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- (54) **Title:** SENSOR SYSTEM, IMPLANTABLE SENSOR AND METHOD FOR REMOTE SENSING OF A STIMULUS IN VIVO

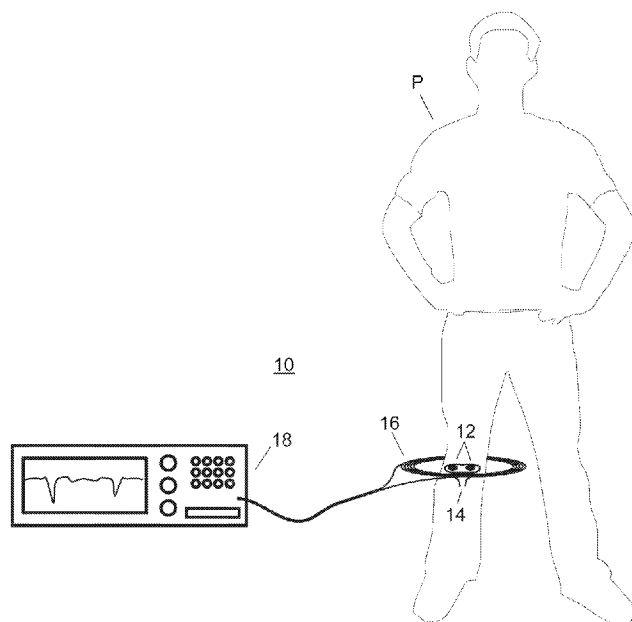


FIGURE 1

(57) **Abstract:** A sensor system (10) for sensing a stimulus in vivo includes an implantable sensor (12). The sensor comprises a passive resonator circuit (13) having a resonant frequency and including at least a pair of generally parallel spirally wound unconnected conductive coils (20), (22) sandwiching a layer of solid dielectric material (24) that manifest a change in property affecting the resonant frequency in response to application of the stimulus to the layer. A resonant frequency of the sensor is modulated by altering the spacing or gap between the coils or altering the overlapping area of the coils. The sensor is energized through application of radio-frequency energy and the responding resonant frequency is detected. The sensor can be advantageously attached to a medical implant to form a practical smart implant for clinical purposes.



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SENSOR SYSTEM, IMPLANTABLE SENSOR AND METHOD FOR REMOTE SENSING OF A STIMULUS IN VIVO

FIELD OF THE INVENTION

[0001] This invention relates generally to a sensor system for remotely sensing a stimulus and, more particularly, to a sensor system employing an implantable sensor especially well suited for in vivo clinical applications.

BACKGROUND ART

[0002] Personalized medicine improves outcomes and reduces costs by enabling more accurate diagnoses and more optimal treatments. Patients are back to health and back to work more quickly, thus reducing the impact on an individual's life and the overall economic burden of disease.

[0003] In orthopedic and neurological surgery, intervention often results in placement of a permanent implant. On a patient-specific basis, the implant's physical environment potentially provides a wealth of diagnostic data regarding the progression of healing and prognosis of an outcome. Earlier detection of failure fosters earlier revision. Earlier diagnosis of healing fosters earlier return to work. In this way, the clinical utility of smart implants in musculoskeletal disease is vast. There are clinical indications in many areas of clinical medicine which are opportunities for smart implant-based diagnosis, intra-operative monitoring and personalized post-operative care to reduce the burden of the disease.

[0004] For musculoskeletal diseases, implants are an opportune vehicle for facilitating personalized medicine. "Smart implants" can be used to house implantable sensors that measure the local physical environment and provide quantitative real time patient-specific data that cannot be obtained any other way. Such data can be provided to the caregiver or directly to the patient to facilitate accurate diagnoses, guide treatments, and optimized rehabilitation and therapy.

[0005] Since the 1960's, the clinical value of implantable sensors in orthopedic and neurological surgery has been demonstrated in the research literature. Yet, for the last 45 years, the technology has not been translated into clinical practice.

Implantable systems for research have been too bulky, too expensive, prone to failure due to complexity, and have necessitated surgical modification to the clinical implants which act as vehicles to carry sensors into the body. This has relegated implantable sensors to pre-clinical studies and very small patient populations in research studies. For smart implants to become part of clinical practice, the sensors must be robust, inexpensive, and compatible with off-the-shelf implants.

BRIEF SUMMARY OF THE INVENTION

[0006] To translate implantable sensing into clinical practice, the present invention provides a sensor system for sensing a stimulus in vivo including an implantable sensor comprising a passive resonator circuit having a resonant frequency and including at least a pair of generally parallel spirally wound unconnected conductive coils sandwiching a layer of solid dielectric material that manifests a change in property affecting the resonant frequency in response to application of the stimulus to the layer. The resonant frequency of the simple implantable sensor is read wirelessly using an external radiofrequency (R.F.) antenna. The external antenna both energizes the system and senses the resonant frequency. The resonant frequency is modulated by the stimulus of interest. The sensors can be tuned, e.g. by appropriate selection of the dielectric material, to be sensitive to physical parameters such as force, absolute pressure, or temperature, to measure proximity or relative motion, or to measure specific pathogens, such as bacteria to detect infection.

[0007] The new sensor system is fundamentally different from previous systems used in orthopedic applications. The sensor is extremely simple employing only a pair of flat parallel coils, each behaving as both an inductor and a capacitor. There is no battery. There is no telemetry. There are no electrical connections. Because the system is so simple, it is also extremely inexpensive (both materials and fabrication). It is also robust because there are no electrical connections to fail. Significantly, because of its small size, there is little or no modification required of the host implant. To our knowledge, Applicants are the first to adapt and implement this genre of sensor to clinical applications.

[0008] There are multiple clinical applications for this invention, e.g., in orthopedics and neurosurgery: (i) monitoring of fracture healing and early detection of non-union; (ii) monitoring spine fusion and early detection of pseudarthrosis following spinal arthrodesis; (iii) intra-and post-operative measurement of force balance in the knee for arthroplasty; (iv) early detection of osteolysis and implant loosening following total hip arthroplasty; and (v) early detection of local infection around an implant.

[0009] The sensor and sensor system of the present invention may also be advantageously employed in other clinical and medical applications, for example, vascular, cardiac, gastrointestinal, etc., and non-medical applications, such as monitoring pressure in a pipe, or other stimuli or parameters in remote, hostile, or inaccessible environments.

[0010] In one aspect of the present invention, a sensor system for sensing a stimulus in vivo is provided. The sensor system includes a sensor implantable in a patient. The sensor includes at least a first single component L-C element, a second single component L-C element spaced from and electrically unconnected to the first element, and a solid dielectric layer sandwiched between the first element and the second element. The solid dielectric layer has a property that varies in response to application of the stimulus to the solid dielectric layer. The system further includes an energizer, external to the patient, energizing the first element and the second element with radiofrequency energy such that the energized first element and second element form a passive resonator circuit having a resonant frequency that varies with the property. A detector, also external to the patient, determines the resonant frequency of the passive resonator circuit as a measure of the stimulus applied to the dielectric layer in vivo.

[0011] The stimulus to be sensed may be force, load, strain, shear, temperature, absolute pressure, displacement, pH, deformation, a chemical marker and/or a biomarker.

[0012] The variable property of the solid dielectric layer may comprise surface deformation, surface displacement, layer dimension, layer size, layer shape, layer volume, capacitance and/or inductance.

[0013] The sensor is preferably devoid of an enclosure and readily attachable to a medical implant without modifying geometry of the implant. Preferably, the first element comprises a first flat spiral shaped conductive coil wound clockwise, and the second element comprises a second flat spiral shaped conductive coil wound counterclockwise.

[0014] The sensor system may include at least one additional sensor providing multi-axial sensing of the stimulus and/or concurrent sensing of multiple stimuli.

[0015] The energizer and the detector of the sensor system may be combined, and, advantageously, may comprise a grid dip oscillator and an antenna.

[0016] In another aspect, the present invention provides a method of sensing a stimulus in vivo. The method includes: selecting a solid dielectric material that manifests a change in property in response to application of the stimulus to the solid dielectric material; implanting, in a position in a patient subject to the stimulus, a passive resonator circuit having a resonant frequency and comprising at least a pair of generally parallel spirally wound unconnected conductive coils sandwiching a layer of the solid dielectric material, stimulus produced variations in the property affecting the resonant frequency; energizing the passive resonator circuit with radiofrequency energy from a source external to the patient; remotely detecting the resonant frequency of the energized passive resonator circuit, and determining a value of the stimulus applied to the layer of dielectric material in vivo from the detected resonant frequency.

[0017] The implanting step of the method preferably comprises attaching the passive resonator circuit to a medical implant. The determined value of the stimulus may be used for: determining progression of healing, outcome prognosis, detection of implant failure, intra-operative monitoring, and/or personalized post-operative care.

[0018] In a further aspect, the present invention provides a sensor for sensing a stimulus. The sensor includes a passive resonator circuit having a resonant frequency and including at least a pair of generally parallel spirally wound unconnected conductive coils sandwiching a layer of solid dielectric material that manifests a change in property affecting the resonant frequency in response to application of the stimulus to the layer.

[0019] Preferably, the passive resonator circuit is un-encapsulated, adapted to operate in an aqueous environment, and is remotely energized, batteryless and telemetryless.

[0020] Also, preferably, a first coil of the pair is wound clockwise and a second coil of the pair is wound counterclockwise.

[0021] The first coil and the second coil are, preferably, flat, substantially parallel to each other and disposed on opposite sides of the solid dielectric layer. The first and second coils may either be simply stacked adjacent to, or adhered to, respective opposite surfaces of the solid dielectric layer.

[0022] The first and second coils may comprise insulated wires wound concentrically that maintain their respective shape after being wound. The windings of each coil may be bonded together to maintain their respective shape. The sensor may further include a substrate to maintain the shape of the wound coil. The substrate may comprise an epoxy, a polymer, an elastomer, a ceramic, a composite material and/or a rigid support material.

[0023] Each coil preferably comprises a conductor wound concentrically and continuously around itself from a central point outward with an insulator between windings.

[0024] Advantageously, at least one coil of the sensor may be a micro machined or a micro fabricated part.

