(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 February 2001 (22.02.2001)

PCT

(10) International Publication Number
WO 01/12092 A1

(51) International Patent Classification[7]: A61B 19/00

(21) International Application Number: PCT/US00/21625

(22) International Filing Date: 8 August 2000 (08.08.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/148,592 14 August 1999 (14.08.1999) US

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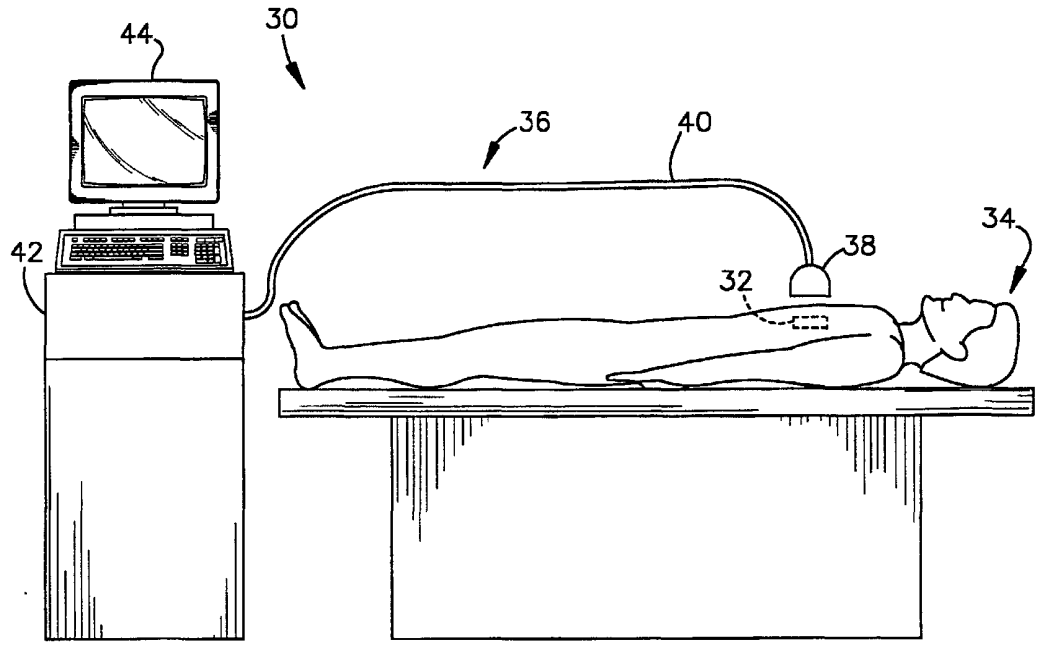
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: REMOTELY INTERROGATED DIAGNOSTIC IMPLANT DEVICE WITH ELECTRICALLY PASSIVE SENSOR



(57) Abstract: An implant device (32) is provided which is responsive to an external interrogation circuit (42).

WO 01/12092 A1

TITLE: REMOTELY INTERROGATED DIAGNOSTIC IMPLANT DEVICE WITH ELECTRICALLY PASSIVE SENSOR

Technical Field

The present invention relates generally to medical implant devices, and more particularly to devices which may be interrogated remotely from outside the body.

Background of the Invention

Various types of medical implant devices have been developed over the years. In many instances, such devices enable humans to live longer, more comfortable lives. Implant devices such as pacemakers, artificial joints, valves, grafts, stents, etc. provide a patient with the opportunity to lead a normal life even in the face of major heart, reconstructive, or other type surgery, for example.

It has been found, however, that the introduction of such implant devices can sometimes lead to complications. For example, the human body may reject the implant device which can ultimately lead to infection or other types of complications. Alternatively, the implant device may malfunction or become inoperative. Therefore, it is desirable to be able to monitor the condition of the implant device. On the other hand, it is highly undesirable to have to perform invasive surgery in order to evaluate the condition of the device.

Still further, it is desirable to be able to monitor conditions related to the use of implant devices. For example, in heart patients it may be helpful to know the amount of blood flowing through a stent or graft in order to evaluate the health of the patient. Again, however, it is undesirable to have to perform invasive surgery in order to evaluate such conditions.

Techniques have been developed which enable the function of an implant device to be monitored remotely from outside the body of the patient. These techniques involve including one or more sensors in the device for sensing the condition of the device. The device further includes a small transceiver for processing the output of the sensors and transmitting a signal

based on the output. Such signal typically is a radio frequency signal which is received by a receiver from outside the body of the patient. The receiver then processes the signal in order to monitor the function of the device.

While such conventional techniques may be effective in avoiding the need to perform invasive surgery, there are however several drawbacks associated therewith. For example, the transceiver included in the implant device typically includes complex electrical circuitry such as mixers, amplifiers, microprocessors, etc. for receiving an interrogation signal and for transmitting a response signal based on the output of the sensors. Such complex circuitry has a relatively high cost associated therewith. In addition, the complexity of the circuitry increases the likelihood that the device itself may be defective. This would then require further invasive surgery and could even result in physical harm to the patient.

In view of the aforementioned shortcomings associated with conventional implant devices, there is a strong need in the art for a medical implant device which can be remotely interrogated but which does not require complex electrical circuitry such as a transceiver with mixers, amplifiers, microprocessors, etc. There is a strong need for a medical implant device which carries out a function within a human or other living animal, and can be remotely interrogated simply and reliably. There is a strong need for such an implant device which permits most or all of the sensor circuitry to be embedded directly within the device.

Summary of the Invention

The present invention is responsive to the aforementioned shortcomings with conventional devices, and is directed towards an implant device to be implanted within a living animal and responsive to an interrogation circuit having an exciter/interrogator element which is located outside the living animal. The implant device includes a structure implantable within the living animal and operatively configured to carry out or assist in carrying out a function within the living animal. The implant device further includes an electrically passive sensing circuit integral with the structure for

sensing a parameter associated with the function, the sensing circuit including an inductive element wherein the sensing circuit has a frequency dependent variable impedance loading effect on the interrogation circuit in response to an interrogation signal provided by the exciter/interrogator element, the impedance loading effect varying in relation to the sensed parameter. In another embodiment, active elements are combined to produce a varying impedance loading effect.

To the accomplishment of the foregoing and related ends, the invention, then, comprises the features hereinafter fully described and particularly pointed out in the claims. The following description and the annexed drawings set forth in detail certain illustrative embodiments of the invention. These embodiments are indicative, however, of but a few of the various ways in which the principles of the invention may be employed. Other objects, advantages and novel features of the invention will become apparent from the following detailed description of the invention when considered in conjunction with the drawings.

Brief Description of the Drawings

Fig. 1 is an environmental view illustrating a system including a remotely interrogated medical implant device and exciter/interrogator unit in accordance with the present invention;

Fig. 2 is a simplified block diagram of the system of Fig. 1;

Fig. 3 is a schematic diagram of the system including the remotely interrogated medical implant device and exciter/interrogator unit in accordance with the present invention;

Fig. 4 is a more detailed schematic diagram representing the remotely interrogated medical implant device and exciter/interrogator unit in accordance with the present invention;

Fig. 5 is a representative graph of primary current (as detected by voltage across a sense resistor) vs. excitation frequency for the circuit of Fig. 4;

Fig. 6a is a partial cut-away side view of a remotely interrogated stent in accordance with a first embodiment of the present invention;

Figs. 6b and 6c illustrate different equivalent circuits for the stent in accordance with the present invention;

Fig. 7a is a side view of a remotely interrogated stent in accordance with a second embodiment of the present invention;

Figs. 7b and 7c are partial cross-sectional views illustrating possible configurations of the stent in accordance with the present invention;

Fig. 7d represents the equivalent circuit of the stent in Fig. 7a;

Fig. 8a is a side view of a remotely interrogated stent in accordance with a third embodiment of the present invention;

Fig. 8b is a simplified electrical diagram of the stent shown in Fig. 8a;

Fig. 9a is a side view of a remotely interrogated stent in accordance with a fourth embodiment of the present invention;

Fig. 9b is a simplified electrical diagram of the stent shown in Fig. 9a;

Fig. 10 is a partial cut-away side view of a remotely interrogated graft in accordance with a fifth embodiment of the present invention;

Fig. 11a is a side view of a remotely interrogated graft in accordance with a sixth embodiment of the present invention;

Figs. 11b and 11c are partial cross-sectional views illustrating possible configurations of the graft in accordance with the present invention;

Fig. 12 is a is a side view of a remotely interrogated graft in accordance with a seventh embodiment of the present invention;

Fig. 13 is a perspective view of a remotely integrated graft in accordance with an eighth embodiment of the present invention;

Fig. 14a and 14b represent a side view and end view, respectively, of a remotely interrogated graft in accordance with a ninth embodiment of the present invention;

Fig. 14c is a perspective view of a strain gaged annulus included in the graft represented in Figs. 14a and 14b;

Fig. 14d represents an equivalent circuit of the graft in Figs. 14a and 14b;

Fig. 15a is a side view, partially cut away, of a remotely interrogated graft in accordance with a tenth embodiment of the present invention;

Fig. 15b represents an equivalent circuit of the graft in Fig. 15a.

Figs. 16a, 16b and 16c represent a remotely interrogated graft which combines impedance loading and active electronics according to another aspect of the invention;

Fig. 17 represents an alternate embodiment of a sensing circuit which is provided in accordance with the present invention;

Fig. 18 represents another embodiment of a system including remotely interrogated implant device in accordance with the present invention;

Fig. 19 illustrates a further embodiment of a remotely interrogated graft in accordance with the present invention; and

Fig. 20 is a cross-section of the graft shown in Fig. 19.

Description of the Preferred Embodiments

The present invention will now be described with reference to the drawings, wherein like reference numerals are used to refer to like elements throughout.

Referring initially to Fig. 1, a system for remotely interrogating a medical implant device in accordance with the invention is generally designated 30. The system 30 includes a medical implant device 32 which is implanted in a living animal such as a human patient 34. As is discussed in more detail below, the medical implant device 32 can be any of a wide variety of different types of devices including, for example, a stent, graft, artificial joint, etc.

The device 32 is configured to carry out or assist in carrying out a function within the patient 34. For example, in the case of a stent the device 32 prevents the closing of an arterial wall and permits the flow of blood therethrough. In the case of a graft, the device 32 serves to couple blood flow between two separate ends of an artery. The device 32 may instead consist of an artificial hip or knee which facilitates movement of the leg of the

patient 34. Other functions include, but are not limited to, a hemodialysis shunt and spinal brace, for example.

The device 32 includes a sensing circuit (not shown in Fig. 1) which serves to sense a parameter associated with the function performed by the device. For example, in the case of a stent or graft the sensor may be used to detect the degree of restenosis which occurs within the device 32. Alternatively, for example, the sensing circuit may detect an amount of strain or displacement which occurs in an artificial hip or knee. Still further, the sensor may serve to sense the condition of the implant device in carrying out its intended function. For example, in the case of a pacemaker the sensor may detect the pulse rate.

The system 30 further includes interrogation instrumentation 36 for remotely interrogating the implant device 32 in order to evaluate the device function. The instrumentation 36 includes an exciter/interrogator unit 38 which is positioned outside the patient 34 in close proximity to the implant device 32. As will be discussed in more detail below, the exciter/interrogator unit 38 serves to excite the sensing circuit within the device 32. The sensing circuit is designed to have a variable impedance loading effect on the exciter/interrogator unit 38, which varies in relation to the sensed parameter (e.g., blood flow, amount of restenosis, etc.).

The exciter/interrogator unit 38 is coupled via an electrical cable 40 to the main circuitry 42 included in the interrogation instrumentation 36. The main circuitry 42 includes suitable circuits for driving the exciter/interrogator unit 38 as described below, and for processing the output of the exciter/interrogator unit 38 in order to provide an output to an operator (e.g., display 44). In particular, the variable impedance loading effect of the device 32 on the exciter/interrogator unit 38 is detected at different frequencies and processed to produce a display or the like indicative of the function performed using the device 32.

As will be better understood based on the description which follows, the present invention preferably utilizes magnetic coupling between the exciter/interrogator unit 38 and the implant device 32. The sensing circuit in

the device 32 is a passive circuit designed to have an impedance loading effect on the exciter/interrogator unit 38. In this manner, the sensing circuit can be a very simple, low cost circuit which is less prone to failure. The device 32 does not require an active transmitter, mixer, amplifier, etc. as in other conventional devices. Moreover, the sensing circuit can be embedded within the device structure to reduce the amount of obstruction which occurs in the device and, for example, to increase performance.

Fig. 2 represents a simplified block diagram showing the positional relationship between the implant device 32 and the exciter/interrogator unit 38. The exciter/interrogator unit 38 preferably is a hand-held sized device which is held by a doctor, nurse or medical assistant in close proximity to the implant device 32. Since the system 30 is non-invasive, the exciter/interrogator unit 38 may be placed adjacent the implant device 32 with the body of the patient (e.g., skin, muscle tissue, etc.), designated 50, disposed therebetween. The preferred embodiment of the present invention relies on magnetic and/or electromagnetic coupling (represented by field lines 52) between the exciter/interrogator unit 38 and the implant device 32 to interrogate the device 32 non-invasively.

