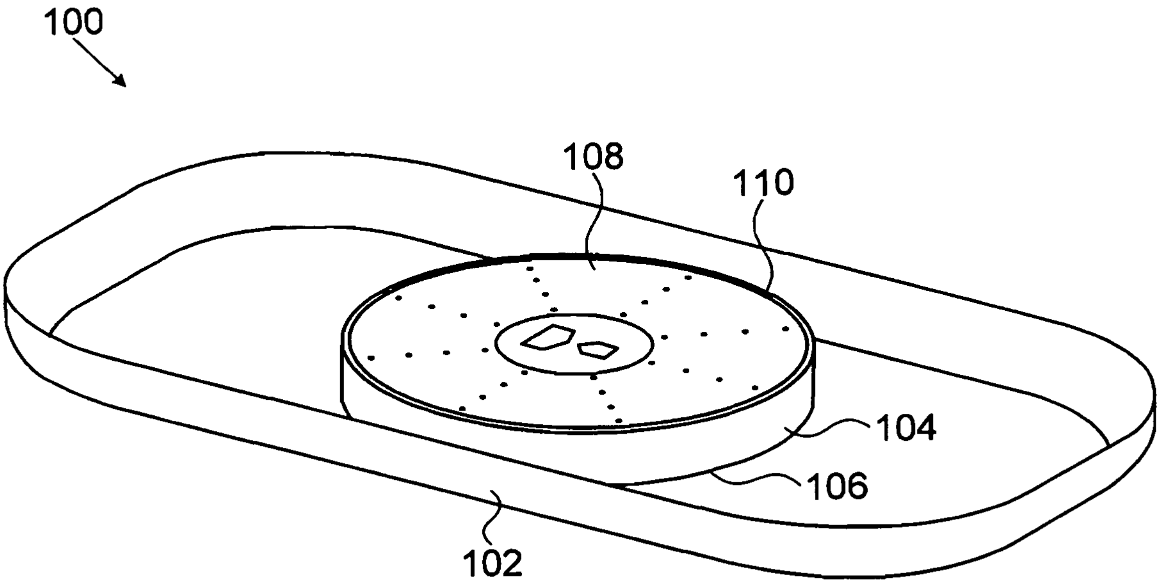

FIG. 7

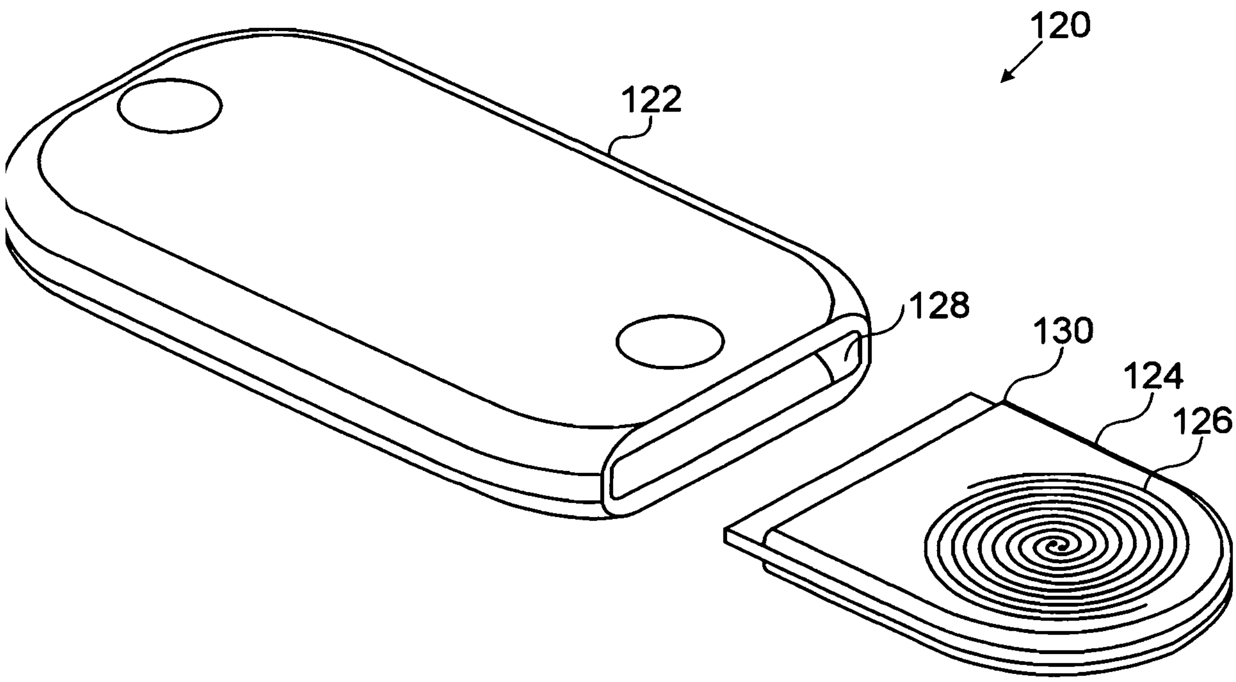

FIG. 8

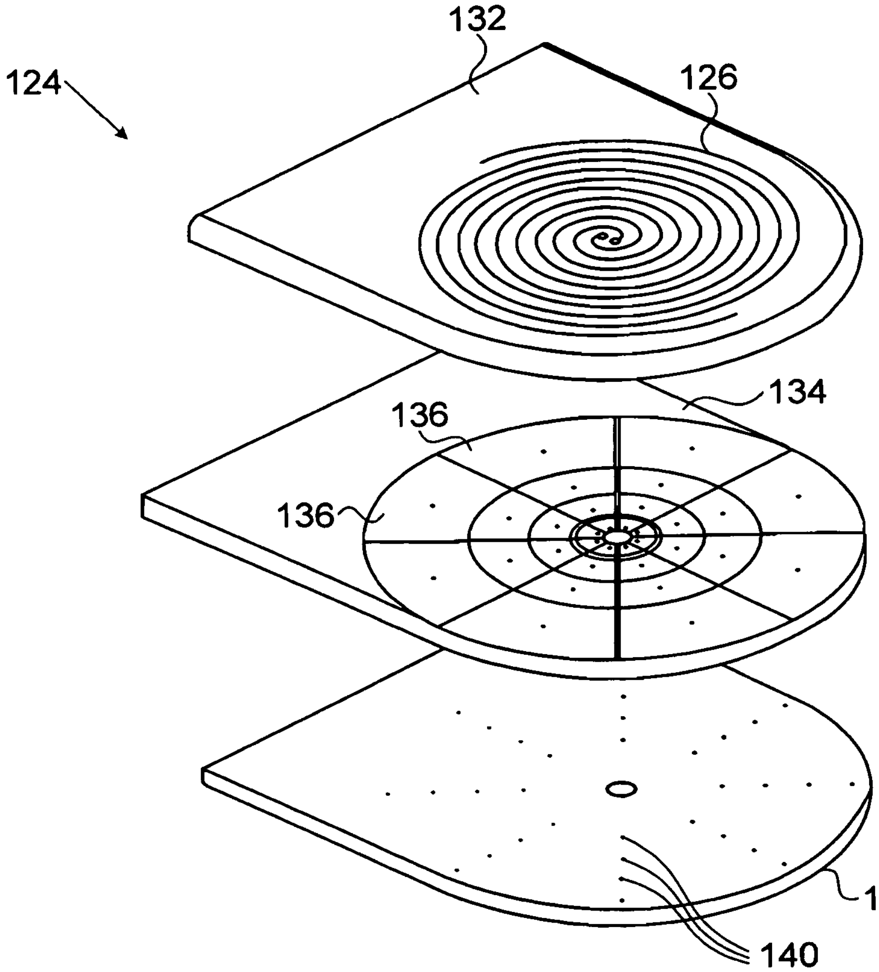

FIG. 9

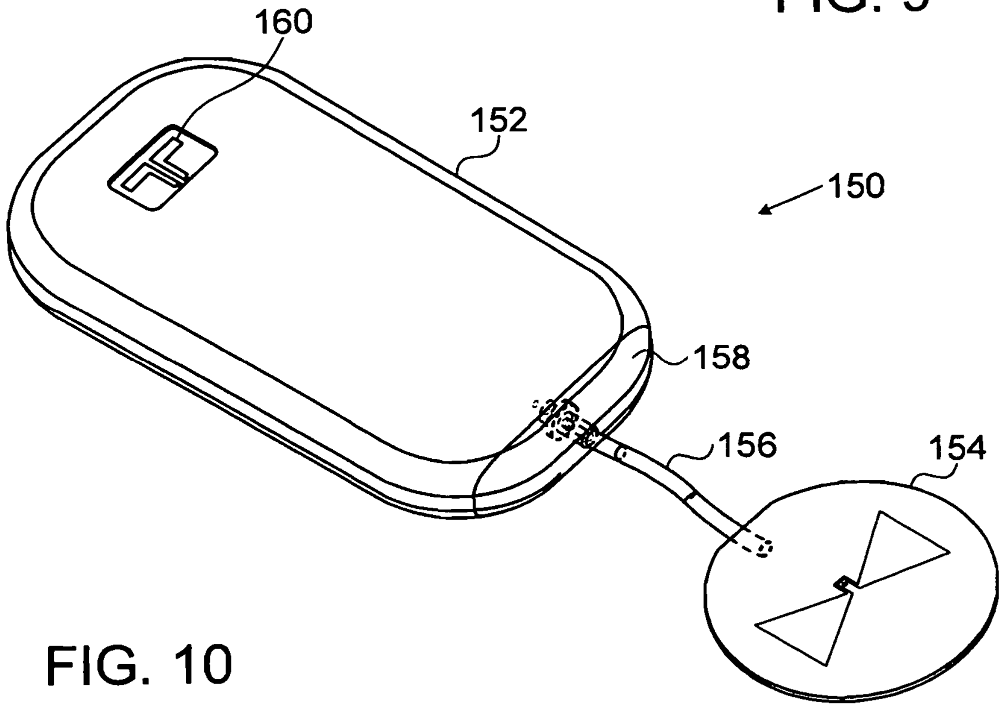

FIG. 10

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- WO 2011067623 PCT **[0002] [0035] [0044]**