[0025] The sensor is advantageously employed in combination with an energizer energizing the passive resonator circuit with radiofrequency energy and a detector

determining a resonant frequency of the passive resonator circuit as a measure of the stimulus applied to the layer of solid dielectric material.

[0026] The passive resonator circuit of the sensor may advantageously be composed of biocompatible material and adapted for implantation in a patient for sensing the stimulus in vivo. This sensor may be attached to a medical implant to form a smart implant.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

[0027] These and other aspects of the present invention will be more fully understood from the following detailed description, read in conjunction with the accompanying drawings, in which:

[0028] Figure 1 depicts a sensor system of the present invention.

[0029] Figure 2 is an enlarged perspective view of a bonded sensor of the current invention.

[0030] Figure 2A depicts the passive resonator circuit formed by the energized sensor of the present invention.

[0031] Figure 3 is an exploded view of the sensor of Figure 2.

[0032] Figure 4 is a cross-sectional view of the sensor of Figure 2.

[0033] Figure 5 is a cross-sectional view of an alternative un-bonded embodiment of the sensor of the present invention.

[0034] Figure 6 depicts coil fabrication on a mandrel according to the present invention.

[0035] Figure 7 is a graph depicting a dip associated with a sensed resonant frequency.

[0036] Figure 8 depicts the sensor of the present invention attached to a smart implant.

[0037] Figure 9 depicts multiple sensors for multi-axial sensing of a stimulus and/or concurrent sensing of multiple stimuli.

[0038] Figure 10 is a graph of the frequency response to force, in air, under mechanical loading, of un-bonded sensors of the present invention.

[0039] Figure 11 is a graph of frequency response to force, in air, under mechanical loading, of bonded sensors of the present invention.

[0040] Figure 12 is a bar graph presenting a parametric analysis of parameter sensitivity of the sensors of the present invention.

[0041] Figure 13 is a graph of frequency change versus dielectric thickness for sensors of the present invention.

[0042] Figure 14 is a graph of frequency change with variation in dielectric thickness.

[0043] Figure 15 is a bar graph indicating the effect of media on grid dip intensity.

[0044] Figure 16 is a graph of frequency versus force of a dielectric saturated in saline.

[0045] Figure 17 is a graph of frequency versus force for a 3 coil configuration of the sensor of the present invention.

DETAILED DESCRIPTION

[0046] As illustrated in Figure 1, the sensor system 10 of the present invention may employ an implantable sensor 12 attached to a medical implant 14 to sense a stimulus in a patient P. As more fully discussed below, the sensor 10 may comprise a passive resonator circuit of unique design. The sensor of this “smart implant” is wirelessly energized by a remote energizer 16 preferably associated with a resonant frequency detector 18.

[0047] The sensor system 10 may be used for measurement of displacement, deformation, strain, shear, force, load, absolute pressure, temperature, pH, or other physical, chemical or biological stimulus or parameter.

[0048] In simple form, a passive resonator circuit is comprised of two electrical components, a capacitor (C) and an inductor (L). When the two component L-C circuit is excited with radiofrequency (RF) energy, it resonates. The resonant frequency is a function of both the inductance and the capacitance. When either one changes, the resonant frequency is modulated.

[0049] The resonant frequency of the implantable passive resonator circuit 13 can easily be measured wirelessly via an external antenna using a grid dip oscillator which serves as both the energizer 16 and detector 18 of the sensor system. The oscillator generates RF energy and sweeps a range of frequencies around the resonant frequency of the sensor. The RF energy causes the sensor to resonate. At its resonant frequency, the sensor absorbs energy which is observed as a “dip” on the oscillator. If the resonant frequency of the sensor changes, the dip will move accordingly. In this way, changes in the resonant frequency of the sensor can be read dynamically. Other techniques and equipment may also be used to determine the resonant frequency.

[0050] Through a simple design, an L-C circuit can, for example, function as a passive, stand-alone force sensor. Physically, two coils of electrical conductors in close proximity to each other form an inductor. Similarly, two flat parallel conductive plates separated by a thin layer of dielectric material form a capacitor. If the distance between the two plates of the capacitor changes, the capacitance is modulated and the resonant frequency changes accordingly. Applying a force to the capacitor will cause the dielectric layer between the plates to deform which reduces the gap between the plates which modulates capacitance and alters the resonant frequency. In this way, a simple L-C circuit can function as a force sensor.

[0051] In accordance with the present invention, the passive resonator circuit is further simplified by employing a pair of unconnected single component L-C elements sandwiching a layer of solid dielectric material. The inductor and capacitor components of the standard L-C circuit are combined into a single flat spirally wound

conductive coil. A pair of such coils, preferably wound in opposite directions, and disposed in parallel and concentrically aligned on opposite sides of the layer of solid dielectric material form the implantable sensor of the present invention.

[0052] Figures 2-4 depict a first embodiment of the implantable sensor 12 of the present invention. The sensor comprises a passive resonator circuit 13, diagrammatically depicted in Figure 2A, having a resonant frequency and includes at least a pair of generally parallel, flat, spirally wound unconnected conductive coils 20, 22 sandwiching a layer 24 of solid dielectric material that manifests a change in property affecting the resonant frequency in response to application of the stimulus to the layer. The stimulus may, for example, be an axial force, represented by the arrow F in Figure 4, resulting in a decrease in spacing between coils 20, 22, or shear, represented by the arrow S in Figure 4, altering overlapping areas of the coils. In the version of Figure 2, the coils 20, 22 are adhered to opposite faces of the layer of solid dielectric material by a suitable adhesive 26, such as a biocompatible polymer, elastomer, or composite; cyanoacrylate being presently preferred. The coils are substantially concentric but preferably wound in opposite directions, i.e., one is wound clockwise while the other is wound counterclockwise. The shape of the windings of each coil may be generally circular, oval, square, rectangular or of other geometry.

[0053] The passive resonator circuit 13 of the present invention need not be encapsulated so that stimuli directly applied to the layer of solid dielectric material may be measured.

[0054] For clinical and other applications, a passive resonator circuit composed only of an unconnected pair of single component L-C elements sandwiching a solid dielectric layer is highly robust due to the absence of an electrical interconnector that may fail.

[0055] In one embodiment, each coil 20, 22 may comprise a wire 28 wound concentrically around itself from a central point outward. The wire 28 is wound continuously with only a thin insulator 30 between windings. In place of the wire,

any conductor, whether flat, round or other shape in cross-section, can be used. The insulator 30 between windings can be air or any other dielectric material.

[0056] Each coil 20, 22 is, preferably, substantially flat and wound in a flat plane. In a preferred embodiment, an adhesive 32, such as an epoxy, is used to maintain the shape and orientation of the coiled wires so that they stay in an essentially flat configuration once wound. Of course, other materials can be used to maintain the shape of each coil including solid supporting materials or a stiff insulating jacket on the wires themselves. The sensor may further include a substrate to maintain the shape of the wound coil. The substrate may comprise an epoxy, a polymer, an elastomer, a ceramic or a composite material.

[0057] In the preferred embodiment, the coils are between 1 mm and 6 mm in diameter although smaller and larger diameter coils may be used. The thickness of the conductor is preferably between 0.05 mm and 0.25 mm although other thicknesses may be employed. In the preferred embodiment, the number of turns in a coil ranges from 25 to 250 although more or less turns may be used.

[0058] The Applicants have fabricated implantable sensors comprising flat inductor coils, which also advantageously serve as capacitive plates. The coils have been fabricated from 30, 34, 38, and 40 gauge copper magnet wire, although any conductive wire (including silver, gold, platinum, etc.) will work. The wires were hand wound into a coil around a mandrel using two glass slides to maintain the planar shape of the coil. See Figure 6. M bond A E-15 epoxy (from Vishay Micromediation Group) was used to maintain the wire in the desired shape, although any slow curing epoxy or the equivalent may be used. The sample coils had a diameter of about 5 mm but larger or smaller coils may be employed.

[0059] This mandrel-glass slide-coil assembly is placed in an oven to allow the epoxy to polymerize. The coils are then removed from the mandrel apparatus. The centers of each coil may then be filled with epoxy and allowed to polymerize.

[0060] Once individual coils are fabricated, they are then assembled into sensors. To fabricate sensors, pairs of coils, preferably, but not necessarily, oppositely wound, are aligned concentrically. The coils need not be concentrically aligned, but

inductance is maximized when they are aligned. A biocompatible and hydrophobic dielectric is preferably applied between the two coils. Any dielectric can be used, but a biocompatible hydrophobic dielectric is optimal for implantable sensors.

[0061] The dielectric can be applied as a liquid using a number of application techniques including manually dropping it onto one or both coils or spin coating one or both coils. The dielectric can also be applied as a solid by placing a thin sheet of polymer between the coils. For example, silicone conformal coatings, polyurethanes, and epoxies may be used as a dielectric. A dielectric of any layer thickness can be used, but layers in the range of 1-100 μm are optimal. In certain applications, the solid dielectric may be porous. The coils are then assembled into pairs. The coils can either be bonded together using, for example, initially liquid dielectric (Figures 2-4) or they can remain as an unbound “stack” simply sandwiching the layer of solid dielectric material (Figure 5). The properties of the sensors at low force are dictated by whether they are bound or not.

[0062] As an alternative, the sensors may be fabricated using micro machining and/or micro fabrication techniques including etching, deposition, micro machining, etc. Employing these standard techniques and available equipment, conductive coils sandwiching a dielectric can be fabricated with automated processes in batches, thus facilitating rapid and inexpensive fabrication of the sensors.

[0063] The sensor system of the present invention may be “tuned” to measure different stimuli by choosing a dielectric material having desired properties. A dielectric with high coefficient of thermal expansion will be sensitive to changes in temperature. A dielectric with very low stiffness (modulus of elasticity) would be sensitive to changes in force. A dielectric material such as a hydrogel which is sensitive to pH swells when pH changes. This swelling changes the spacing between the two coils resulting in a change in resonant frequency of the sensor. For each sensor, an appropriate dielectric is chosen based upon the physical parameter or other stimulus to be measured and those parameters to which the sensor should be insensitive.