More particularly, the preferred embodiment of the present invention introduces sensor technology developed in the aerospace industry into medical implant devices. Commonly owned U.S. Patent No. 5,581,248 describes in detail how magnetic coupling between an interrogation circuit and a sensor coil, based on an impedance loading effect, can be used to interrogate an embedded sensor. Heretofore, however, no one has thought to utilize such technology in medical implant devices. The entire disclosure of U.S. Patent No. 5,581,248 is incorporated herein by reference.

Fig. 3 illustrates the electrical configuration of the exciter/interrogator unit 38 and implant device 32 in more detail. The exciter/interrogator unit 38 includes an exciter/interrogator coil 52, a voltage controlled oscillator 54, and a load sensing resistor 56. The oscillator 54 provides an excitation signal to the exciter/interrogator coil 52 and the load sensing resistor 56 which are coupled in series. The exciter/interrogator unit 38 is coupled via the cable 40

to the main circuitry 42 which includes signal conditioning electronics 58 and a data processing and control section 60. The data processing and control section 60 produces a control signal on line 62 for controlling the frequency and the magnitude of the excitation signal that the oscillator 54 applies to the exciter/interrogator coil 52. The exciter/interrogator coil 52, sensing resistor 56 and oscillator 54 provide a resonant exciter/interrogator circuit that is used to induce currents in a coil within the implant device 32 in order to perform interrogation.

More specifically, the implant device 32 includes a sense coil 64 which is embedded in the structure of the implant device. As is discussed in more detail below in connection with Figs. 6a, 7a, 8a, etc., the implant device 32 may be any type of implant such as a stent or graft. The sense coil 64 may be integrally secured to a surface of the stent or graft, for example, or even formed directly within the structure. The sense coil 64 is part of a passive resonant sensing circuit 65 which includes, for example, a capacitor 66 and a sensing element 68 in electrical series with the sense coil 64. The sensing element 68 can be any sensor which produces a variable impedance (e.g., resistance, capacitance or inductance), or which produces an output that can be converted into a variable impedance that can change or modulate the impedance of one or more of the resonant circuit components.

As shown in Fig. 3, the sensing element 68 is represented by a variable resistance which varies based on a sensed parameter. In an alternative embodiment, the sensing element 68 may provide a capacitance, inductance and/or resistance which varies based on a sensed parameter. As long as the sensing element 68 in combination with the sense coil 64 alone or together with one or more elements (e.g., capacitor 66) form a resonant sensing circuit 65 (e.g., LC or LRC), the benefits of the invention may be obtained.

The sensing element 68 can be any of a variety of known types of sensors which may be used to sense a functional parameter within the living body. Such parameters may include, but are not limited to, vascular parameters such as blood flow rate, blood pressure, oxygen content, cholesterol, restenosis, glucose level, temperature, etc.; hemotology

parameters such as blood gases, blood chemistry, hemoglobin content, etc., and skeletal/muscular parameters such as force, strain, displacement, etc. As mentioned above, the sensing element 68 itself may be characterized as an impedance based sensor whose resistance, capacitance and/or inductance varies directly with respect to frequency as a function of the sensed parameter, or another type sensor whose output can be converted into a variable impedance. Exemplary sensor types include electrical, piezoelectric, sonic optical, microfluidic, chemical, membrane, thermal, magnetohydrodynamic, an NMR varient, magnetic, magnetostrictive, biological, microelectromechanical sensors (MEMs), etc.

In the particular examples discussed below, the sensing element 68 may be a MEMs device whose impedance varies as a function of the amount or rate of blood flow through a stent or graft. Alternatively, the sensing element 68 may be a surface acoustic wave (SAW) device which can detect blood flow. In yet another alternative, the sensing element 68 may be a piezoelectric device within a stent or graft for detecting blood pressure.

According to yet another embodiment discussed below, the sensing element 68 may be included within the sense coil 64 itself. For example, the embodiments of Figs. 7a, 8a, 9a, etc. as described below incorporate the sense coil 64 within the tubular housing of a stent or graft. Changes in the amount of blood flow through the stent or graft and/or the occurrence of restenosis therein affect the overall inductance of the sense coil 64. Hence, the sense coil 64 alone or in combination with one or more other sensing elements 68 may be used to vary the impedance of the resonant sensing circuit based on the sensed parameter.

As is explained more fully in the aforementioned '248 patent, the basic operation of the system 30 of Fig. 3 according to the invention is as follows. The sensing circuit 65 exhibits a resonant frequency which is defined as the frequency which is the point of maximum sensitivity to changes in the excitation current I_P for a given change in the impedance of the sensing element 68. The resonant frequency f_s is determined by the sum total of the reactive elements of the circuit which includes the inductance of the sense

coil 64 and the exciter/interrogator coil 52, as well as the capacitance 66 (and parasitic capacitances C_{P1} and C_{P2} shown in Fig. 4) and the value of a coupling constant K. The amplitude of the current through the coil 64 is also a function of the sensing element 68, particularly at the resonant frequency of the sensing circuit 65. When the exciter/interrogator coil 52 has an AC signal applied, current in the primary or exciter/interrogator coil 52 induces current in the secondary or sense coil 64, as in an air gap transformer. This current in the sense coil 64, however, is reflected back to the exciter/interrogator coil 52 by the mutual coupling of the two coils. The sensing resistor 56 is used to detect the current in the exciter/interrogator coil 52.

When the excitation frequency is approximately at the resonant frequency of the sensing circuit 65, the current in the exciter/interrogator coil 52 changes maximally in relation to the value of the sensing element 68. Thus, the condition of the sensing element 68 can be determined as a function of the detected current in the exciter/interrogator coil 52. Using an amplifier 72, the signal conditioning electronics 58 amplifies the voltage developed across the sensing resistor 56 by the exciter/interrogator circuit current I_P. This amplified voltage is then rectified and low pass filtered via a rectifier and low pass filter circuit 74 to provide a DC voltage output V_{dc}. The control circuit 60 then uses the DC value to determine the state or output of the sensing element 68.

Fig. 4 provides a more detailed circuit model of an exciter/interrogator unit 38 and the implant device 32. As shown, the exciter/interrogator unit 38 includes the exciter/interrogator coil 52 that has a determinable inductance L_P. The coil 52 and associated components of the exciter/interrogator unit 38 also will exhibit an overall parasitic capacitance, C_{P1}, that appears in parallel with the coil inductance. The exciter/interrogator unit 38 further includes the variable frequency oscillator 54 and the sensing resistor 56 used to sense the primary or excitation current I_P. Thus, all components in the exciter/interrogator unit 38 are known quantities for each application.

The resonant sensing circuit 65 includes the sense coil 64 which has a determinable inductance, L_S, in one embodiment; or in another embodiment an

inductance which varies in relation to the sensed parameter. In such embodiment, the sense coil 64 itself forms part of the sensing element 68. The sense coil 64 also has an associated parasitic capacitance, which parasitic capacitance is in effect part of the capacitance C_{P2} which is a discrete capacitor selected to optimize the sensitivity of the device 32 to changes in the value of the sensing element 68. In other words, the value of C_{P2} can be selected, such as based on experimental data for specific circuits, to maximize the current I_P induced in the exciter/interrogator unit 38 as a function of changes in the resistance of the sensing element 68. The sensing circuit 65 also includes the additional discrete capacitor 66 which is selected to adjust the frequency at which the change in current vs. change in sensing element resistance ratio is optimized.

Thus, for the sensing circuit 65, all of the component parameters are known quantities except the coupling constant, K, and the value of the sensing element 68 output. Accounting for the coupling constant K as described more fully in the '248 patent, the DC output of the signal conditioning electronics 58 is indicative of the sensed parameter of the implant device 32.

Fig. 5 is a graph showing in a representative manner a typical frequency response characteristic of the circuit of Fig. 4. By comparing a family of curves determined by monitoring the primary current I_P vs. excitation frequency for different K values (in this example for $K=0.1$, $K=0.5$ and $K=0.9$) and different resistance values for the sensing element 68, the sensed parameter (e.g., blood flow rate, degree of restenosis, etc.) may be determined.

Fig. 6a presents a first embodiment of the present invention in which the medical implant device 32 is a stent. As is known, a stent is a round, spring-like device that provides mechanical support to the wall of a blood vessel such as an artery. As is shown in Fig. 6a, the stent 32 is inserted within a blood vessel 80. The stent 32 is a tube shaped structure made up of a generally helical formed wall 82. The stent 32 prevents the walls of the

blood vessel 80 from collapsing while providing a path 84 through which blood may flow.

The wall 82 typically is formed of stainless steel or some other material (e.g., a composite and/or plastic material) which is biocompatible within the body. Depending on the embodiment, the wall 82 preferably is made of a non-conductive material or materials in one case, or a conductive material in another case. In this particular embodiment, the wall 82 preferably is made of a non-conductive material such as plastic. The sense coil 64 is formed on an outer (or inner surface) of the tube shaped structure. Alternatively, the sense coil 64 may be embedded within the wall 82. The sense coil 64 is coupled via electrical conductors 86 and one or more through holes 87 to the remainder of the sensing circuit 65 which is formed on an inner surface of the wall structure 82. The sensing element 68 in such an embodiment may be a MEMs device whose capacitance and/or resistance varies as a function of the amount of restenosis which forms on the element 68 within the stent 32. Alternatively, the sensing element 68 may be a piezoelectric device which produces an impedance output which varies as a function of the pressure of the blood flowing within the stent 32. If desirable, the sense coil 64 and all or part of the remainder of the sensing circuit 65 may be covered with a protective coating material to avoid corrosion or other related problems.

Upon being implanted within the vessel 80, the exciter/interrogator unit 38 (Fig. 3) can be positioned outside the body of the patient in close proximity to the stent 32. The exciter/interrogator unit 38 serves to excite the sense coil 64 which in turn induces a current in the load resistor 56 which varies as a result of the variable impedance loading effect of the sensing circuit 65 with respect to frequency. Thus, as the output of the sensing element 68 varies based on the build up of restenosis, change in blood pressure, or other desired parameter, such variation may be detected remotely.

Fig. 6b illustrates the equivalent circuit for the sensing circuit 65 in an embodiment where the sensing element 68 provides a resistance which varies in response to a sensed parameter. Fig. 6c illustrates an equivalent circuit for

the sensing circuit 65 in an embodiment where the sensing element 68' produces an output which varies in capacitance based on the sensed parameter. In each case, the impedance loading effect of the sensing circuit 65 varies in accordance with the sensed parameter by virtue of the resonance of the circuit being affected.

An alternative embodiment for a stent 32 is shown in Fig. 7a. In this particular embodiment, the helical shaped wall 82 preferably is made of a molded plastic. The sense coil 64 is made up of a conductive wire 92 embedded through several turns in the wall of the helix 82 as shown in cross-section in Fig. 7b. Return wires 94 embedded in and traversing the helix 82 are provided to connect the respective ends of the coil 64 to the remainder of the resonant sensing circuit 65 mounted on the helix 82 as in the previous embodiment. During manufacture, the sense coil 64 may serve as the frame about which the molded plastic helix 82 is formed.

The embodiment of Fig. 7c varies slightly from that shown in Figs. 7a and 7b. In this particular embodiment, the return wires 94 are formed on the inner surface of the helix 82. Such embodiment simplifies the manufacturing process by allowing the helix 82 to be formed without the return wires 94 traversing the helical turns in an embedded manner.

Fig. 7d illustrates generally the equivalent circuit for the stent 32 shown in Figs. 7a thru 7c. As will be appreciated, the sensing element 68 may be a resistive device as before, or some other type of sensor. In each case, the sense coil 64 provides a means for magnetic coupling between the exciter/interrogator coil 52 and the resonant sensing circuit 65. As blood flow, restenosis, etc. varies within the stent 32, the impact of such variation on the impedance loading effect of the resonant sensing circuit 65 on the exciter/interrogator unit 38 may be detected with respect to frequency. Such information can then be utilized in ascertaining the precise rate of blood flow, degree of restenosis, etc. via the data processing and control 60. As will be appreciated, in each of the embodiments discussed herein the particular type of sensing element 68 will be dictated, of course, by the particular parameter

of interest and the manner in which the output of the exciter/interrogator unit 38 is processed.

Fig. 8a illustrates another embodiment of a stent 32 which utilizes the conductive properties of a metal-type helix wall 82. The helix wall 82 is made of metal and therefore can itself form the sense coil 64. The metal helix is electrically isolated via a non-conductive coating, for example. Each end 96 of the helix is connected to the remainder of the resonant sensing circuit 65 via return wires 94 as shown in phantom in Fig. 8a. As in the previous embodiments, the resonant sensing circuit with the sensing element 68 may be mounted on the inner surface of the stent 32. Fig. 8b diagrammatically represents the electrical circuit of this particular embodiment.

In each of the embodiments which utilize the body 82 of the stent 32 to form the sense coil 64, e.g., the embodiments of Figs. 7a, 7c and 8a, it will be appreciated the inductance of the sense coil 64 may itself vary as a function of the sensed parameter. In such instance, the sense coil 64 serves as a sensing element in addition and/or in place a discrete sensing element 68. More particularly, the sense coil 64 formed within the helix may be considered an inductive element. It is combined with a discrete capacitor 66 and resistance 68 to form an LRC resonant sensing circuit 65.