- US 20110130800 A **[0003] [0035] [0040]**
- US 20100256462 A **[0004]**
- WO 2009031149 PCT **[0004]**
- US A5404877 A **[0005]**
- US 4240445 A **[0006]**
- WO 2011067623 A **[0040]**

专利名称(译)	植入式射频传感器
公开(公告)号	EP2595694B1 · 公开(公告)日 2016-06-01
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	A61N1/375 A61B5/01 A61B5/0205 A61B5/0215 A61B5/042 A61B5/053 A61B5/145 A61N1/365 A61N1/37 A61N1/372 A61B5/00 A61B5/05
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 EP2595694A1
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。

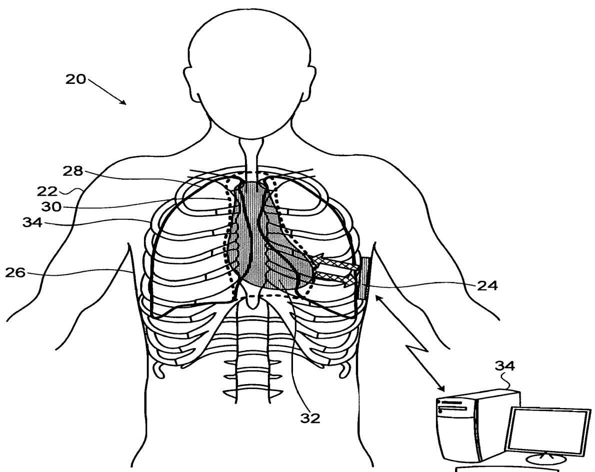

FIG. 1