[0064] The resonant frequency of the passive resonator circuit of the present invention is governed by the following relationships:

$$1. \quad C = \frac{\epsilon A}{l}$$

$$2. \quad L_{coil} = \frac{r^2 N^2}{(2r + 2.8d) \times 10^5}$$

$$3. \quad L_{Total} = L_{coil\ 1} + L_{coil\ 2} + 2M$$

$$4. \quad f = \frac{1}{2\pi\sqrt{LC}}$$

[0065] Where C is capacitance, ϵ is the emissivity, A is the area of only the conductor of the coil, l is the spacing between the coils, r is the mean coil radius, N is the number of turns in the coil, and d is the coil depth ($r_{outer} - r_{inner}$), L_{Total} is the total circuit inductance, M is the mutual inductance between the coils, and f is the resonant frequency which is calculated from the system inductance (L) and capacitance (C).

[0066] For clinical applications, the sensor 12 of the present invention may be adapted to operate in an aqueous environment by encapsulating the conductor of each coil in a hydrophobic insulator, such as a polymer, elastomer, ceramic or composite. (polyethylene, PVC, Teflon or epoxy are currently preferred), and advantageously attached, by a biocompatible adhesive or otherwise, to a medical implant 14 to function as a “smart implant”, as illustrated in Figure 8. Due to its small size and simplicity, the sensor can advantageously be attached to the medical implant with little or no modification to the geometry of the medical implant. For other applications, the sensor may be attached to any support structure or be free-standing.

[0067] As depicted in Figure 9, multiple sensors, e.g. 12, 12', may be employed in a sensor system of the present invention for multi-axial sensing of a stimulus or concurrent sensing of multiple stimuli.

[0068] For resonant frequency measurements, a 75 ohm Agilent ENA L-RF Network Analyzer (E5062A) with a 75 ohm co-axial cable and a loop antenna was used to read the sample sensors. There are a number of antenna configurations that

can be used to energize and read the sensors. These include flat coils, loops, spirals, etc. and combined multi-component arrays of these components. In one configuration, the Network Analyzer was set up to read channel S11, although a number of different Network Analyzers in different configurations could be used.

[0069] Displayed data were normalized to a stored background data set to enhance signal to noise ratio. The frequency sweep contained multiple points, e.g. about 100 points, usually over a 75 MHz range. For sensors of about 6 mm diameter fabricated from 38 gauge copper magnet wire, the resonant frequency ranges were from 25 to 125 MHz. The resonant frequency is visualized as a dip in a displayed S11 signal on the network analyzer, as illustrated in Figure 7.

[0070] After fabrication, sensors were loaded in axial compression using a mechanical testing machine to characterize the response to force. Loading and unloading profiles were attained by loading sensors through various force ranges while simultaneously recording resonant frequency and displacement. In air, the changes in frequency decrease with increasing load, as illustrated in Figures 10 and 11. When the coils are not bonded to the layer of solid dielectric material, there is an initial non-linear toe-in region, as shown in Figure 10. When the coils are bonded together on opposite sides of the dielectric layer, there is no toe-in region and the force-frequency relationship is generally linear, as shown in Figure 11. Sensitivity of the sensor to load is dependent on several properties including the starting dielectric gap and the modulus of the dielectric, as shown by comparing Figures 10 and 11. The data were highly repeatable for each tested sensor.

[0071] Figure 10 shows loading trials for three 6.5 mm diameter un-bonded sensors fabricated from 38 gauge wire. In air, under mechanical loading, the un-bonded sensors respond with decreasing frequency.

[0072] Figure 11 shows loading trials for three 6.5 mm diameter bonded sensors fabricated from 38 gauge wire. In air, under mechanical loading, bonded (but electrically unconnected) sensors respond linearly with decreasing frequency.

[0073] The effects of coil diameter, wire gauge, coil spacing (dielectric thickness), and dielectric modulus have been characterized. As shown in Figures 12

and 13, small changes in coil spacing having only a subtle effect on sensor sensitivity relative to the substantial change from diameter, gauge and modulus. As expected, change in frequency correlates strongly to change in coil spacing (dielectric thickness) as shown in Figure 14.

[0074] Importantly, the intensity of the grid dip (energy absorption) by the sensor was not affected by introduction of water, saline, or up to 5 mm of cortical bone between the sensor and the antenna, as shown in Figure 15. The introduction of bone did not affect the resonant frequency relative to measurements in air, but reading through water reduced the resonant frequency by 16.7% and reading through saline reduced the resonant frequency by 29.4%.

[0075] Immersion in saline does have one substantial and unpredicted effect on sensor performance. Once the dielectric reaches equilibrium with respect to moisture absorption, the response of the sensor to axial loading is substantially altered. Once the dielectric is saturated, axial load causes an increase in sensor frequency with increased loading, as shown in Figure 16. The change in frequency is linear with respect to load. The response of the sensor in saline is dependent on the dielectric properties.

[0076] To increase the inductance and lower the resting resonant frequency of the sensor, additional spirally wound conductive coils with intervening layers of solid dielectric material can be added to the sensor. Figure 17 illustrates the loading results of a sensor comprising a stack of three unconnected spiral coils with dielectric between each of the coil pairs. More than 3 coils may also be employed.

[0077] The present invention thus provides a wireless, batteryless and telemetryless sensor system employing a simplified passive resonator circuit with no electrical connections. With no electrical connections to fail, the sensors are robust. They may be unenclosed and require no hermetic seal, are extremely inexpensive to fabricate and because of their very small size and simple construction, require little or no implant modification. Significantly, these implantable sensors enable daily clinical usage in smart implants. The use of such smart implants in personalized medicine will improve outcomes and reduce costs by enabling more accurate diagnoses and more

optimal treatments. Patients with such smart implants will be back to health and back to work more quickly, thus reducing the impact on an individual's life and the overall economic burden of disease.

CLAIMS

What is claimed is:

1. A sensor system (10) for sensing a stimulus in vivo, comprising:

a sensor (12) implantable in a patient, the sensor including at least a first single component L-C element (12), a second single component L-C element (22) spaced from and electrically unconnected to the first element, and a solid dielectric layer (24) sandwiched between the first element and the second element, the solid dielectric layer having a property that varies in response to application of the stimulus to said solid dielectric layer;

an energizer (16), external to said patient, energizing the first element and the second element with radiofrequency energy such that the energized first element and second element form a passive resonator circuit (13) having a resonant frequency that varies with said property; and

a detector (18), external to the patient, determining the resonant frequency of the passive resonator circuit as a measure of the stimulus applied to the dielectric layer in vivo.
2. The sensor system (10) of claim 1, wherein the stimulus comprises at least one of force, load, strain, shear, temperature, absolute pressure, displacement, pH, deformation, chemical marker and biomarker.
3. The sensor system (10) of claim 1, wherein the variable property comprises at least one of surface deformation, surface displacement, layer dimension, layer size, layer shape, layer volume, capacitance and inductance.
4. The sensor system (10) of any one of claims 1-3, wherein the sensor (12) is devoid of an enclosure.
5. The sensor system (10) of any one of claims 1-3, wherein the first element (20) comprises a first flat spiral shaped conductive coil wound clockwise, and

the second element (22) comprises a second flat spiral shaped conductive coil wound counterclockwise.

6. The sensor system (10) of claim 1, wherein the sensor (12) is attached to a medical implant (14).

7. The sensor system (10) of claim 6, wherein the sensor (12) is attached to said medical implant (14) without modifying geometry of the implant.

8. The sensor system (10) of claim 1, wherein said stimulus comprises force and the variable property comprises a dimension of the solid dielectric layer, or the stimulus comprises strain and the variable property comprises surface displacement.

9. The sensor system (10) of claim 1, further comprising at least one additional said sensor (14') providing multi-axial sensing of said stimulus and/or concurrent sensing of multiple stimuli.

10. The sensor system (10) of claim 1, wherein the energizer (16) and the detector (18) comprise a grid dip oscillator and an antenna.

11. A method of sensing a stimulus in vivo, comprising:

selecting a solid dielectric material that manifests a change in property in response to application of the stimulus to the solid dielectric material;

implanting in a position in a patient subject to the stimulus, a passive resonator circuit (13) having a resonant frequency and comprising at least a pair (20), (22) of generally parallel spirally wound unconnected conductive coils sandwiching a layer (24) of the solid dielectric material, stimulus produced variations in said property affecting said resonant frequency;

energizing the passive resonator circuit with radiofrequency energy from a source external to the patient;

remotely detecting the resonant frequency of the energized passive resonator circuit; and

determining a value of the stimulus applied to the layer of dielectric material in vivo from the detected resonant frequency.

12. The method of claim 11, wherein the implanting comprises attaching the passive resonator circuit (13) to a medical implant (14), and further comprising using the determined value of the stimulus for at least one of: determining progression of healing, outcome prognosis, detecting implant failure, intra-operative monitoring, and personalized post-operative care.

13. A sensor (12) for sensing a stimulus, comprising a passive resonator circuit (13) having a resonant frequency and including at least a pair (20), (22) of generally parallel spirally wound unconnected conductive coils sandwiching a layer (24) of solid dielectric material that manifests a change in property affecting the resonant frequency in response to application of the stimulus to the layer.

14. The sensor (12) of claim 13, wherein the stimulus comprises at least one of force, load, strain, shear, temperature, absolute pressure, displacement, pH, deformation, chemical marker and biomarker.

15. The sensor (12) of claim 13, wherein the variable property comprises at least one of surface deformation, surface displacement, layer dimension, layer size, layer shape, layer volume, capacitance and inductance.

16. The sensor (12) of any one of claims 13-15, wherein the passive resonator circuit (13) is un-encapsulated.

17. The sensor (12) of claim 16, wherein the passive resonator circuit (13) is adapted to operate in an aqueous environment.

18. The sensor (12) of claim 16, wherein the passive resonator circuit (13) is remotely energized, batteryless and telemetryless.

19. The sensor (12) of claim 13, wherein a first coil (20) of said pair is wound clockwise, and a second coil (22) of said pair is wound counterclockwise.

20. The sensor (12) of claim 19, wherein the first coil (20) and the second coil (22) are flat, substantially parallel to each other, and disposed on opposite surfaces of the solid dielectric layer (24).

21. The sensor (12) of claim 20, wherein the first coil (20) and the second coil (22) are adhered to respective opposite surfaces of the solid dielectric layer (24).