The inductance of the sense coil 64 depends directly on the magnetic permeability of the material inside it. Since iron strongly affects permeability, the amount of blood in the stent 32 as a fraction of the available volume (reduced by restenosis) will modulate the permeability and hence the resonant frequency of the sensing circuit 65. The resonant frequency can be determined by inductively coupling the stent 32 to the exciter/interrogator unit 38 via the externally generated swept frequency magnetic field. Knowledge of the resonant frequency then allows a determination of the inductance of the coil 64. Since the value of inductance depends on the degree of restenosis, an estimate of its occlusion of the stent 32 can be made.

The embodiments of Figs. 7c and 8a each include some type of direct linear connection via the return wires 94 between the sense coil 64 and the

remainder of the resonant sensing circuit 65. Such design may not be optimum from a biocompatibility standpoint or manufacturing standpoint. Figs. 9a and 9b represent an embodiment which eliminates the need for such return wires 94. In this case, a double helix configuration is used to complete the resonant circuit.

As is shown more clearly in Fig. 9b, the helix wall 82 is made of conductive metal and from one end to the other forms part of the coil 64. The return wire 94 is a second helix with the same pitch as the helix 82 but having an axial direction which is reversed relative to the helix 82. The return wire 94 is connected to one end of the helix 82 and returns to the other end where the resonant sensing circuit 65 can be closed with the capacitance 66 and resistance 68. Electrically, such configuration doubles the inductance L of the coil 64, and currents in the two helical sections 82 and 94 will produce magnetic fields which add rather than cancel. In the presence of a changing magnetic field, conversely, the current in the circuit 65 is doubled.

Other embodiments may include a stent 32 which has a uniform wall rather than a helix shaped wall. In such case, the sense coil 64 may be formed on a surface as in the embodiment of Fig. 6a. Alternatively, the sense coil 64 may be embedded in the structure as in the embodiments of Figs. 7b and 7c, for example.

Fig. 10 illustrates an embodiment of the invention wherein the implant device 32 comprises a graft for joining separate ends 100 of a blood vessel. The graft 32 is a tube shaped structure 102 made up of metal such as stainless steel, or a composite and/or plastic material. Using known techniques, the graft 32 is implanted within the patient by securing respective ends 100 of a blood vessel to corresponding ends of the graft 32. Consequently, blood will flow through the interior of the graft 32 as represented by arrow 84.

As in the case of the stent described above, the resonant sensing circuit 65 can be any combination of a sense coil 64, a capacitor 66, a resistor 68, etc. One or more of these components presents an impedance which varies as a function of the parameter to be sensed. Similar to the

stent, it is desirable with the graft 32 to sense remotely the degree of restenosis and/or blood flow in the device. By using impedance-based sensing devices, the frequency dependent impedance loading effect of the sensing circuit may be detected externally using the exciter/interrogator unit 38 as previously described.

The embodiment of Fig. 10 is similar to that of Fig. 6a where the sense coil 64 is mounted on a surface of the tube structure 100. The sensing element 68 and capacitor 66, for example, are mounted on an interior surface of the structure 100. Electrical connections to the coil 64 are provided by conductors 86 and vias 87. Operation is fundamentally the same as described above in relation to the stent embodiment.

Figs. 11a thru 11c illustrate an embodiment of a graft 32 analogous to the stent of Figs. 7a thru 7c. The structure 100 is made of a non-conductive material and the windings of the coil 64 are embedded directly within the tube. Again, for example, the structure 100 may be molded plastic or the like with the coil 64 serving as a skeletal support.

Fig. 12 represents an embodiment of a graft 32 which uses a double helix structure similar to the stent in Fig. 9a. In this case, however, since the structure 100 is uniform rather than helical, two separate helical wires 104 and 106 are embedded along the length of the tube 102. Electrically speaking, the circuit is identical to that shown in Fig. 9b. As the amount of blood/restenosis varies in the graft 32, the inductance of the helical wires 104 varies which changes the impedance loading effect on the exciter/interrogator unit 38.

Fig. 13 illustrates yet another embodiment of a graft 32 (or stent) which is remotely interrogated in accordance with the present invention. In the case of a tube shaped structure 102 serving as the body of the graft or stent, a conventional device may be modified by placing a desired number of windings around the outer surface of the structure 102 to form the sense coil 64. The capacitor 66 or other fixed components may similarly be mounted on the outer surface. The sensing element 68 is mounted on the inside surface and connected through vias 87 to the coil 64 and capacitor 66 to form the

LRC resonant sensing circuit 65. Alternatively, the sensing element 68 may be mounted on the outer surface also, provided the sensing element is capable of sensing the desired parameter through the structure 102.

Subsequently, a laminate sheath 110 is applied over the outer surface of the structure 102 and heated to form an integrated graft 32. The sensing circuit 65 can then be interrogated in the same manner described above in connection with the other embodiments.

Figs. 14a and 14b illustrate another embodiment of the invention represented by a remotely interrogated graft 32, for example. The graft 32 again includes a tube shaped structure 102 as in the previous embodiments, and is inserted between separate ends of a blood vessel. The graft 32 also includes a resonant sensing circuit 65 as in the previous embodiments. For example, the resonant sensing circuit 65 includes a sense coil 64 and capacitance 66 mounted on or within the tube 102 as in any of the previous embodiments described herein. In the present embodiment, however, the sensing element 120 in the sensing circuit 65 includes an annulus 122 which is fitted around the outer circumference of the tube 102. As is shown in Fig. 14c, the annulus 122 serves as a carrier for one or more strain gage elements 124 which are mounted to the inner surface of the annulus 122. In the case of more than one strain gage element 124, the elements may be distributed about the inner circumference of the annulus 122. In another embodiment, for example, the strain gage elements 124 may be mounted on the outer surface of the annulus 122 or on both the inner and outer surfaces.

The annulus 122 with the strain gage elements 124 is designed to sense changes in pressure within the graft 32. As the diameter of the tube 102 expands or contracts in the direction noted by arrow P in Fig. 14a, such changes are detected by the strain gage elements 124 on the annulus 122. An output produced by the strain gage elements 124 varies in impedance as a function of the change in pressure, and the output is coupled to the remainder of the sensing circuit 65 via electrical lines 126. Consequently, a change in pressure within the graft 32 results in a frequency dependent variation in the

impedance loading effect of the sensing circuit 65 similar to the embodiments discussed above.

It has been shown that a change in pressure exerted by the blood within a graft or shunt is a reliable indicator of vascular problems. Such problems may include clogging within the graft or shunt, for example, or clogging within the vessel. Thus, the sensing circuit 65 can be interrogated remotely by sweeping the frequency of the excitation signal in order to detect changes in the pressure, and hence potential vascular problems.

In the preferred embodiment, the tube 102 is made of a thin, compliant material which tends to deform measurably as a result of changes in blood pressure within the graft 32. As a particular example, the tube 102 is a conventional graft made of a compliant woven fabric. The tube 102 may include the sense coil 64 (shown diagrammatically in Figs. 14a and 14b) mounted on the side of the tube 102 similar to the embodiment of Fig. 10. Alternatively, for example, the sense coil 64 may be formed within a helical tube 102 similar to the embodiments of Figs. 11a and 12. The capacitance 66 is mounted on the tube 102 and is electrically connected to the sense coil 64 and the sensing element 120 as shown in Fig. 14d, for example.

The annulus 122 is made of a thin, flexible material such as a polyimide film or a polyimide film mounted on a metal annulus 122, for example. The annulus 122 includes the strain gage elements 124 formed on the inner and/or outer surface of the annulus. In the exemplary embodiment, the strain gage elements 124 are piezoresistive devices whose resistance changes as a function of mechanical strain of the annulus in the direction of its circumference. The piezoresistive devices are formed using MEMs technology, patterned lithography, etc. either directly on the annulus 122 material, or are subsequently mounted to the annulus via adhesive, etc. The outputs of the strain gage elements 124 are combined in parallel, series, as a Wheatstone bridge, etc., via conductive lines 130 formed on the annulus 122, for example. The conductive lines 130 are coupled to lines 126 to produce a resistance across lines 126 which consequently varies as a function of the pressure exerted on the annulus 122 by the tube 102.

The material of which the annulus 122 is made is preferably stiffer than the woven fabric or other compliant material making up the tube 102. Prior to the graft 32 being installed, the annulus 122 is formed around the circumference of the tube 102 so as to slightly compress the tube 102. As a result, any expansion which occurs in the tube 102 due to blood flowing therethrough will result in an expansion of the annulus 122, and hence a change in the output resistance of the strain gage elements 124. Experience has shown that with a 6 millimeter ID teflon graft, there is approximately a 0.004 inch increase in diameter of the graft 102, for example, when blood is introduced therethrough at a pressure of 100 millimeters of mercury. Thus, by forming the annulus 122 around the circumference of the tube 102 to be slightly compressed, e.g., on the order of 0.004 inch, the annulus 122 will be subjected to the majority of the load due to blood pressure.

The annulus 122 is adhered to the outer circumference of the tube 102 according to any of a number of suitable techniques. For example, the annulus 122 may be joined with the tube 102 via ultrasonic welding, an adhesive, friction fit, etc. Moreover, the tube 102 may include one or more walls or protrusions on each side of the annulus 122 to prevent movement of the annulus 122 in the axial direction.

Although not shown in the figures, the annulus 122 may include one or more flat spots at which the strain gage elements 124 are located for concentrating the strain forces in the region(s) at which the elements 124 are located. In addition, the flat spots may include small cuts, etc. designed to focus further the strain on the respective elements.

An advantage of the embodiment of Fig. 14a is that the annulus 122 and strain gage elements 124 do not come into direct contract with the flowing blood. Moreover, the annulus 122 makes it possible to measure pressure independent of any shear force the flowing blood may otherwise introduce to a sensing element.

According to one variation of the graft 32 shown in Fig. 14a, the strain gage elements may be made up of other types of strain gages. For example, the elements 124 may be conventional foil type strain gages formed on the

annulus 122. Although the exemplary embodiment involves a strain gage element 124 having a resistance which changes as a function of the amount of strain, another embodiment can incorporate a strain gage which produces a capacitance or inductance that changes as a function of strain as will be appreciated.

In another embodiment, the tube 102 is made of a relatively less compliant material such as stainless steel, or a composite and/or plastic material. For such case, the annulus 122 may be omitted and the strain gage elements 124 may be formed directly on the surface of the tube 102.

Fig. 15a illustrates another embodiment of a graft 32 in accordance with the present invention. The graft 32 again includes a tube shaped body 102 as shown. In this particular example, the tube 102 includes an aperture 140 in which a small, flexible diaphragm 142 is inserted. The diaphragm 142 includes a piezoresistive strain gage element 144 formed thereon whose resistance changes as a function of the deformation of the diaphragm 142. The strain gage element 144 may be a MEMs type device formed on the diaphragm 142 via lithography or the like. Alternatively, the strain gage element 144 may be a foil type element or other type which presents an impedance which varies as a function of deformation of the diaphragm 142. The output of the strain gage element 144 is coupled to the remainder of a sensing circuit 65 formed on or within the tube 102 similar to the previous embodiments discussed above.

The diaphragm 142 with the strain gage element 144 is responsive to changes in pressure P exerted by the blood flowing through the graft 32. As is represented in Fig. 15b, the diaphragm 142 and strain gage element 144 form the sensing element in a sensing circuit 65. As in the previous embodiments, the sensing circuit 65 includes a sense coil 64 and capacitance 66. The sensing circuit 65a has a frequency dependent variable impedance loading effect on the interrogation circuit in response to the interrogation signal provided by the exciter/interrogation unit 38. Such loading effect thus will be indicative of the pressure component P exerted within the graft 32.

Referring now to Fig. 16a, a hemodialysis shunt (or graft) 200 in accordance with another embodiment of the invention is illustrated. In this particular embodiment, an ultrasound transit time or phase shift is used to measure blood flow is the shunt 200. As is described in U.S. Patent No. 4,227,407, the entire disclosure of which is incorporated herein by reference, an ultrasonic transit time or phase shift can be used to measure fluid flow.

According to the preferred embodiment of the present invention, the shunt 200 includes a tube-shaped shunt body 202 with a sleeve 204 which fits over the body 202. The sleeve 204 is made of a relatively rigid material such as plastic, stainless steel, etc., which serves as a reflecting surface for ultrasonic waves which are created within the shunt 200. More particularly, the sleeve 204 includes a pair of piezoelectric crystals 206a and 206b mounted on an inner surface as shown in Figs. 16a and 16b. The piezoelectric crystals 206a and 206b are separated by a distance L along the axis of the shunt body 202. The sleeve 204 is shaped as a polygon with an oppositely facing side 208 relative to the crystals 206a and 206b which serves to reflect an ultrasound wave which is transmitted by one crystal through the shunt body 202 back towards the other crystal as represented by signal path 210. In the exemplary embodiment, the shunt body 202 is made of plastic, woven fabric, or any other material which permits ultrasonic waves to pass through the respective walls and through the blood in order to be reflected by the opposite side 208.