22. The sensor (12) of claim 19, wherein the first coil (20) and the second coil (22) comprise insulated wires (28) wound concentrically that maintain their respective shape after being wound.

23. The sensor (12) of claim 22, wherein windings of each coil are bonded together to maintain their respective shape.

24. The sensor (12) of claim 22, further including a substrate to maintain the shape of the wound coil.

25. The sensor (12) of claim 24, wherein the substrate comprises at least one of an epoxy, a polymer, an elastomer, a ceramic, a composite material, and a rigid support material.

26. The sensor (12) of claim 13, wherein each coil comprises a conductor wound concentrically and continuously around itself from a central point outward with an insulator between windings.

27. The sensor (12) of claim 13, wherein at least one coil of the pair comprises a micro machined or micro fabricated part.

28. The sensor (12) of claim 13, further in combination with an energizer (16) energizing the passive resonator circuit (13) with radiofrequency energy, and a detector (18) determining a resonant frequency of the passive resonator circuit as a measure of the stimulus applied to the layer (24) of solid dielectric material.

29. The sensor (12) of claim 13, wherein the passive resonator circuit (13) is composed of biocompatible material and adapted for implantation in a patient for sensing the stimulus in vivo.

30. A smart implant comprising the sensor (12) of claim 29, in combination with a medical implant (14).

31. A sensor system (10) comprising the smart implant of claim 30, further in combination with an energizer (16), external to the patient, energizing the passive resonator circuit (13) with radiofrequency energy, and a detector (18), external to the patient, determining a resonant frequency of the passive resonator circuit as a measure of the stimulus applied to the layer (24) of solid dielectric material in vivo.

* * * * *

AMENDED CLAIMS

received by the International Bureau on 17 June 2013 (17.06.2013)

What is claimed is:

1. A sensor system (10) for sensing a stimulus in vivo, comprising:

a sensor (12) implantable in a patient, the sensor including at least a first single component L-C element (20), a second single component L-C element (22) spaced from and electrically unconnected to the first element, and a solid dielectric layer (24) sandwiched between the first element and the second element, the solid dielectric layer having a property that varies in response to application of the stimulus to said solid dielectric layer;

an energizer (16), external to said patient, energizing the first element and the second element with radiofrequency energy such that the energized first element and second element form a passive resonator circuit (13) having a resonant frequency that varies with said property; and

a detector (18), external to the patient, determining the resonant frequency of the passive resonator circuit as a measure of the stimulus applied to the dielectric layer in vivo.
2. The sensor system (10) of claim 1, wherein the stimulus comprises at least one of force, load, strain, shear, temperature, absolute pressure, displacement, pH, deformation, chemical marker and biomarker.
3. The sensor system (10) of claim 1, wherein the variable property comprises at least one of surface deformation, surface displacement, layer dimension, layer size, layer shape, layer volume, capacitance and inductance.
4. The sensor system (10) of any one of claims 1-3, wherein the sensor (12) is devoid of an enclosure.
5. The sensor system (10) of any one of claims 1-3, wherein the first element (20) comprises a first flat spiral shaped conductive coil wound clockwise, and

the second element (22) comprises a second flat spiral shaped conductive coil wound counterclockwise.

6. The sensor system (10) of claim 1, wherein the sensor (12) is attached to a medical implant (14).

7. The sensor system (10) of claim 6, wherein the sensor (12) is attached to said medical implant (14) without modifying geometry of the implant.

8. The sensor system (10) of claim 1, wherein said stimulus comprises force and the variable property comprises a dimension of the solid dielectric layer, or the stimulus comprises strain and the variable property comprises surface displacement.

9. The sensor system (10) of claim 1, further comprising at least one additional said sensor (14') providing multi-axial sensing of said stimulus and/or concurrent sensing of multiple stimuli.

10. The sensor system (10) of claim 1, wherein the energizer (16) and the detector (18) comprise a grid dip oscillator and an antenna.

11. A method of sensing a stimulus in vivo, comprising:

- selecting a solid dielectric material that manifests a change in property in response to application of the stimulus to the solid dielectric material;
- implanting in a position in a patient subject to the stimulus, a passive resonator circuit (13) having a resonant frequency and comprising at least a pair (20), (22) of generally parallel spirally wound unconnected conductive coils sandwiching a layer (24) of the solid dielectric material, stimulus produced variations in said property affecting said resonant frequency;
- energizing the passive resonator circuit with radiofrequency energy from a source external to the patient;
- remotely detecting the resonant frequency of the energized passive resonator circuit; and

determining a value of the stimulus applied to the layer of dielectric material in vivo from the detected resonant frequency.

12. The method of claim 11, wherein the implanting comprises attaching the passive resonator circuit (13) to a medical implant (14), and further comprising using the determined value of the stimulus for at least one of: determining progression of healing, outcome prognosis, detecting implant failure, intra-operative monitoring, and personalized post-operative care.

13. A sensor (12) for sensing a stimulus, comprising a passive resonator circuit (13) having a resonant frequency and including at least a pair (20), (22) of generally parallel spirally wound unconnected conductive coils sandwiching a layer (24) of solid dielectric material that manifests a change in property affecting the resonant frequency in response to application of the stimulus to the layer.

14. The sensor (12) of claim 13, wherein the stimulus comprises at least one of force, load, strain, shear, temperature, absolute pressure, displacement, pH, deformation, chemical marker and biomarker.

15. The sensor (12) of claim 13, wherein the variable property comprises at least one of surface deformation, surface displacement, layer dimension, layer size, layer shape, layer volume, capacitance and inductance.

16. The sensor (12) of any one of claims 13-15, wherein the passive resonator circuit (13) is un-encapsulated.

17. The sensor (12) of claim 16, wherein the passive resonator circuit (13) is adapted to operate in an aqueous environment.

18. The sensor (12) of claim 16, wherein the passive resonator circuit (13) is remotely energized, batteryless and telemetryless.

19. The sensor (12) of claim 13, wherein a first coil (20) of said pair is wound clockwise, and a second coil (22) of said pair is wound counterclockwise.

20. The sensor (12) of claim 19, wherein the first coil (20) and the second coil (22) are flat, substantially parallel to each other, and disposed on opposite surfaces of the solid dielectric layer (24).

21. The sensor (12) of claim 20, wherein the first coil (20) and the second coil (22) are adhered to respective opposite surfaces of the solid dielectric layer (24).

22. The sensor (12) of claim 19, wherein the first coil (20) and the second coil (22) comprise insulated wires (28) wound concentrically that maintain their respective shape after being wound.

23. The sensor (12) of claim 22, wherein windings of each coil are bonded together to maintain their respective shape.

24. The sensor (12) of claim 22, further including a substrate to maintain the shape of the wound coil.

25. The sensor (12) of claim 24, wherein the substrate comprises at least one of an epoxy, a polymer, an elastomer, a ceramic, a composite material, and a rigid support material.

26. The sensor (12) of claim 13, wherein each coil comprises a conductor wound concentrically and continuously around itself from a central point outward with an insulator between windings.

27. The sensor (12) of claim 13, wherein at least one coil of the pair comprises a micro machined or micro fabricated part.

28. The sensor (12) of claim 13, further in combination with an energizer (16) energizing the passive resonator circuit (13) with radiofrequency energy, and a detector (18) determining a resonant frequency of the passive resonator circuit as a measure of the stimulus applied to the layer (24) of solid dielectric material.

29. The sensor (12) of claim 13, wherein the passive resonator circuit (13) is composed of biocompatible material and adapted for implantation in a patient for sensing the stimulus in vivo.

30. A smart implant comprising the sensor (12) of claim 29, in combination with a medical implant (14).

31. A sensor system (10) comprising the smart implant of claim 30, further in combination with an energizer (16), external to the patient, energizing the passive resonator circuit (13) with radiofrequency energy, and a detector (18), external to the patient, determining a resonant frequency of the passive resonator circuit as a measure of the stimulus applied to the layer (24) of solid dielectric material in vivo.