Fig. 16c shows the sensing circuit 220 included in the shunt 200 for measuring relative transit times which relate to the flow rate of blood through the shunt 200, and for permitting the shunt to be interrogated remotely based on the aforedescribed impedance loading effect. More particularly, the sensing circuit 220 includes a sense coil 64 which receives an excitation signal from the external exciter/interrogator coil 52 by way of magnetic coupling as in the previous embodiments. The sensing circuit 220 further includes a power supply 222 in this embodiment. The power supply 222 may be a battery which is replaced periodically. Alternatively, and more preferably, the power supply 222 includes a bridge circuit and capacitor.

Immediately prior to measuring the blood flow rate, the exciter/interrogator coil 52 is driven at a predefined frequency. Energy from the exciter/interrogator coil 52 is magnetically coupled to the sense coil 64 which produces an AC voltage at across the terminals 224 of the coil 52 and the input terminals of the power supply 222. The power supply 222 converts the AC voltage into a DC voltage which is stored as charge in a capacitor within the power supply 222. The output of the power supply serves to provide an operating voltage to the various active electronics included in the sensing circuit 220 as further discussed below.

The blood flow rate is measured by providing an excitation signal to the exciter/interrogator coil 52 which consists of bursts of a high frequency signal at a predefined rate. Each burst is magnetically coupled to the sense coil 64 through the body of the patient to produce a voltage spike across the terminals 224 of the sense coil 64. The piezoelectric crystals 206a and 206b are coupled across the terminals 224 by wires 228, and the voltage spike produced by a given burst of the exciter/interrogator coil 52 results in each of the crystals 206a and 206b emitting an ultrasonic pulse. The pulse transmitted by the crystal 206a passes through the shunt body 202 and the blood therethrough so as to reflect off the opposite face 208 and subsequently be received by the crystal 206b. Conversely, the pulse transmitted by the crystal 206b in the opposite direction so as to pass through the shunt body 202 and the blood therethrough in order to be reflected off the opposite face 208 and subsequently received by the crystal 206a.

Since the blood flowing through the shunt 200 will be flowing in a particular direction, the transit time for an ultrasonic pulse emitted from a first one of the crystals 206 to the second will be delayed relative to the transit time of the ultrasonic pulse emitted from the second crystal 206 to the first. Accordingly, there will be a time difference between the time when the first crystal 206 receives a corresponding pulse and the second crystal receives a corresponding pulse. This time difference, as will be appreciated, is related to the blood flow rate.

Such time difference is measured as follows. Following each burst from the exciter/interrogator coil 52, the crystals 206a and 206b will each receive the reflected ultrasonic pulse from the other. The received ultrasonic pulses result in the crystals 206a and 206b producing corresponding electrical pulses, or "echo pulses" following the excitation pulse, across lines 228. The sensing circuit 220 includes a pulse width decoder 230 configured to produce an output pulse having a width which is based on the time period between the two echo pulses. The output pulse from the decoder 230 is provided to a charge accumulator 232 which produces an output voltage which varies as a function of the pulse width of the pulse width decoder 230 output. For example, the charge accumulator 232 may be an RC circuit whose charge builds up as a function of the pulse width. The output of the charge accumulator 232 is provided to a varactor diode 234 included in the sensing circuit 220. The main terminals of the varactor 234 are coupled across lines 228, and the output of the accumulator 232 serves as a control voltage to the varactor 234 to effect a change in the impedance (e.g., capacitance) of the varactor 234 across lines 228 as a function of the accumulator 232 output.

Consequently, the time period between echo pulses produced by the crystals 206a and 206b following an excitation pulse received from the exciter/interrogator coil 52 affects the impedance which appears across the terminals 224 of the sense coil 64. This impedance can then be detected by the exciter/interrogator coil 52 based on the amount of loading which occurs on the exciter/interrogator coil 52 as a result of the impedance of the varactor 234. Accordingly, the impedance loading effect of the sensing circuit 220 on the exciter/interrogator coil 52 is indicative of the flow rate of the blood through the graft 200. The main circuitry 42 (Fig. 1) can then process such information in order to produce an output representing the measured flow rate.

The sensing circuit 220 as described above will essentially produce a time averaged flow rate based on a sequence of excitation pulses each followed by corresponding echo pulses. The pulse width decoder 230

discriminates between the excitation pulses and the echo pulses based on fact that the echo pulses will be several orders of magnitude lower in amplitude. The pulse width decoder 230 is reset by each excitation pulse, and then provides a pulse output having edges which are set by the echo pulses produced across lines 228.

In an embodiment in which the instantaneous blood flow rate is desired, the charge accumulator 232 includes reset terminals (not shown) coupled across lines 228. The charge accumulator reset terminals are configured like the pulse width decoder 230 to discriminate between the excitation pulses and the echo pulses. Upon the occurrence of each excitation pulse the charge accumulator 232 is effectively "zeroed". The resultant pulse produced by the pulse width decoder 230 then serves to charge the charge accumulator 232 to provide a controlled impedance across lines 228. The loading effect of the sensing circuit 220 can then be sensed by sweeping the excitation frequency of the exciter/interrogator coil 52 at a low amplitude prior to the next excitation pulse.

Although the exemplary embodiment relies on transit times to determine flow rate, a different configuration of the piezoelectric crystals 206 can be provided which utilizes a phase difference as will be appreciated. Furthermore, more than one pair of crystals 206 can be used on the sleeve 204 by placing additional pairs on another face and reflecting the ultrasonic pulses off of a different oppositely disposed surface of the sleeve 204. Yet further, in the exemplary embodiment the sleeve 204 is hexagonal in cross section, with mirror like reflection of the ultrasonic pulses occurring at the flat facets. However, cylindrically or spherically curved facets could also be used as well as other shapes, and could proved additional focusing power on the ultrasonic waves.

In addition, an embodiment is also within the scope of the invention whereby the sleeve 204 is omitted and the crystals 206 are disposed along the axis of the shunt 200. The ultrasonic pulses in such case may be transmitted directly between the two crystals without reflection. The crystals 206 may be affixed directly to the body 202 in such case.

While the embodiment of Figs. 16a thru 16c incorporates some active components and possibly a discrete power supply, it still offers advantages over conventional devices which require a radio transmitter or transceiver to provide for remote interrogation. Again, the complexity of a radio transmitter or transceiver increases the cost of the implant device and provides more opportunity for operational problems. The impedance loading effect of the present invention enables the implant device to be interrogated without the need for such a radio transmitter or transceiver.

Fig. 17 represents a sensing circuit 240 which can be used in a stent, graft or other implant device in accordance with another embodiment of the invention. The sensing circuit 240 incorporates a microprocessor or other digital circuitry for processing information which is obtained from one or more biological measurand transducers. The microprocessor provides an output signal indicative of a desired property which is converted into a corresponding impedance value that can be ascertained via the exciter/interrogator coil 52 by virtue of the impedance loading effect of the sensing circuit 240. In this manner, the microprocessor can perform any complex computations, analyses, etc. on the data obtained from the transducer(s), and output a simplified (e.g., positive/negative) response which is interrogated remotely from outside the body.

As specifically shown in Fig. 17, the sensing circuit 240 includes one or more transducers 242 which serve to measure one or more properties within the stent, graft, etc. For example, the transducer(s) 242 may be strain gage, pressure sensor, and/or different types of biosensors. The output of the transducer 242 is provided to an analog-to-digital converter 244 which converts the output of the transducer to a digital signal that is input to a microprocessor 246 included in the sensing circuit 240. The microprocessor 246 executes a program stored internally in non-volatile memory so as to condition and/or analyze the output of the transducer 242 in accordance with a preprogrammed routine. The microprocessor 246 outputs a digital signal indicative of the result of the conditioning and/or analysis to an impedance conversion circuit 248. The output signal may indicate measurands such a

blood pressure, flow rate, biological composition, etc. The value of the output signal is varied by the microprocessor 246 as a function of the measurand.

The conversion circuit 248 includes a switched capacitor network or other circuitry which converts a digital signal into a corresponding impedance value. In the exemplary embodiment, the impedance presented by the conversion circuit 248 is placed across the sense coil 64. Thus, the impedance loading effect of the sensing circuit 248 on the exciter/interrogator coil 52 will vary as a function of the output of the microprocessor 246. A power supply 222 such as the one discussed above in connection with the embodiment of Fig. 16c provides the necessary operating power to the respective circuit elements.

Thus, the present invention as represented in Fig. 17 provides another alternative to an implant device requiring a radio transmitter/transceiver. Such embodiment enjoys a reduction in power consumption, circuit complexity and size, for example.

Fig. 18 illustrates a wireless system 30' which may be used in accordance with the present invention. In this case, the exciter/interrogator unit 38 houses all of the electronics shown in Fig. 3, together with a wireless transmitter (not shown) used to transmit the output from the data processing and control section 60 to main circuitry 42. For example, the unit 38 includes a radio frequency (RF) transmitter which transmits data output from the data processing and control section 60 to an RF receiver (not shown) included in the main circuitry 42 (e.g., using antennas 260). Alternatively, an optical link or other wireless connection may be utilized. A rechargeable power supply (not shown) included in the unit 38 provides the appropriate operating power.

The system 30' provides flexibility which enables one or more units 38 to be networked into a centralized main circuitry 42. For example, in a hospital or other health care facility the unit 38 may be carried about to different patients where an implant device is interrogated. The results of the interrogation are then transmitted to the main circuitry 42 for storage and/or further processing, analysis by an expert, etc. Each unit 38 may include a

keypad or other input means which allows the operator to input the identity of the patient. Such identity is transmitted together with the output of the data processing and control section 60 to the main circuitry 42.

Figs. 19 and 20 illustrate yet another embodiment of a graft 32 which utilizes a concentric cylinder arrangement to provide a capacitance which varies in relation to the pressure of the blood flowing therethrough. More specifically, the tube structure 102 is made up of an inner tube 102a and an outer tube 102b. The inner tube 102a is made of a generally compliant such as thin plastic, whereas the outer tube 102b is made of a relatively rigid material such as a less compliant plastic.

A surface of the inner tube 102a includes an electrically conductive layer 280, and a surface of the outer tube 102b includes an electrically conductive layer 282. Such layers 280 and 282 may be formed via deposition, etc. The inner tube 102a and outer tube 102b are separated by a compliant foam material 284 having a dielectric constant ϵ. Compliant seals 286 are provided at the ends of the tube structure 102 to prevent blood from entering the region between the inner tube 102a and outer tube 102b.

As blood flows through the central passageway 288 of the graft 32, the pressure of the blood will cause the inner tube 102a to expand radially towards the outer tube 102b. This results in the foam 284 compressing and the distance D between the inner and outer tubes decreasing as a function of the blood pressure. In the meantime, the conductive layers 280 and 282 with the foam 284 act as a capacitor having a capacitance which varies as a function of the distance D. Thus, the capacitance of the tube structure 102 as measured across conductive layers 280 and 282 will vary as a function of the blood pressure within the graft 32.

Accordingly, the tube structure 102 will serve as a capacitive sensing element included in the sensing circuit together with the sense coil 64 and discrete capacitor 66 (optional). The conductive layers 280 and 282 are connected to the sense coil 64 and capacitor 66 by wires 290 to form a resonant LC or LRC sensing circuit. Since the capacitance of the tube

structure 102 will vary as a function of blood pressure, so will the impedance loading effect of the sensing circuit with respect to frequency.

The tube structure 102 in Figs. 19 and 20 therefore provides a manner in which the blood pressure within the graft 32 can be interrogated according to the above-described principles.

Although the invention has been shown and described with respect to certain preferred embodiments, it is obvious that equivalents and modifications will occur to others skilled in the art upon the reading and understanding of the specification. For example, various other types of implant devices can benefit from the present invention and the invention is not intended to be limited only to stents and grafts in its broadest application. The present invention includes all such equivalents and modifications, and is limited only by the scope of the following claims.

What is claimed is:

1. An implant device responsive to an interrogation circuit having an exciter/interrogator element which is located outside a living animal, the implant device comprising:

a structure implantable within the living animal and operatively configured to carry out or assist in carrying out a function within the living animal;

an electrically passive sensing circuit integral with the structure for sensing a parameter associated with the function, the sensing circuit including an inductive element wherein the sensing circuit has a frequency dependent variable impedance loading effect on the interrogation circuit in response to an interrogation signal provided by the exciter/interrogator element, the impedance loading effect varying in relation to the sensed parameter.

2. The implant device of claim 1, wherein the structure comprises a composite structure and at least a portion of the sensing circuit is embedded in the composite structure.

3. The implant device of claim 2, wherein the inductive element is embedded in the composite structure.

4. The implant device of claim 1, wherein the interrogation signal is swept in frequency.

5. The implant device of claim 1, wherein the structure is a stent insertable in a blood vessel to facilitate blood flow through the vessel.

6. The implant device of claim 5, whrein the sensing circuit forms an LRC resonant circuit whose resonant frequency is a function of the sensed parameter.

7. The implant device of claim 5, wherein the stent comprises a composite structure and the inductive element is embedded in the composite structure.

8. The implant device of claim 5, wherein the inductive element is a double helix structure.

9. The implant device of claim 5, wherein the sensed parameter represents a degree of restenosis within the stent.

10. The implant device of claim 1, wherein the structure is a graft insertable in line with an existing blood vessel for facilitating blood flow through the vessel.

11. The implant device of claim 10, wherein the sensing circuit forms an LRC resonant circuit whose resonant frequency is a function of the sensed parameter.

12. The implant device of claim 10, wherein the graft comprises a composite structure and the inductive element is embedded in the composite structure.

13. The implant device of claim 10, wherein the inductive element is a double helix structure.

14. The implant device of claim 10, wherein the sensed parameter represents a degree of restenosis within the graft.

15. The implant device of claim 1, wherein the sensing circuit comprises a SAW sensor having an output dependent upon the sensed parameter to produce changes in the impedance loading effect of the sensing circuit.

16. The implant device of claim 15, wherein the sensing circuit comprises a MEMs sensor having an output dependent upon the sensed parameter to produce changes in the impedance loading effect of the sensing circuit.

17. The implant device of claim 1, wherein the impedance loading effect of the sensing circuit varies in relation to the sensed parameter as a function of at least one of inductance, capacitance, resistance, resistance and inductance, resistance and capacitance, inductance and capacitance, and inductance, resistance and capacitance.

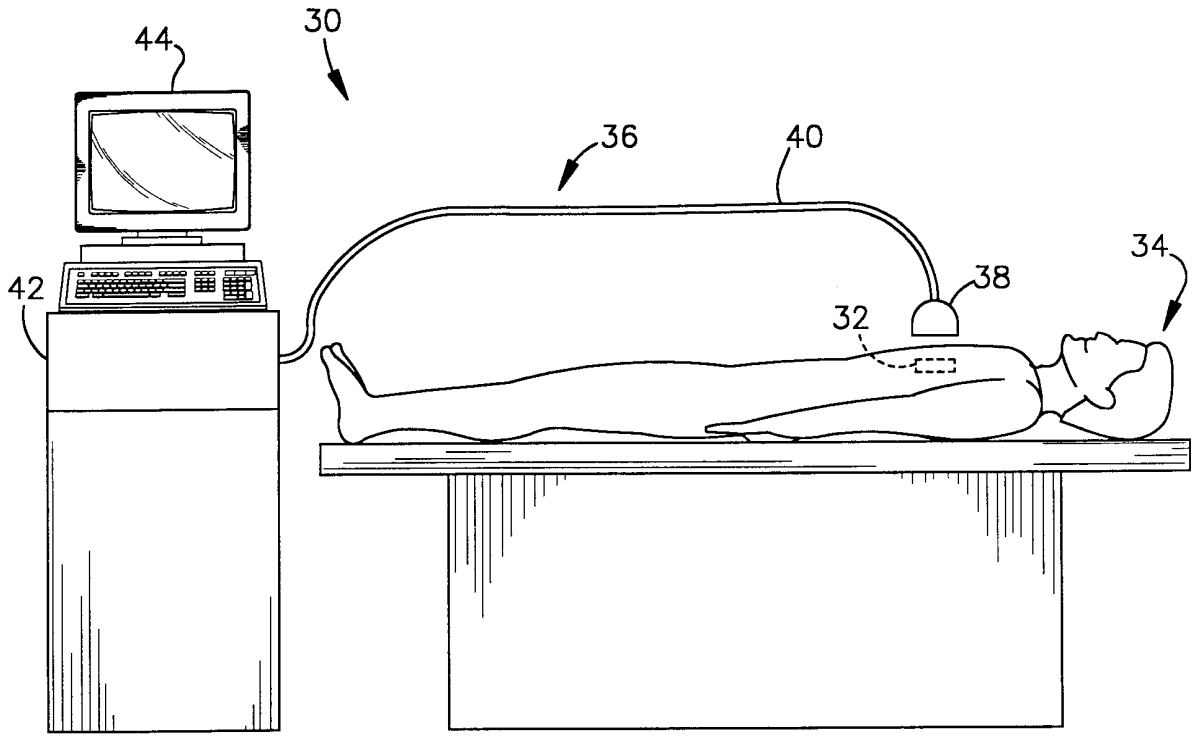
18. The implant device of claim 1, wherein the inductive element comprises a coil.

19. The implant device of claim 1, wherein the sensing circuit is laminated at least in part to a surface of the structure.

20. An implant device responsive to an interrogation circuit having an exciter/interrogator element which is located outside a living animal, the implant device comprising:

a structure implantable within the living animal and operatively configured to carry out or assist in carrying out a function within the living animal;

an electrically passive sensing circuit integral with the structure for sensing a parameter associated with the function, the sensing circuit including an inductive element wherein the sensing circuit has a frequency dependent variable impedance loading effect on the interrogation circuit in response to an interrogation signal provided by the exciter/interrogator element, the impedance loading effect varying in relation to the sensed parameter.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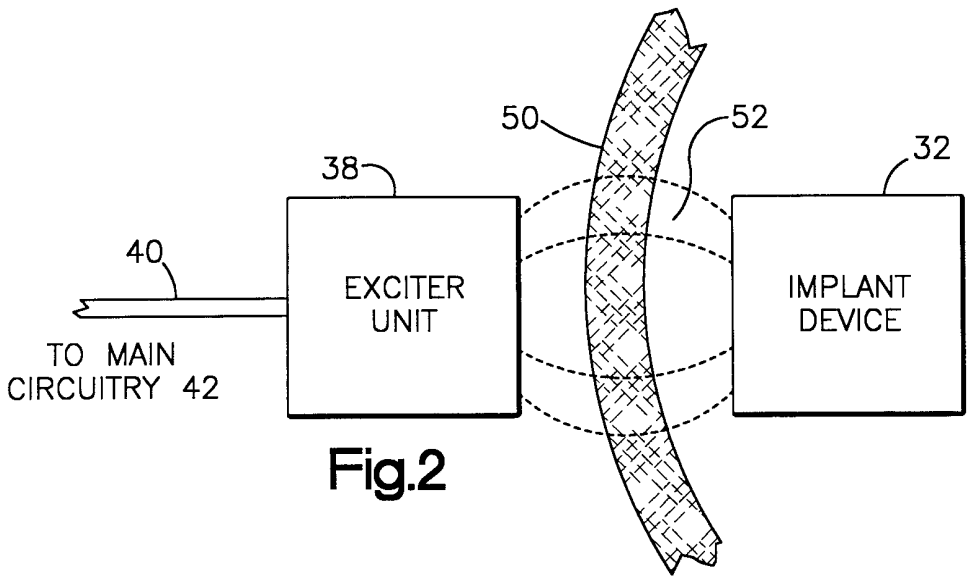
32

Fig.1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32
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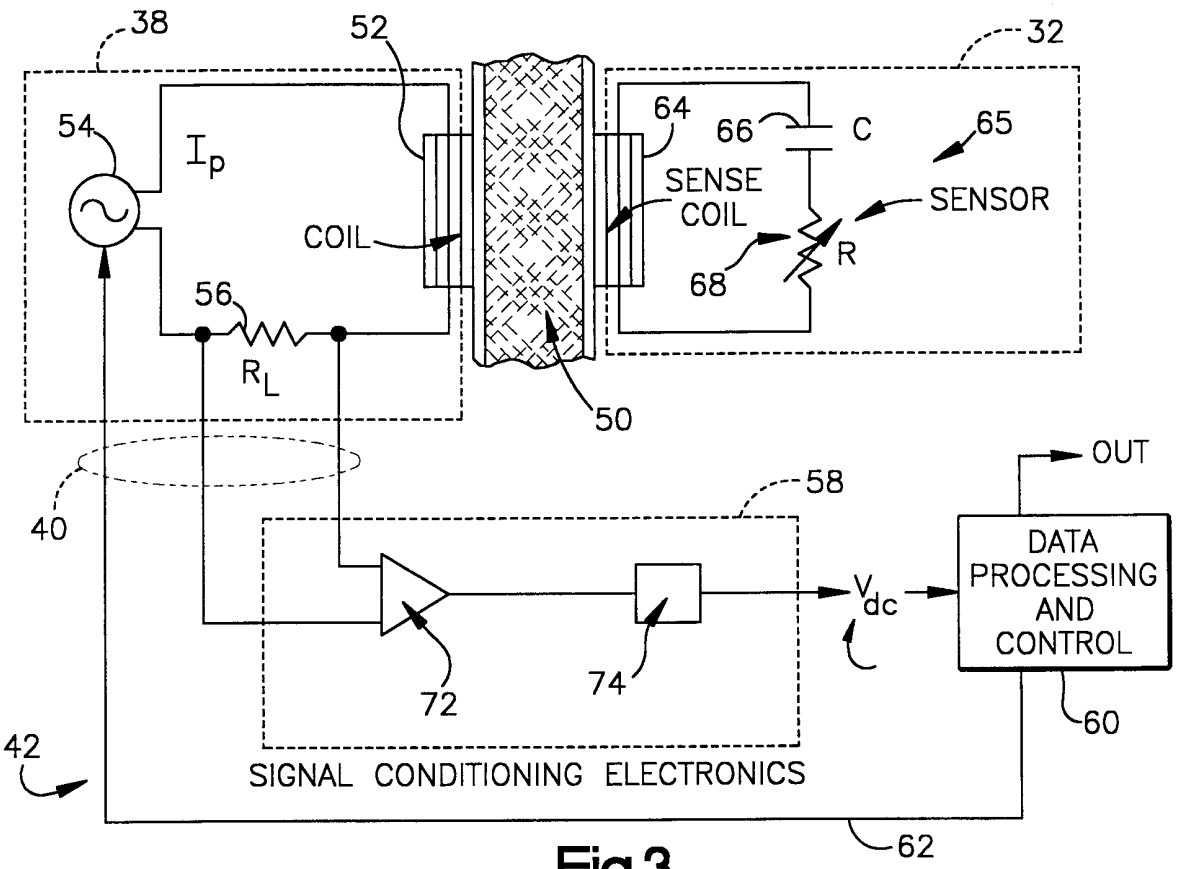
IMPLANT DEVICE
TO MAIN CIRCUITRY 42

Fig.2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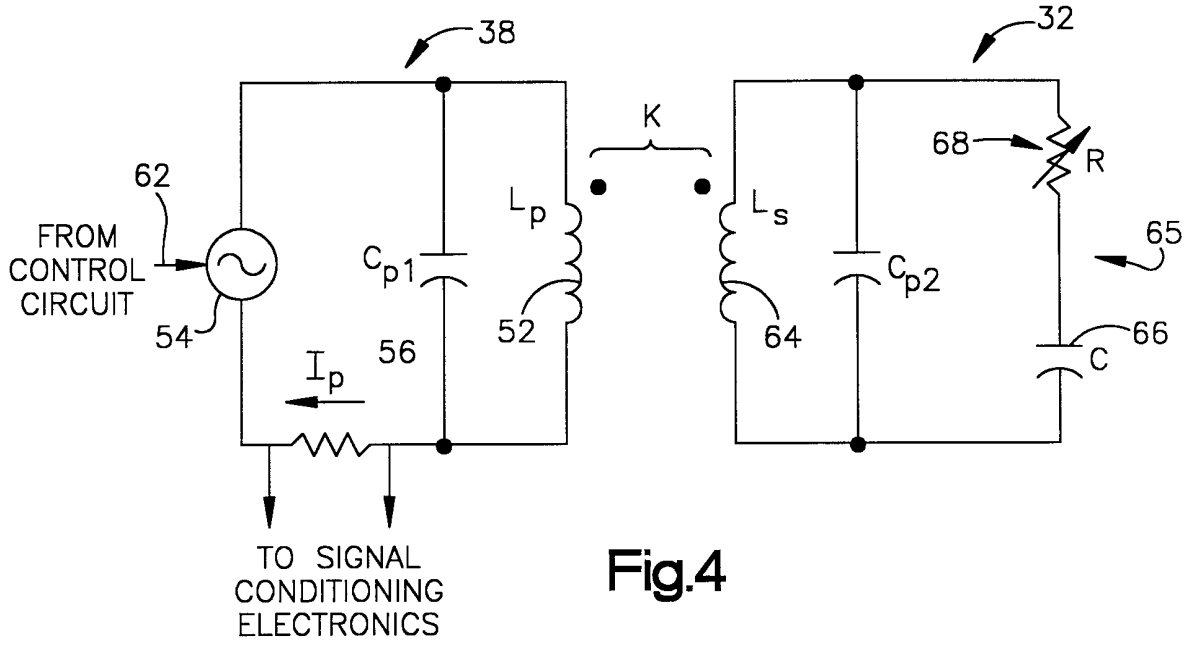
SIGNAL CONDITIONING ELECTRONICS
62

Fig.3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C
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TO SIGNAL CONDITIONING ELECTRONICS