* * * * *

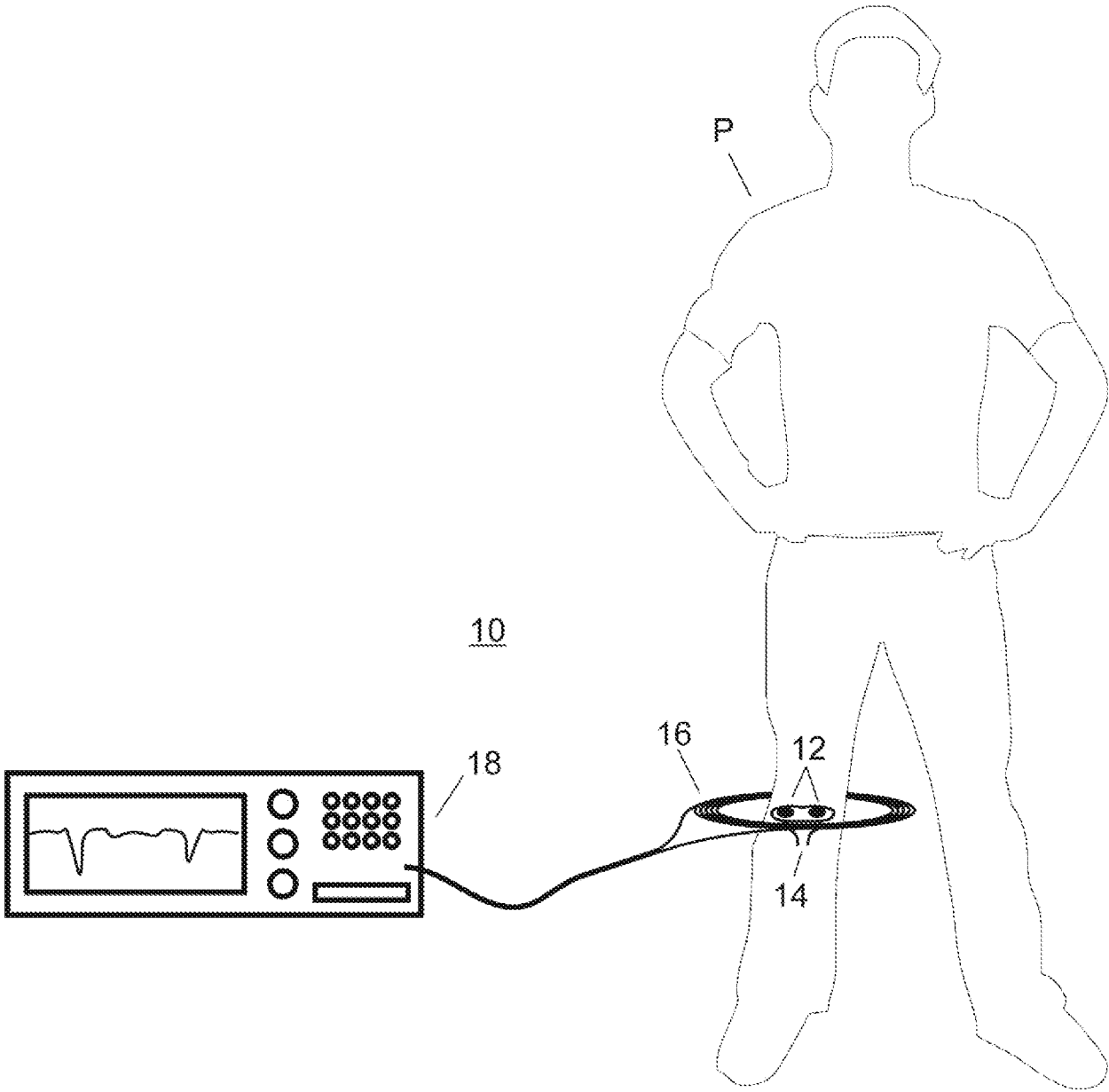
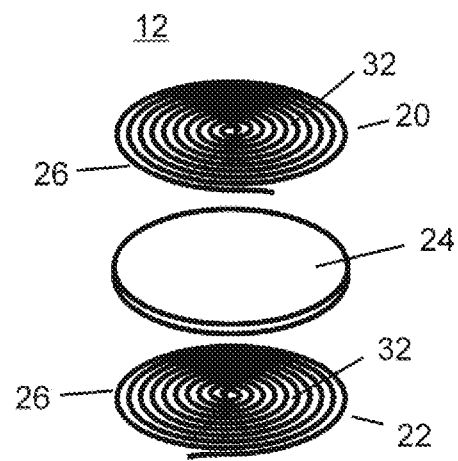
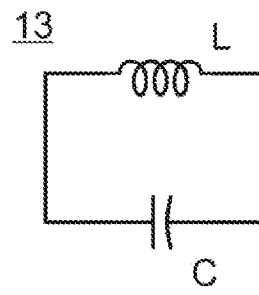
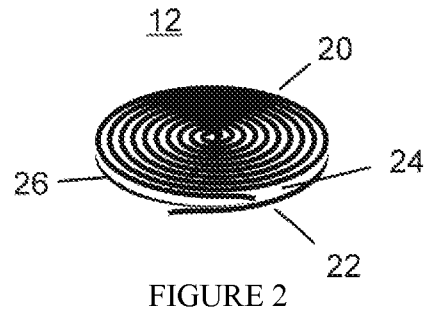