Fig.4

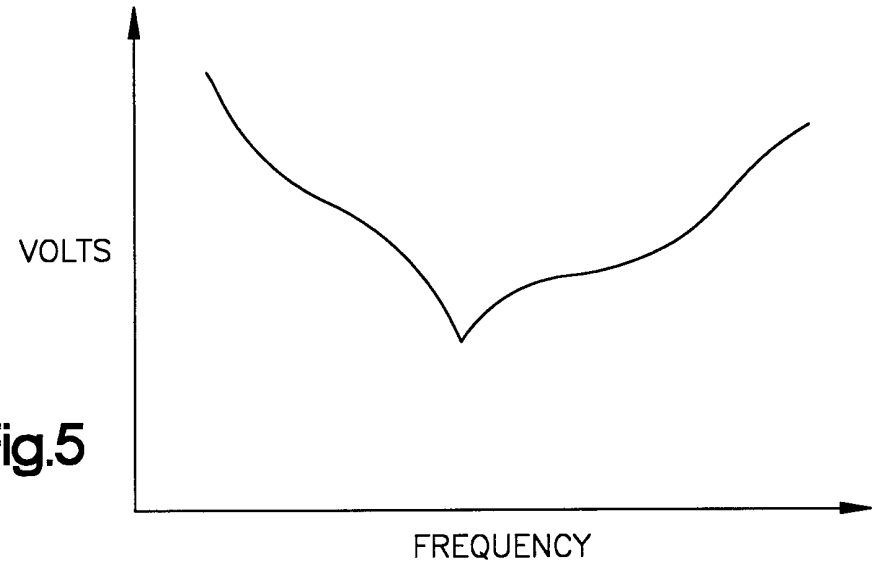

Fig.5

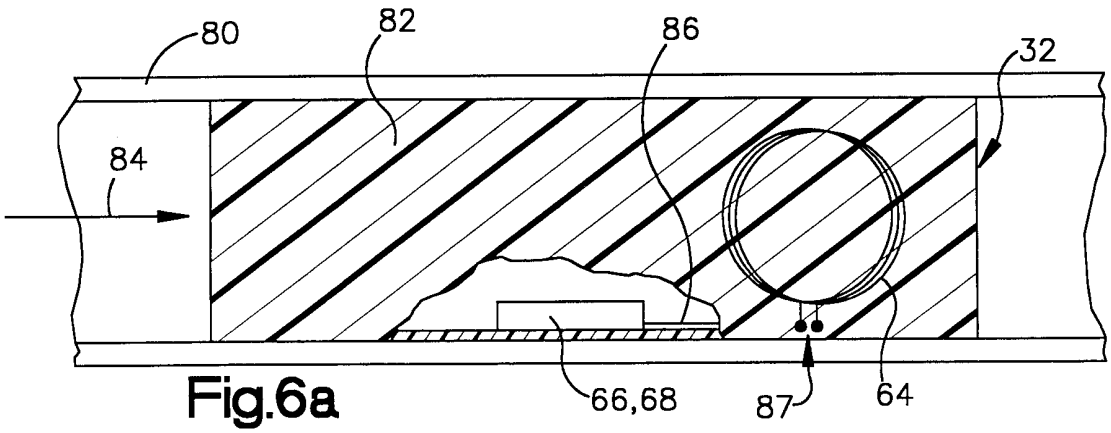

Fig.6a

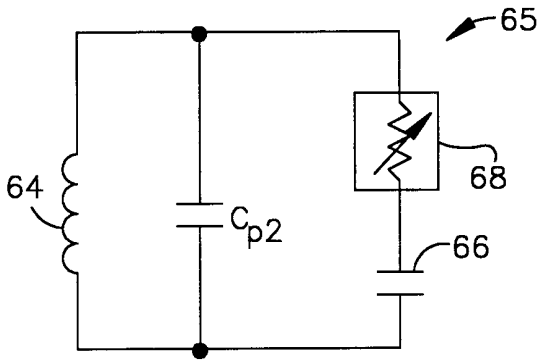

Fig.6b

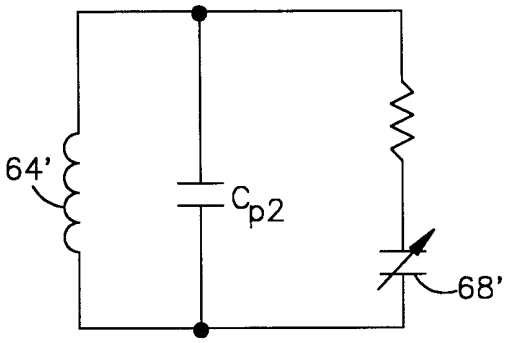

Fig.6c

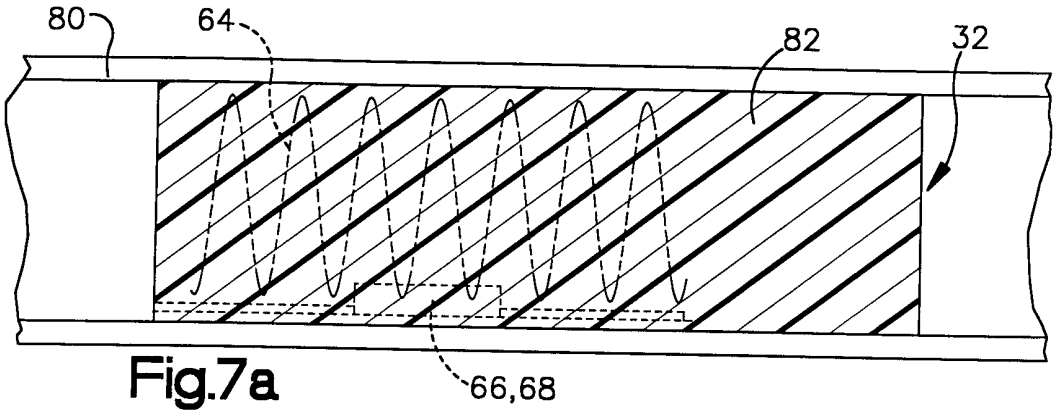

Fig.7a

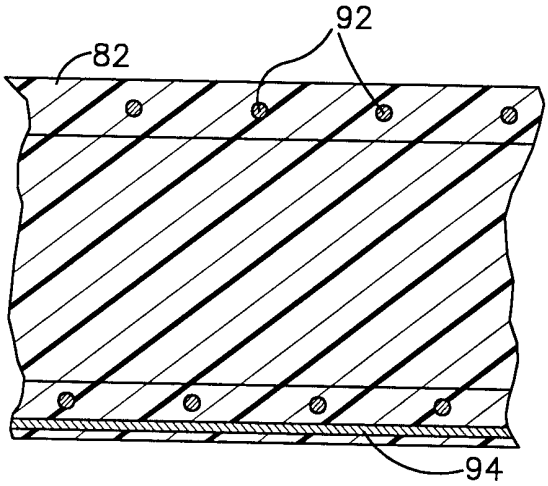

Fig.7b

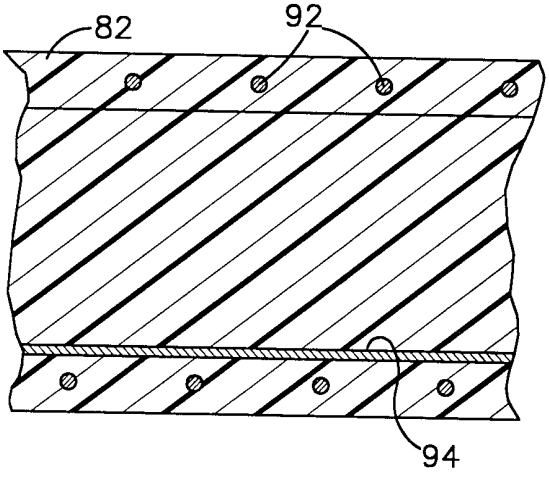

Fig.7c

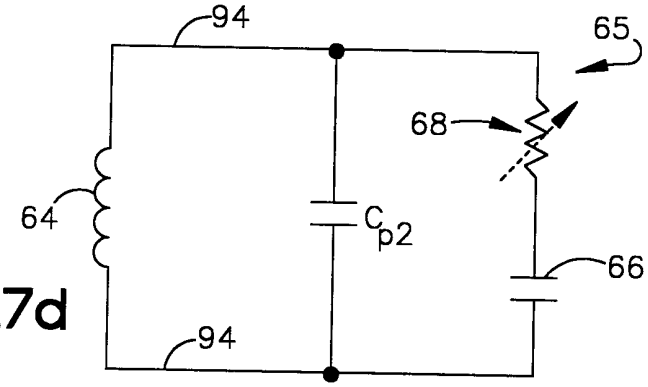

Fig.7d

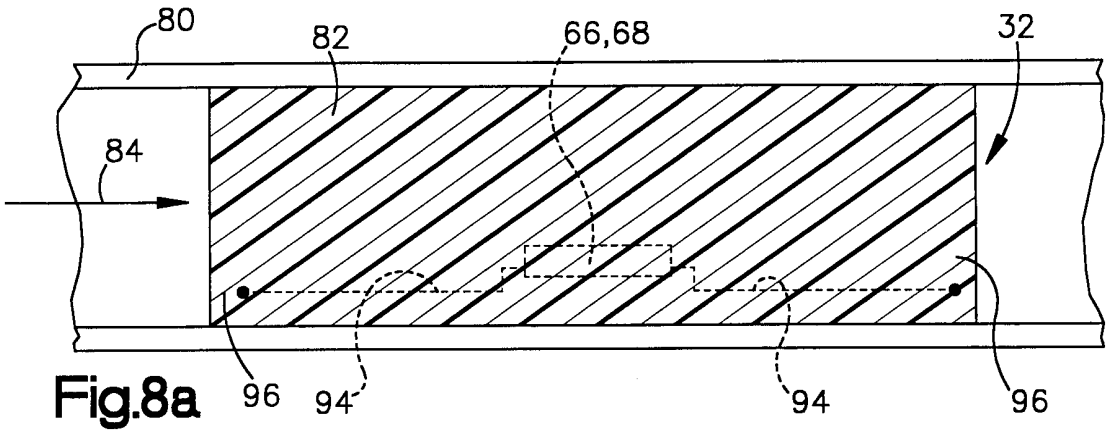

Fig.8a

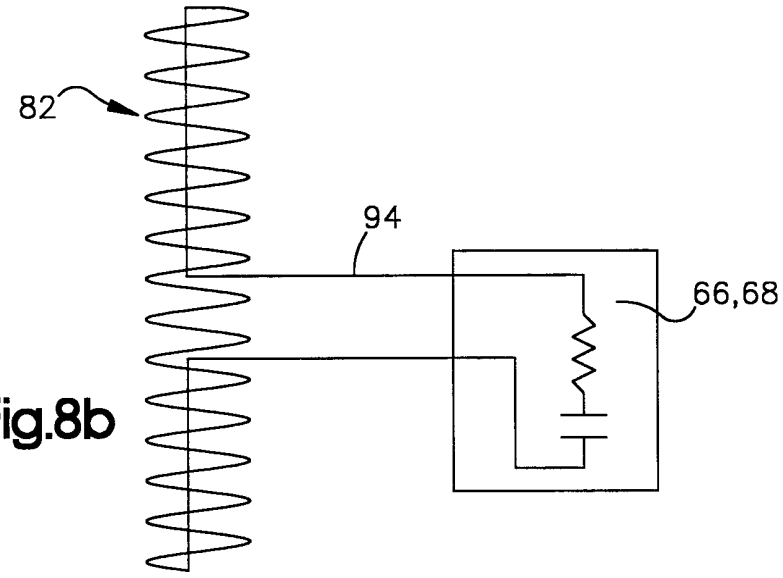

Fig.8b

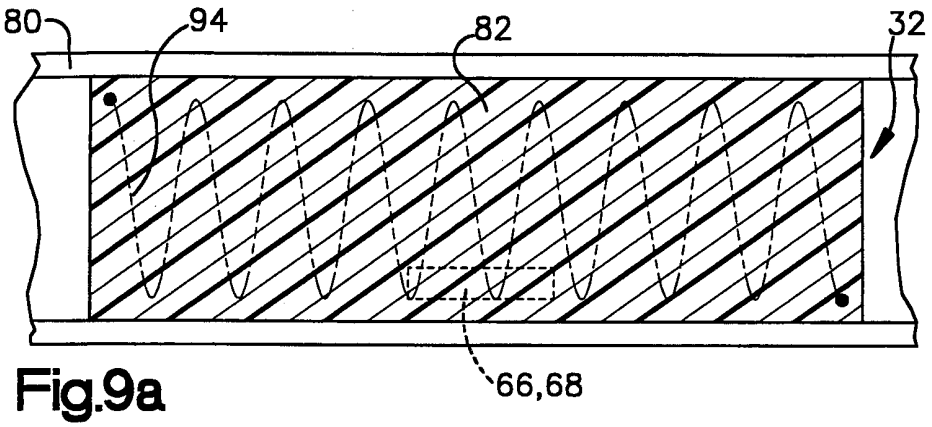

Fig.9a

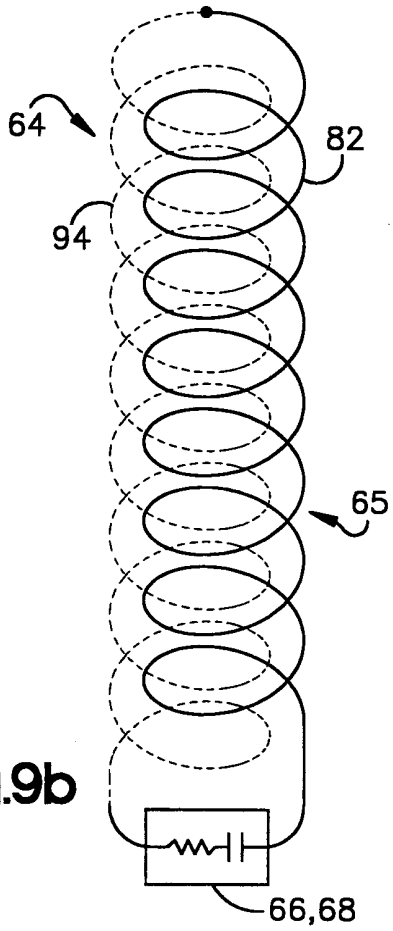

Fig.9b

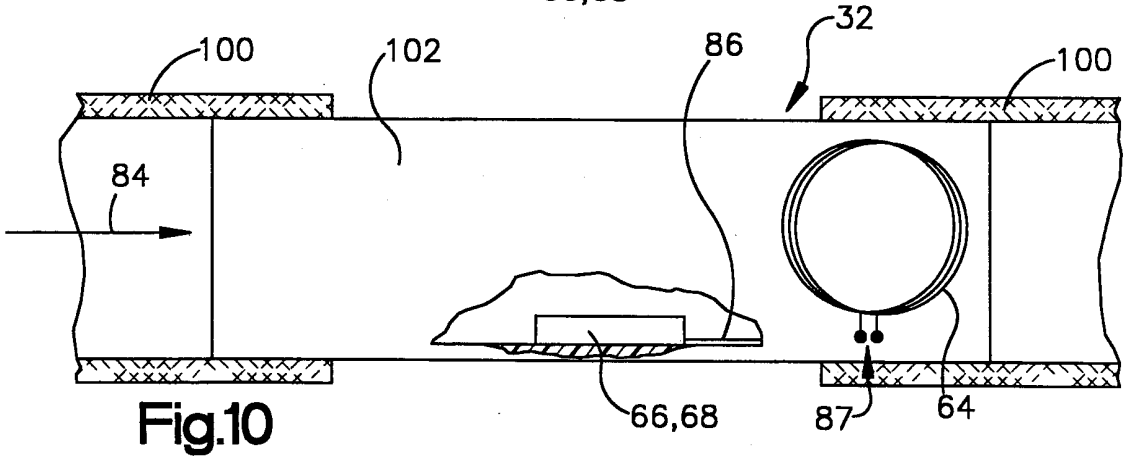

Fig.10

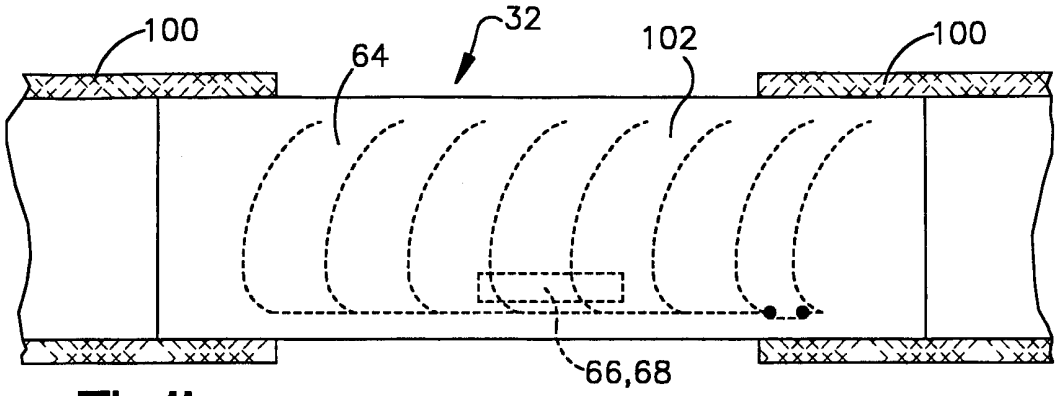

Fig.11a

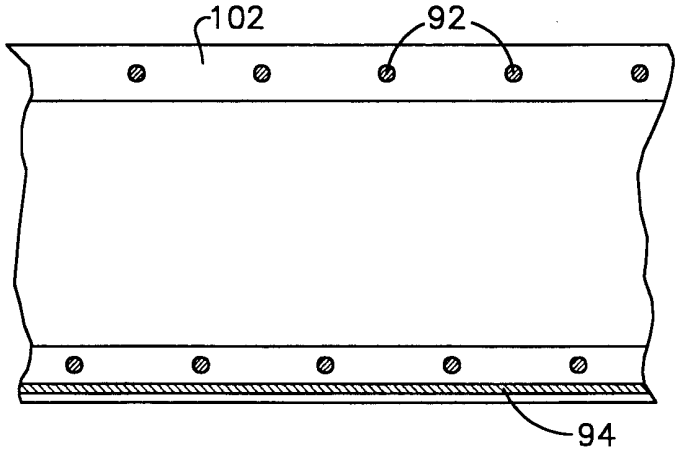

Fig.11b

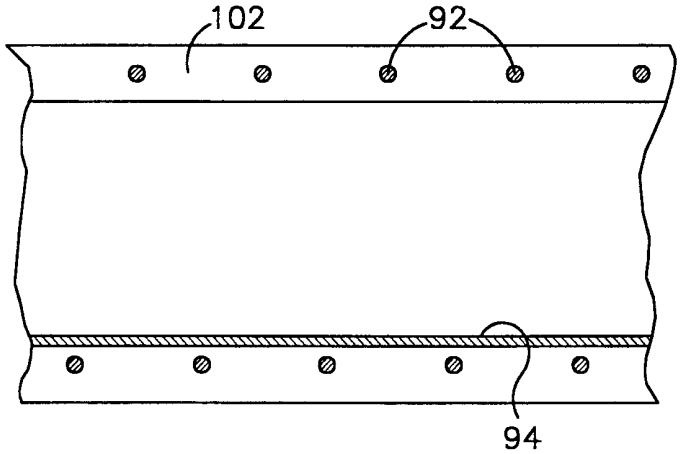

Fig.11c

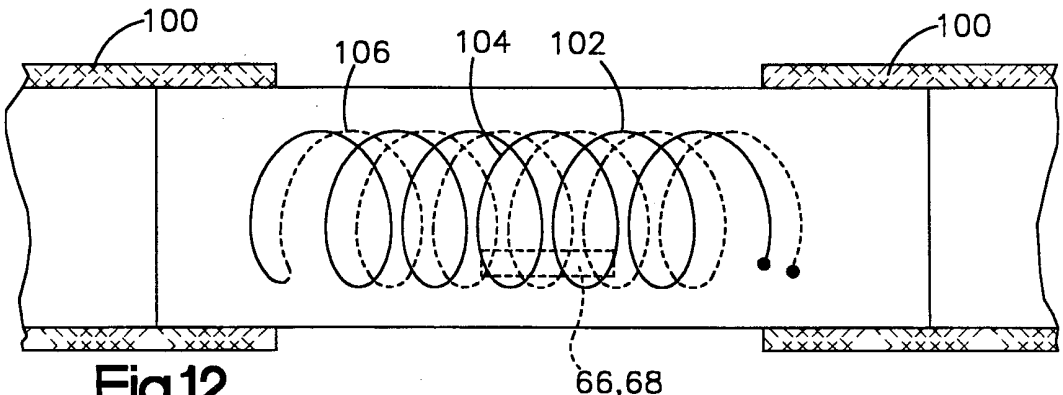

Fig.12