FIGURE 1



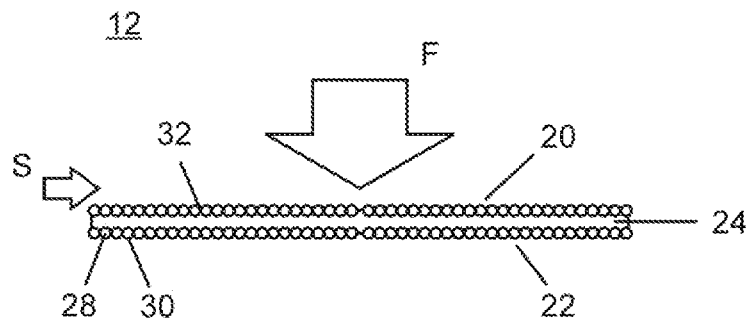


FIGURE 4

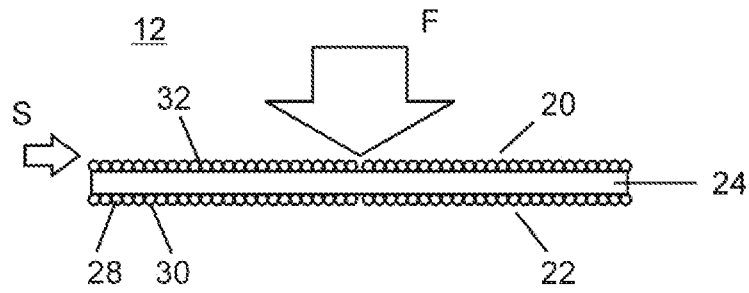


FIGURE 5

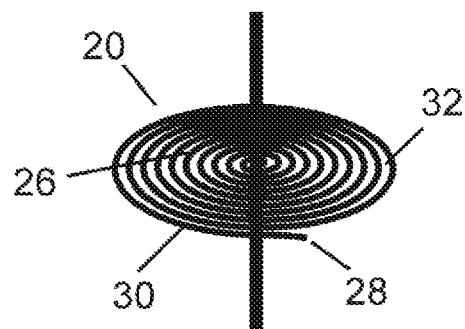


FIGURE 6

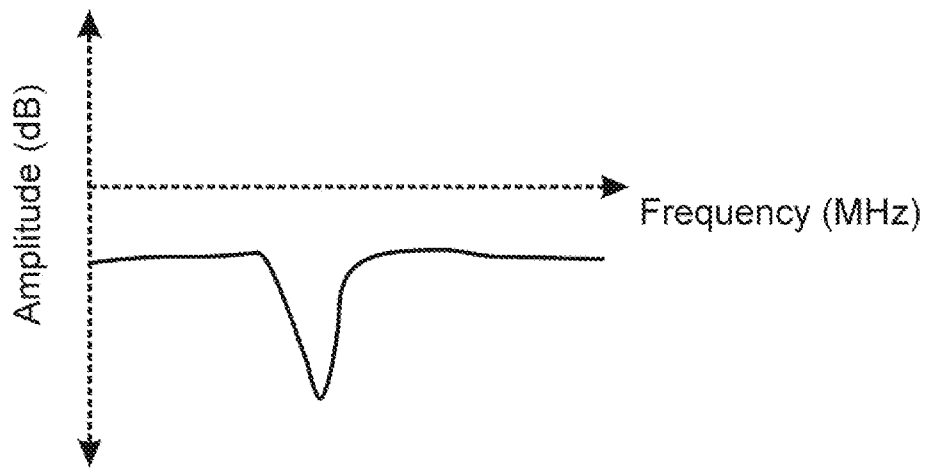


FIGURE 7

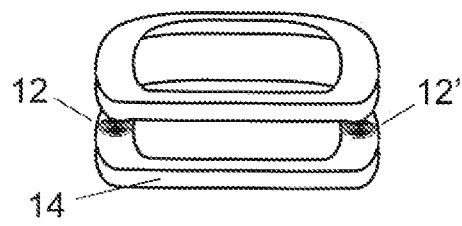


FIGURE 8

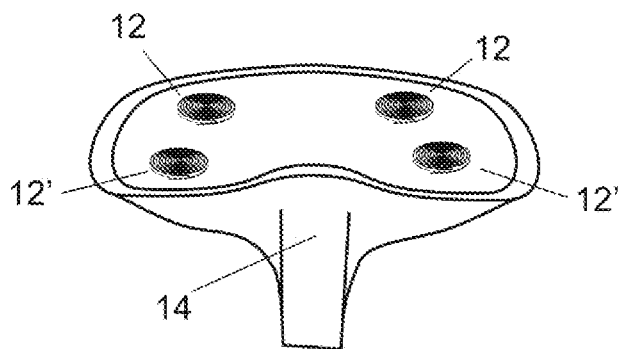


FIGURE 9

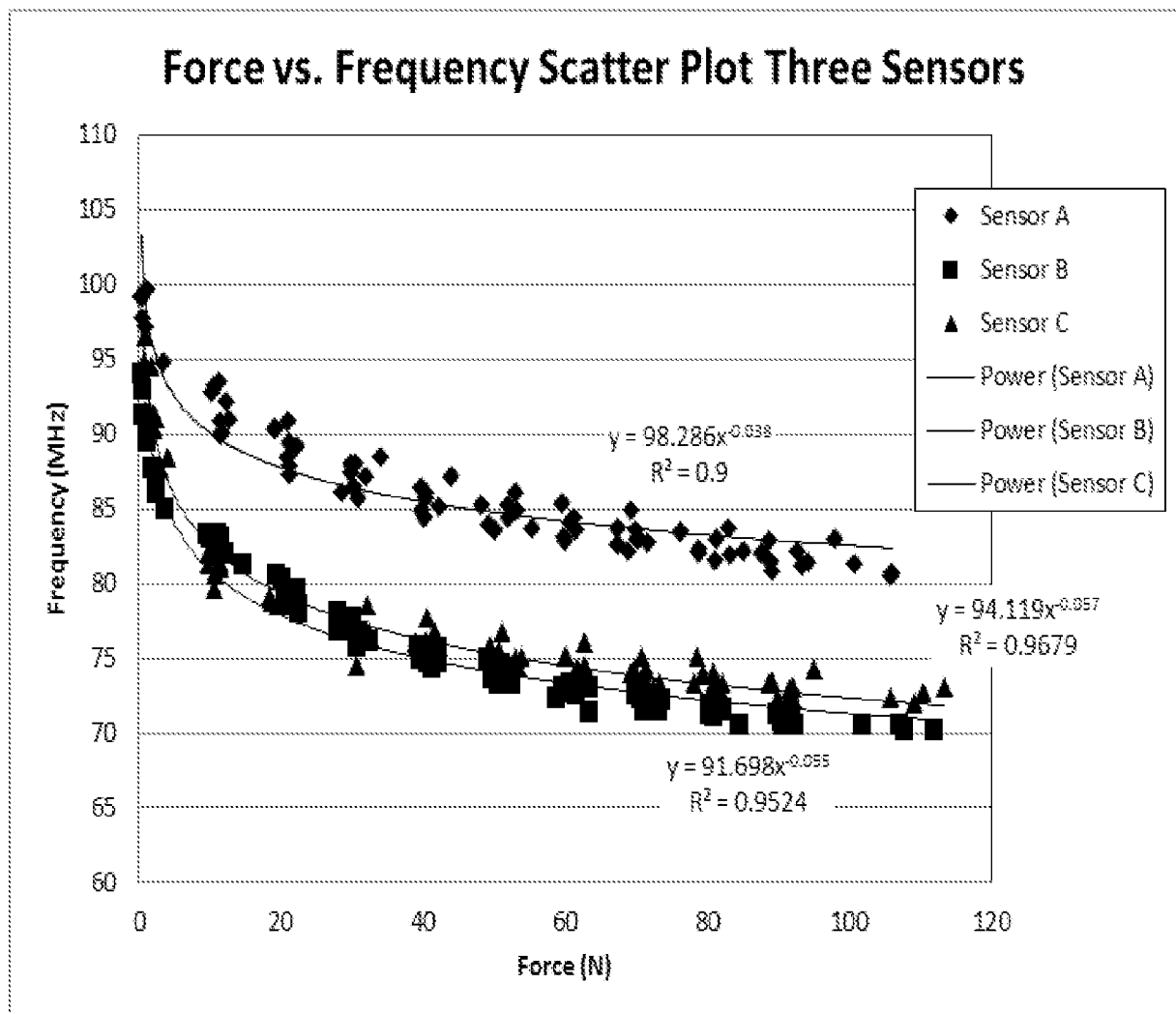


FIGURE 10

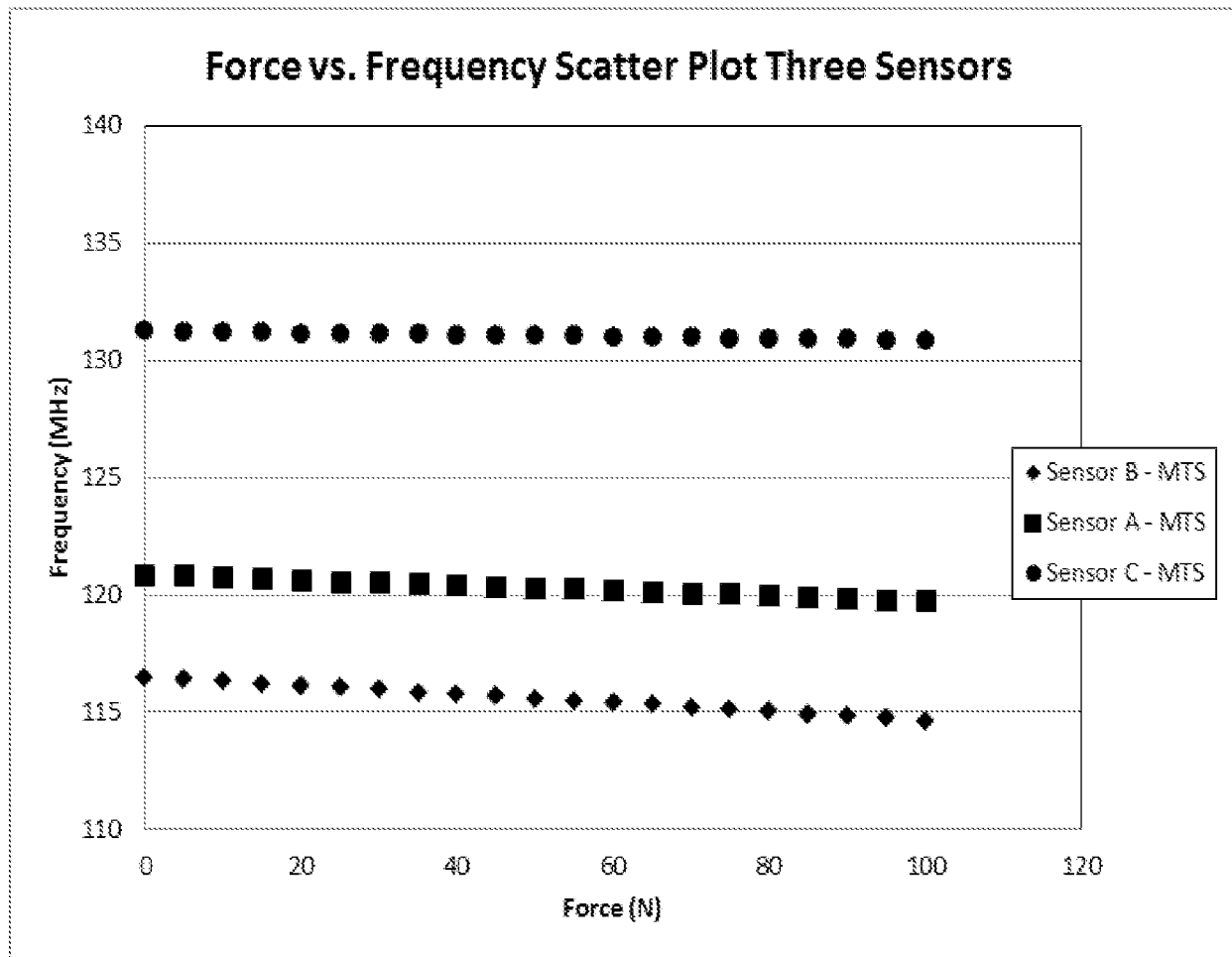


FIGURE 11

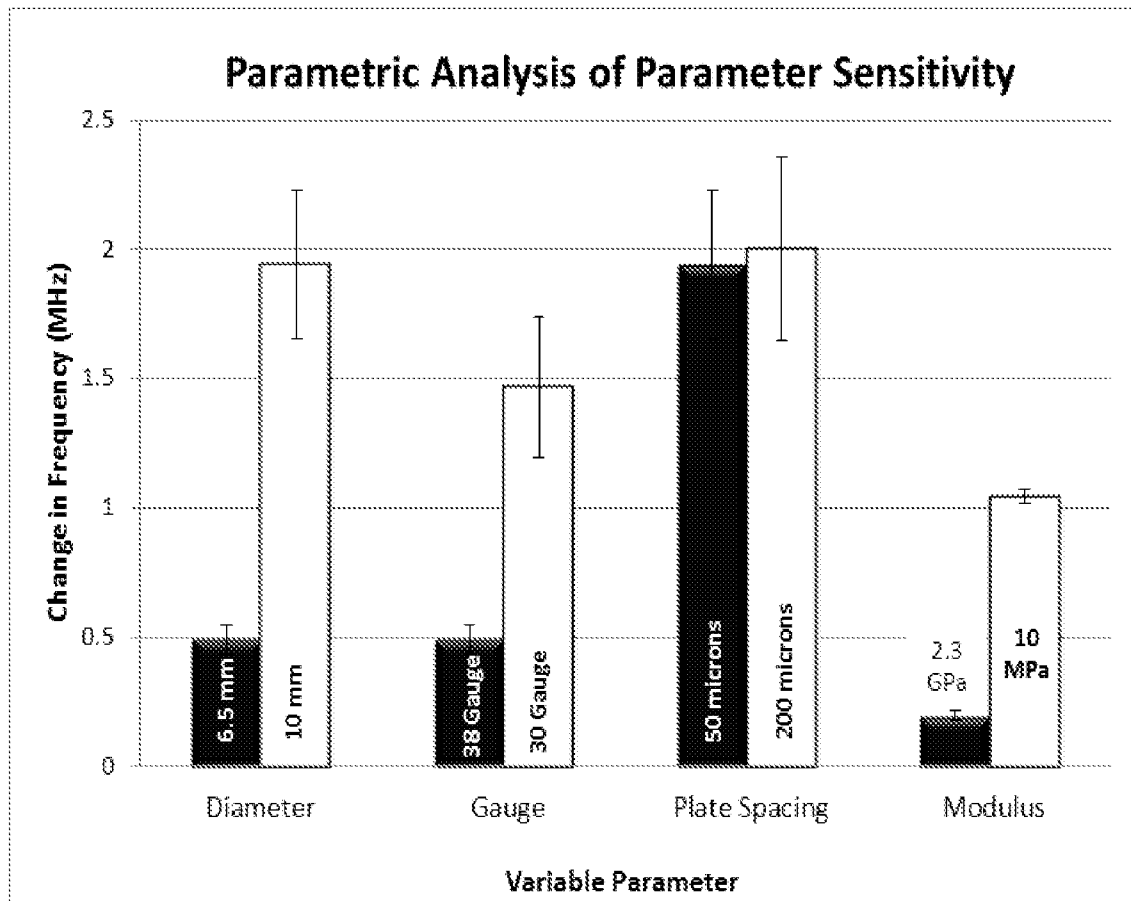


FIGURE 12

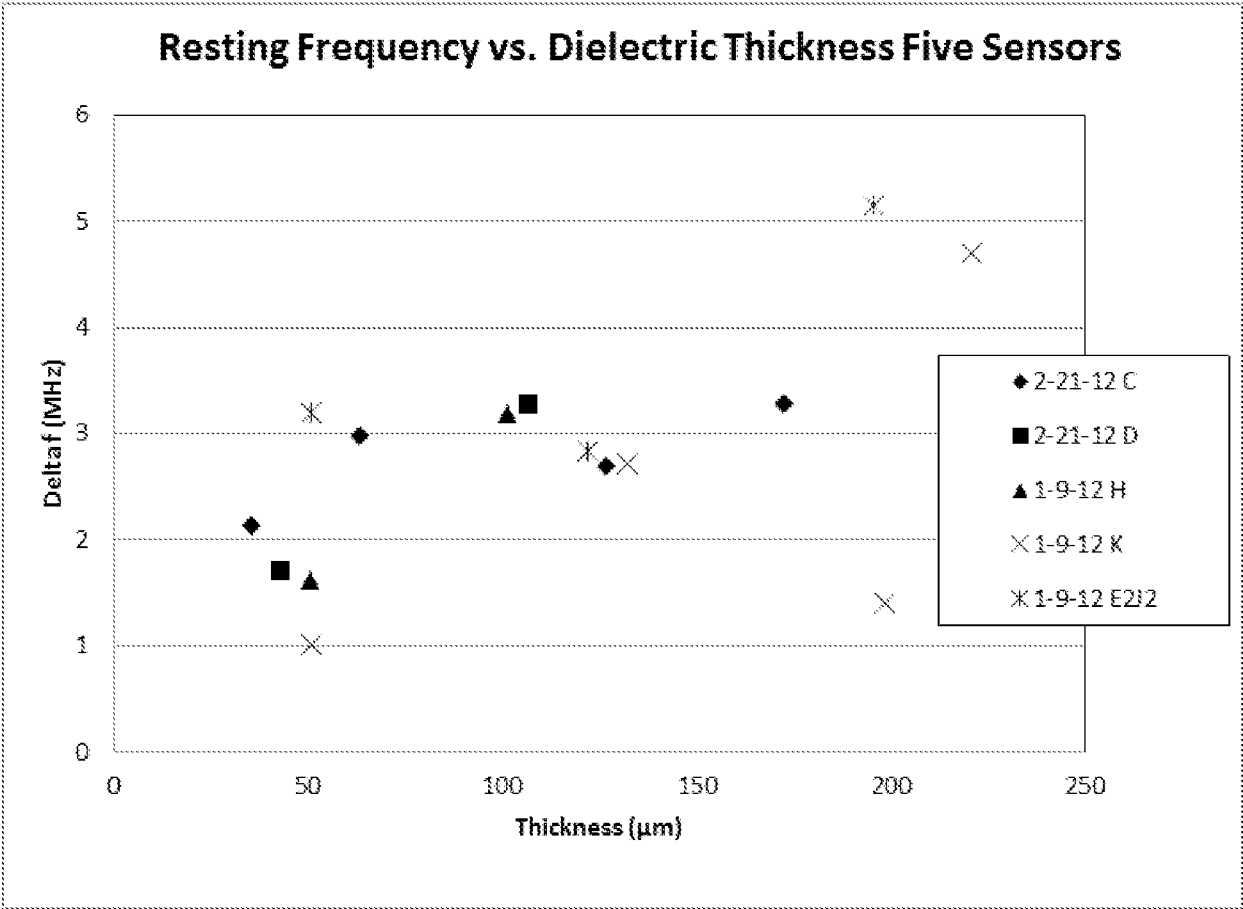


FIGURE 13

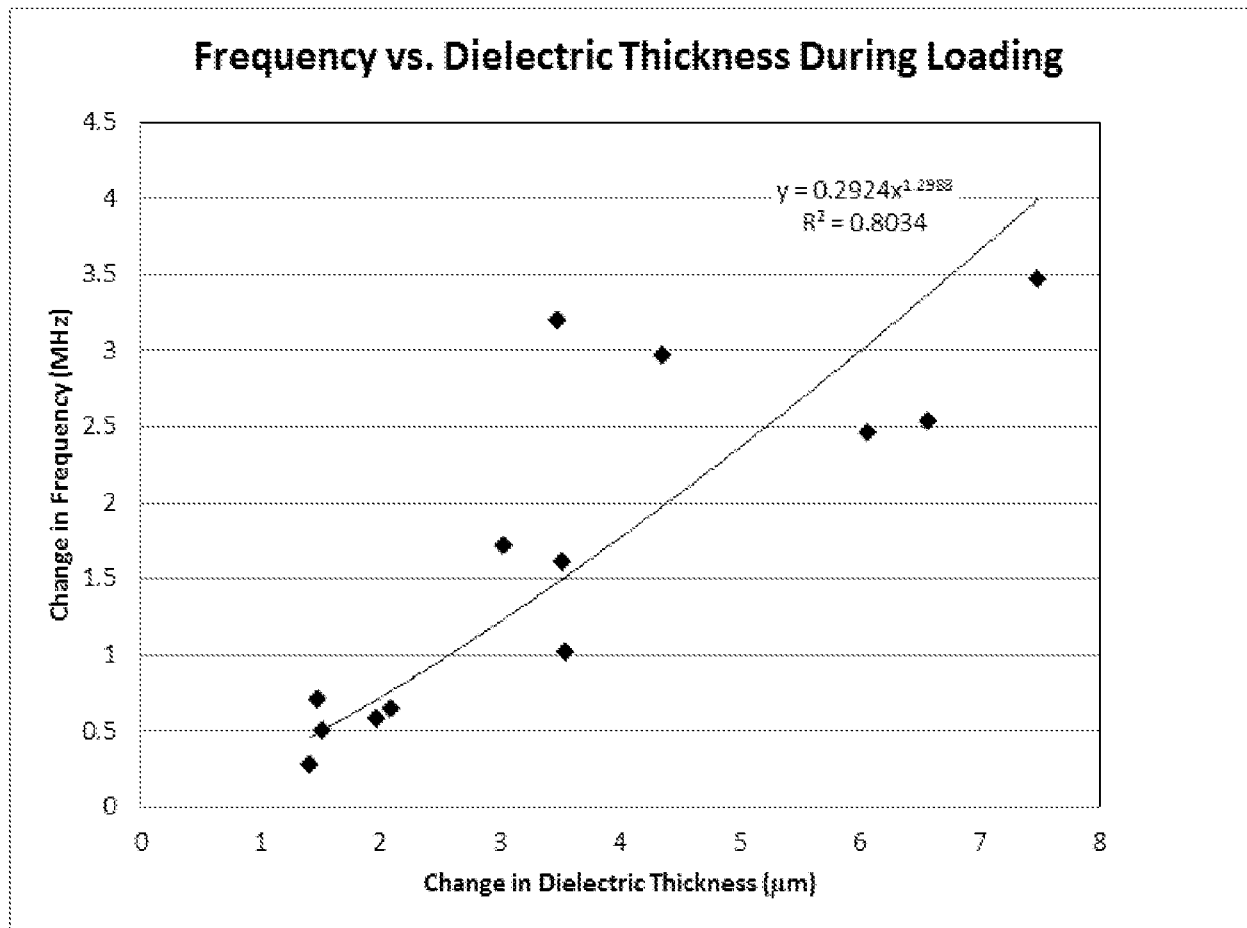


FIGURE 14

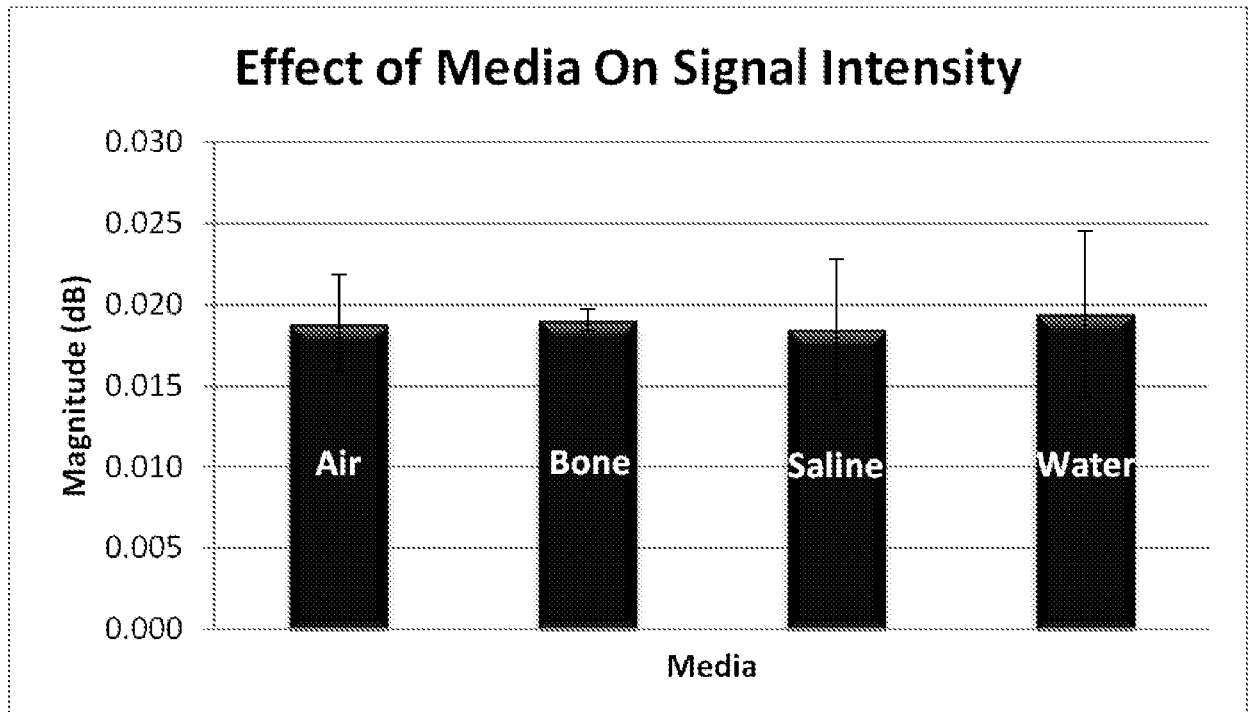


FIGURE 15

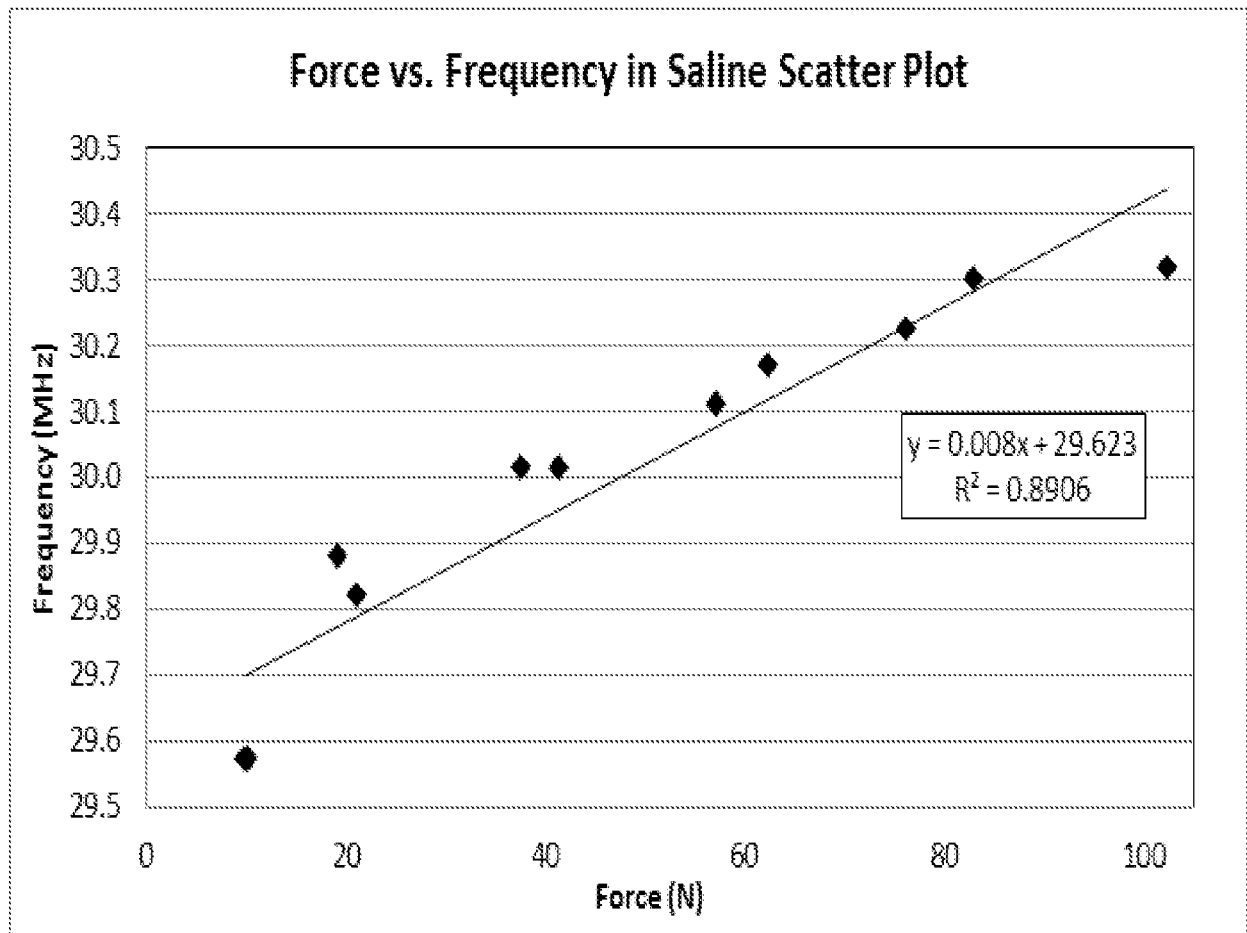


FIGURE 16

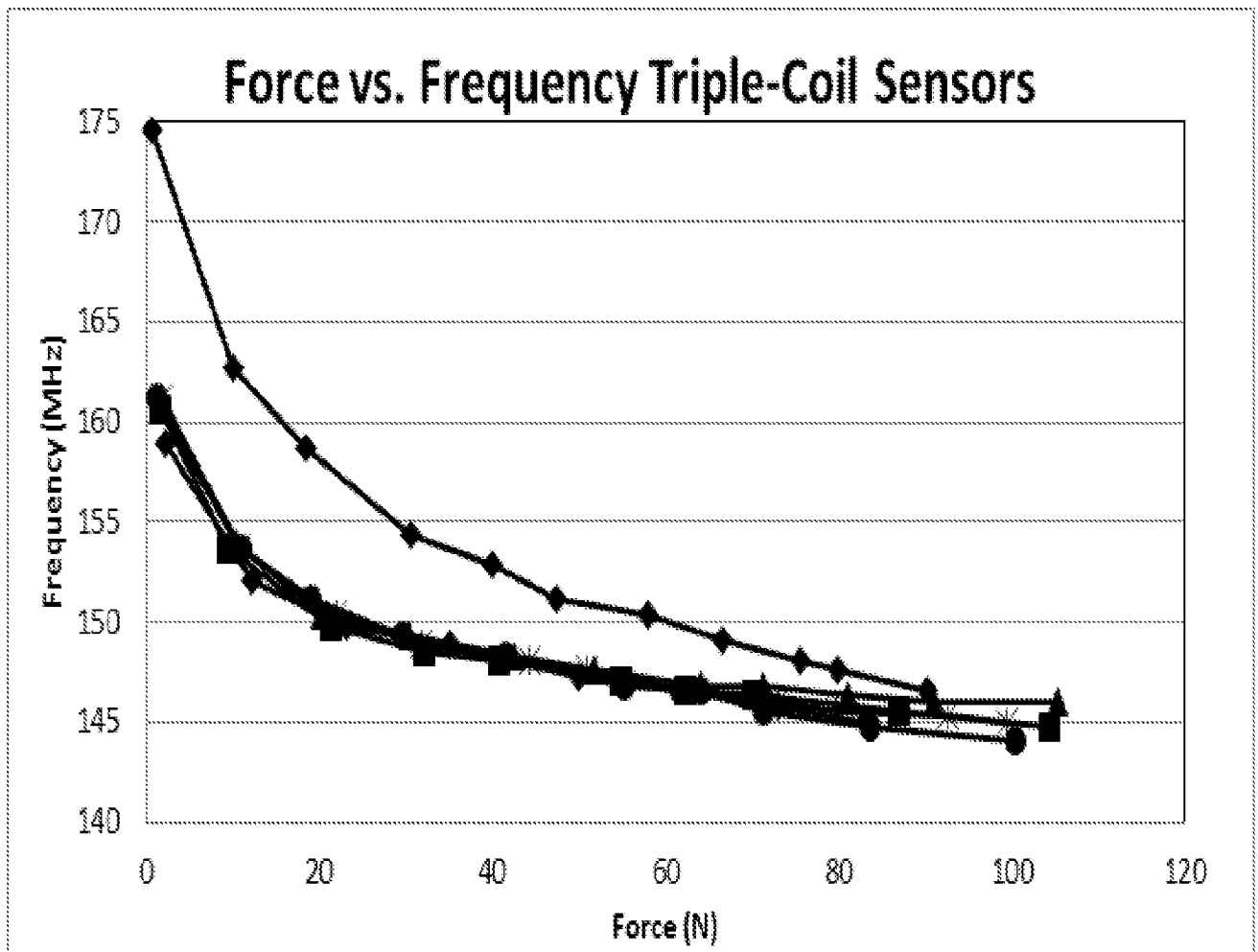


FIGURE 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/024706**A. CLASSIFICATION OF SUBJECT MATTER****A61B 5/00(2006.01)i, A61N 1/372(2006.01)i**

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)

A61B 5/0; A61B 19/00; A61B 5/05; A61B 5/02; A61B 5/145

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: sensor, passive circuit, resonant frequency

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01-12092 A1 (BF GOODRICH COMPANY) 22 February 2001 See abstract, pages 5-10, claim 1 and figures 1-6c.	1-31
A	US 2001-0016683 A1 (DARROW CHRISTOPHER B. et al.) 23 August 2001 See abstract, paragraphs [0027]-[0032] and figure 3.	1-31
A	US 2004-0082867 A1 (ESCH VICTOR C. et al.) 29 April 2004 See abstract, paragraphs [0034]-[0038] and figures 1-5.	1-31
A	US 2011-0282175 A1 (GEISSLER RANDOLPH K. et al.) 17 November 2011 See abstract, paragraphs [0027]-[0032] and figures 1-3b,6.	1-31
A	US 6939299 B1 (PETERSEN KURT et al.) 06 September 2005 See abstract, column 6, line 29 - column 8, line 25 and figures 1A-4A.	1-31



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"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

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search

28 May 2013 (28.05.2013)

Date of mailing of the international search report

30 May 2013 (30.05.2013)

Name and mailing address of the ISA/KR

Korean Intellectual Property Office
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302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

KIM, Tae Hoon

Telephone No. 82-42-481-8407



INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2013/024706

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 01-12092 A1	22.02.2001	AU 2000-39123 A1 AU 6625600 A CA 2364869 A1 EP 1162914 A1 JP 2003-532440 A US 6206835 B1 WO 00-56210 A1 WO 01-12092 A1	09.10.2000 13.03.2001 28.09.2000 19.12.2001 05.11.2003 27.03.2001 28.09.2000 22.02.2001