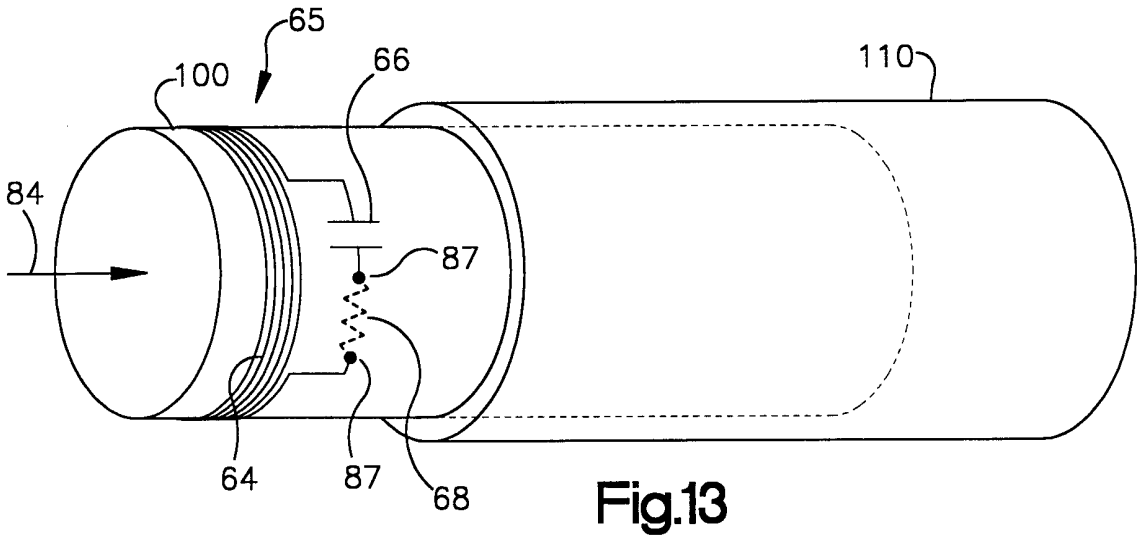

Fig.13

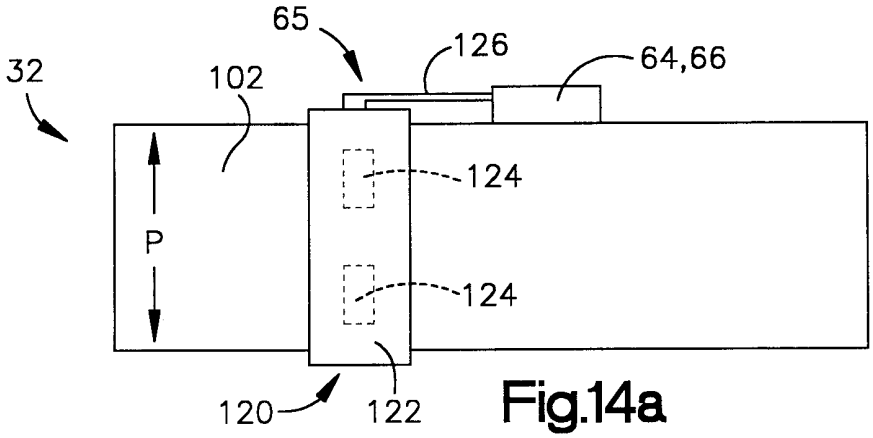

Fig.14a

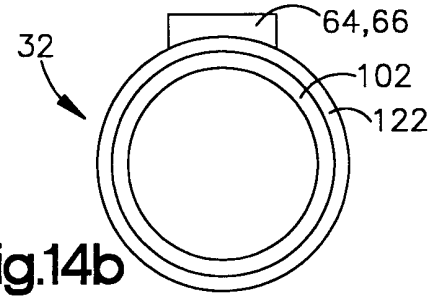

Fig.14b

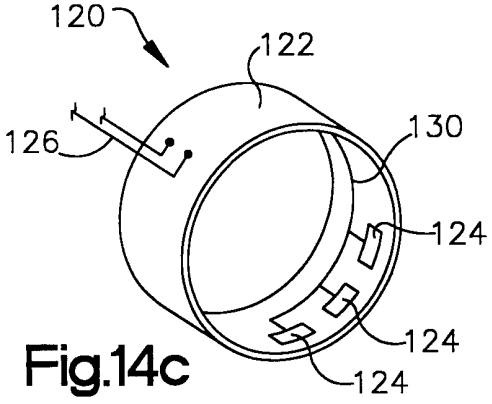

Fig.14c

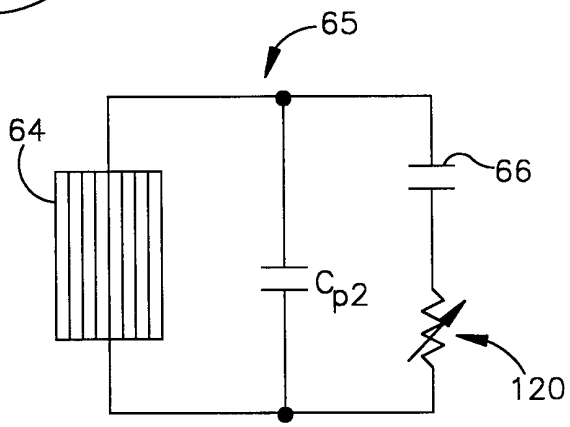

Fig.14d

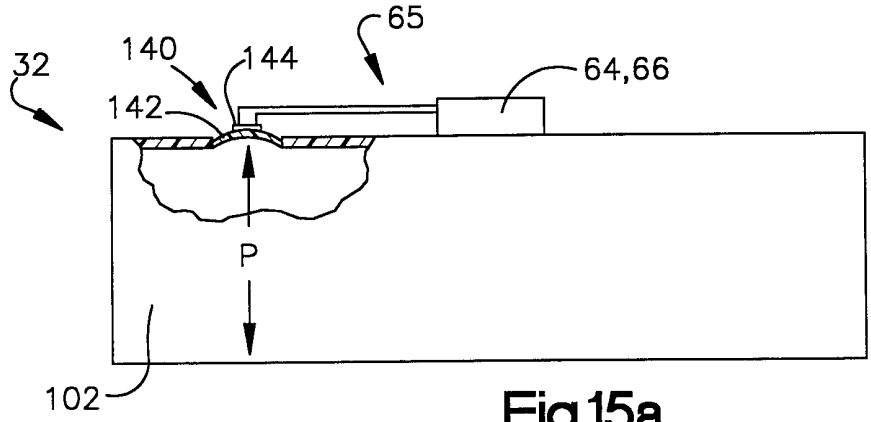

Fig.15a

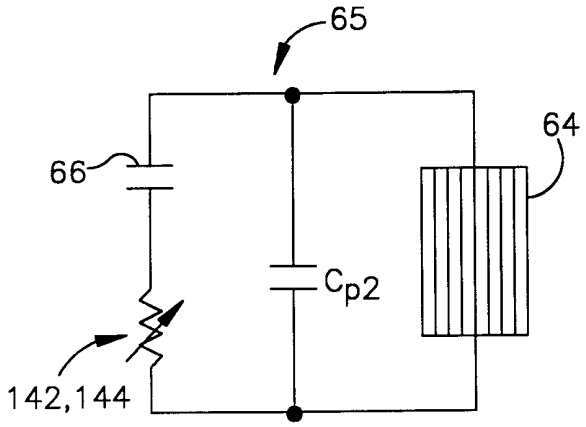

Fig.15b

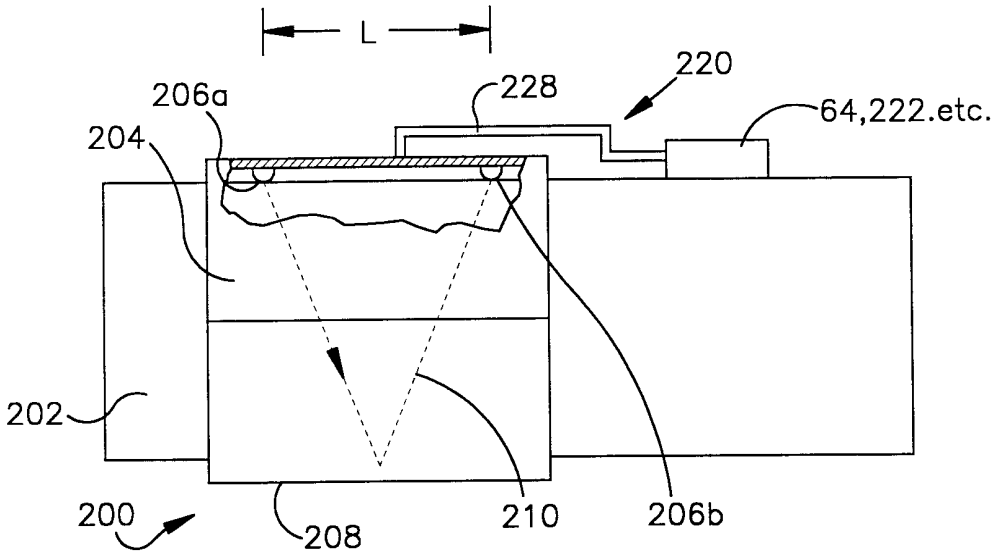

Fig.16a

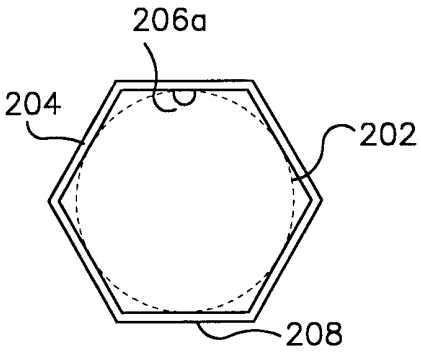

Fig.16b

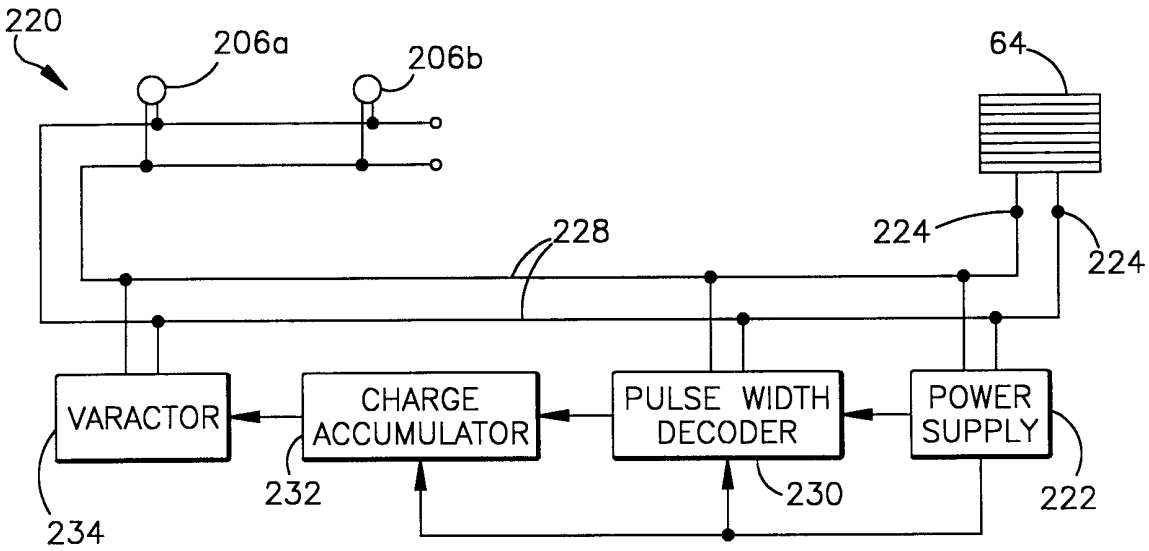

Fig.16c

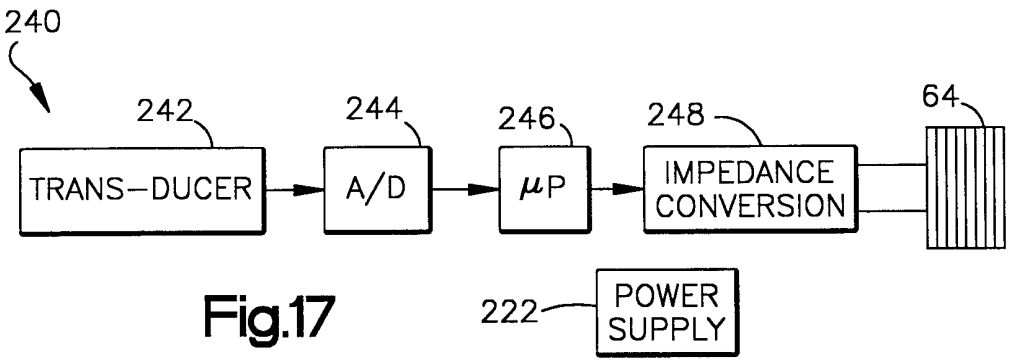

Fig.17

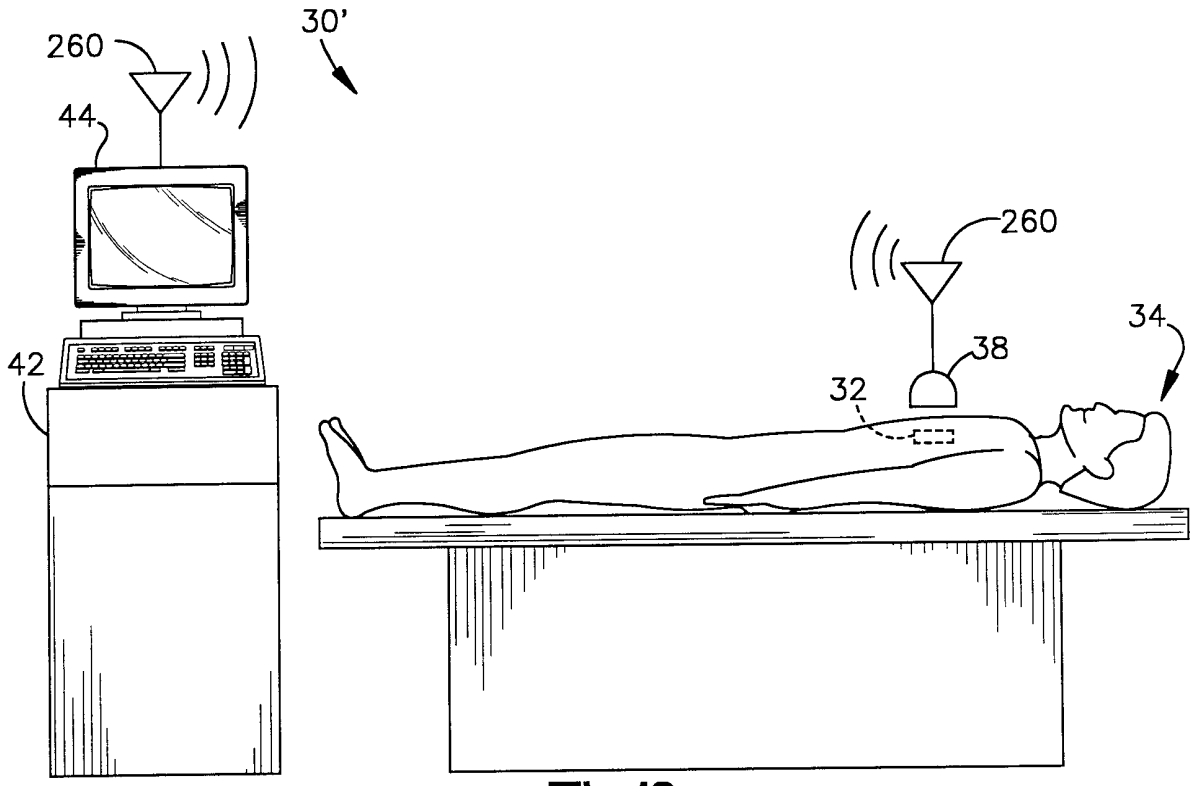

Fig.18

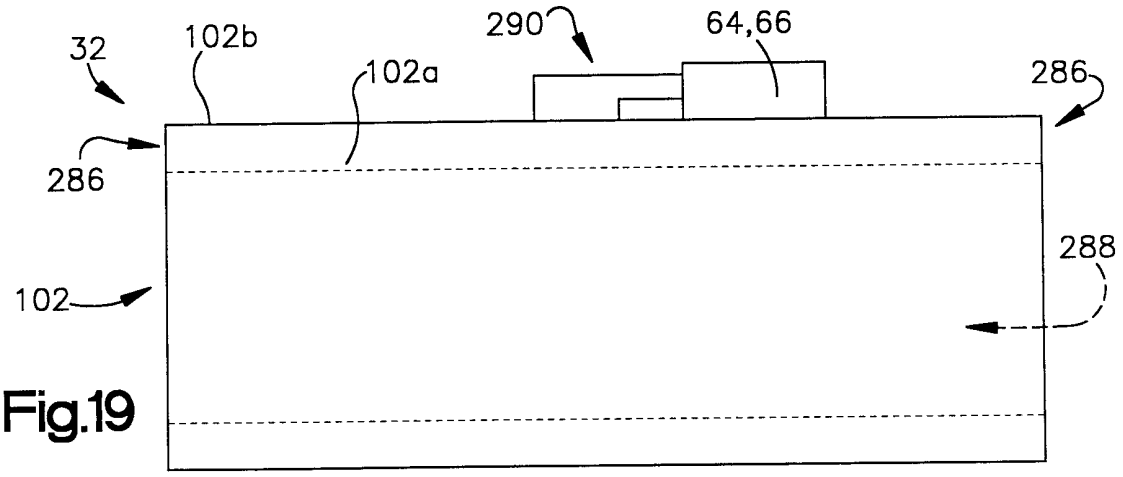

Fig.19

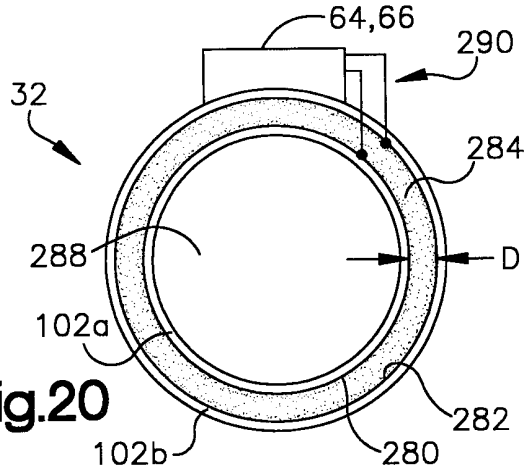

Fig.20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/21625

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 19/00
US CL : 128/899

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)

U.S. : 128/899; 340/870.31; 607/30, 31, 32, 33, 61; 600/454

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST: implant, interrogate, stent, graft, coil

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98/29030 A (GOVARI et al) 09 July 1998, see whole document.	5-9
Y	US 5,807,258 A (CIMOCHOWSKI et al) 15 September 1998, see whole document.	1, 10-16, 20
Y	US 5,807,397 A (BARRERAS) 15 September 1998, see whole document.	1-4, 17-20

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

*	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 document 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 11 OCTOBER 2000	Date of mailing of the international search report 08 NOV 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer BRIAN SZMAL Telephone No. (703) 308-0858

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