US 2001-0016683 A1	23.08.2001	AU 1102400 A AU 2000-11024 A1 US 6201980 B1 US 6480730 B2 WO 00-19888 A1 WO 00-19888 A9	26.04.2000 26.04.2000 13.03.2001 12.11.2002 13.04.2000 22.08.2002
US 2004-0082867 A1	29.04.2004	None	
US 2011-0282175 A1	17.11.2011	WO 2011-143324 A1	17.11.2011
US 6939299 B1	06.09.2005	None	

专利名称(译)	传感器系统，可植入传感器和用于远程感测体内刺激的方法		
公开(公告)号	EP2811895A1	公开(公告)日	2014-12-17
申请号	EP2013746850	申请日	2013-02-05
[标]申请(专利权)人(译)	IO手术		
申请(专利权)人(译)	IO手术，LLC		
当前申请(专利权)人(译)	IO手术，LLC		
[标]发明人	LEDET ERIC HOWARD WACHS REBECCA ANN COLE KEEGAN PAUL FIORELLA DAVID		
发明人	LEDET, ERIC, HOWARD WACHS, REBECCA, ANN COLE, KEEGAN, PAUL FIORELLA, DAVID		
IPC分类号	A61B5/00 A61N1/372		
CPC分类号	A61B5/4851 A61B5/0002 A61B5/0031 A61B5/01 A61B5/03 A61B5/053 A61B5/1036 A61B5/14539 A61B5/14546 A61B5/4504 A61B5/686 H01F5/003 H01F5/06		
优先权	61/633225 2012-02-07 US 61/688898 2012-05-24 US		
其他公开文献	EP2811895A4		
外部链接	Espacenet		

摘要(译)

用于感测体内刺激的传感器系统 (10) 包括可植入传感器 (12)。传感器包括无源谐振器电路 (13)，其具有谐振频率并且包括至少一对大致平行的螺旋缠绕的未连接的导电线圈 (20)，(22)，其夹着一层固体电介质材料 (24)，其表现出变化。响应于对层施加刺激而影响共振频率的性质。通过改变线圈之间的间隔或间隙或改变线圈的重叠区域来调制传感器的谐振频率。通过施加射频能量激励传感器，并检测响应的共振频率。传感器可以有利地连接到医疗植入物上，以形成用于临床目的的实用智能植入物。