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(54) ACOUSTIC PHYSIOLOGICAL SENSOR

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Publication Classification

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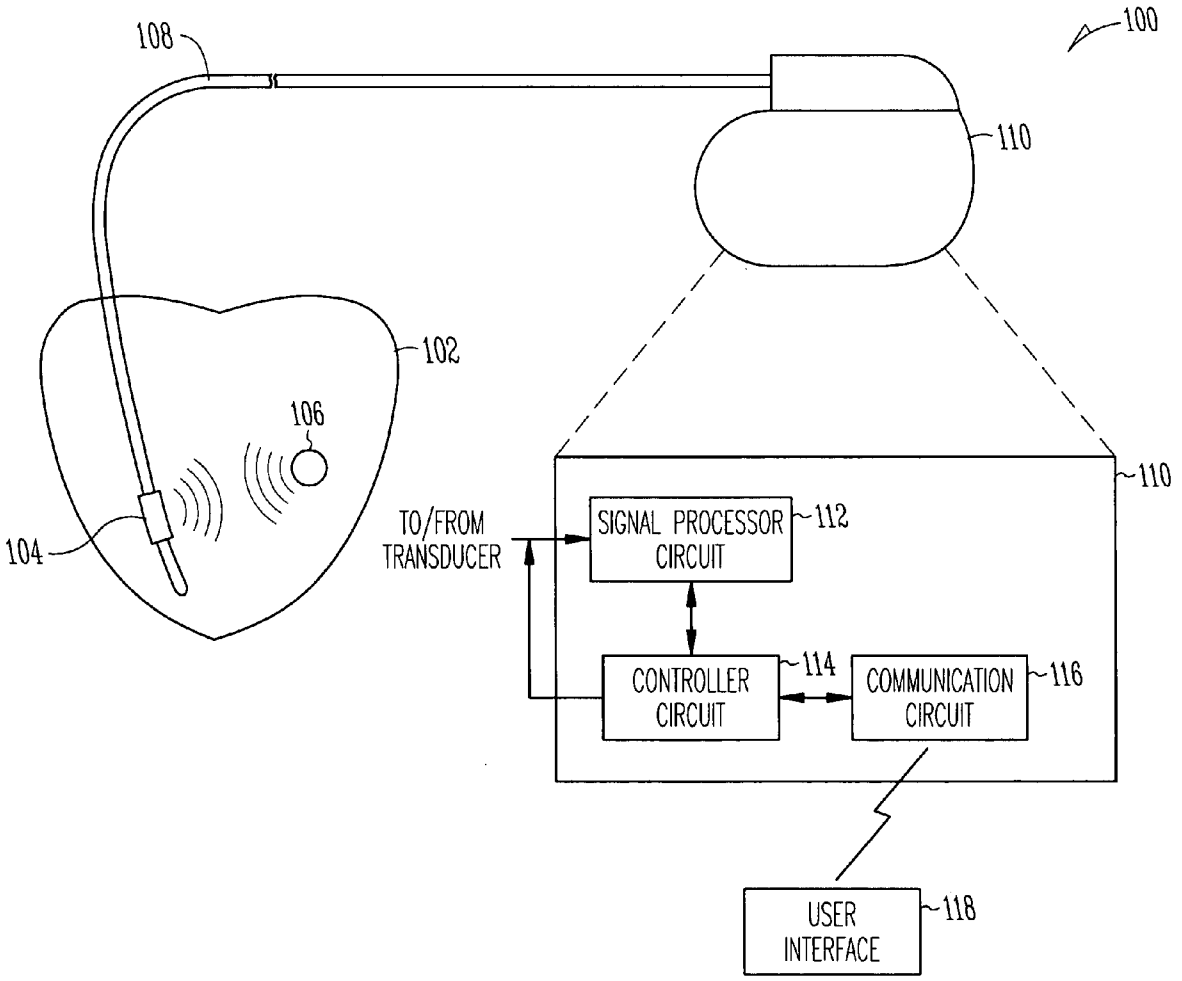
(52) **U.S. Cl.** **600/528**

(57) **ABSTRACT**

This document describes, among other things, a body having at least one acoustically detectable property that changes in response to a change in a physiological condition, such as ischemia. The body is positioned with respect to a desired tissue region. At least one acoustic transducer is used to acoustically detect a change in physical property. In one example, the body is pH sensitive and/or ion selective. A shape or dimension of the body changes in response to pH and/or ionic concentration changes resulting from a change in an ischemia state. An indication of the physiological condition is provided to a user.



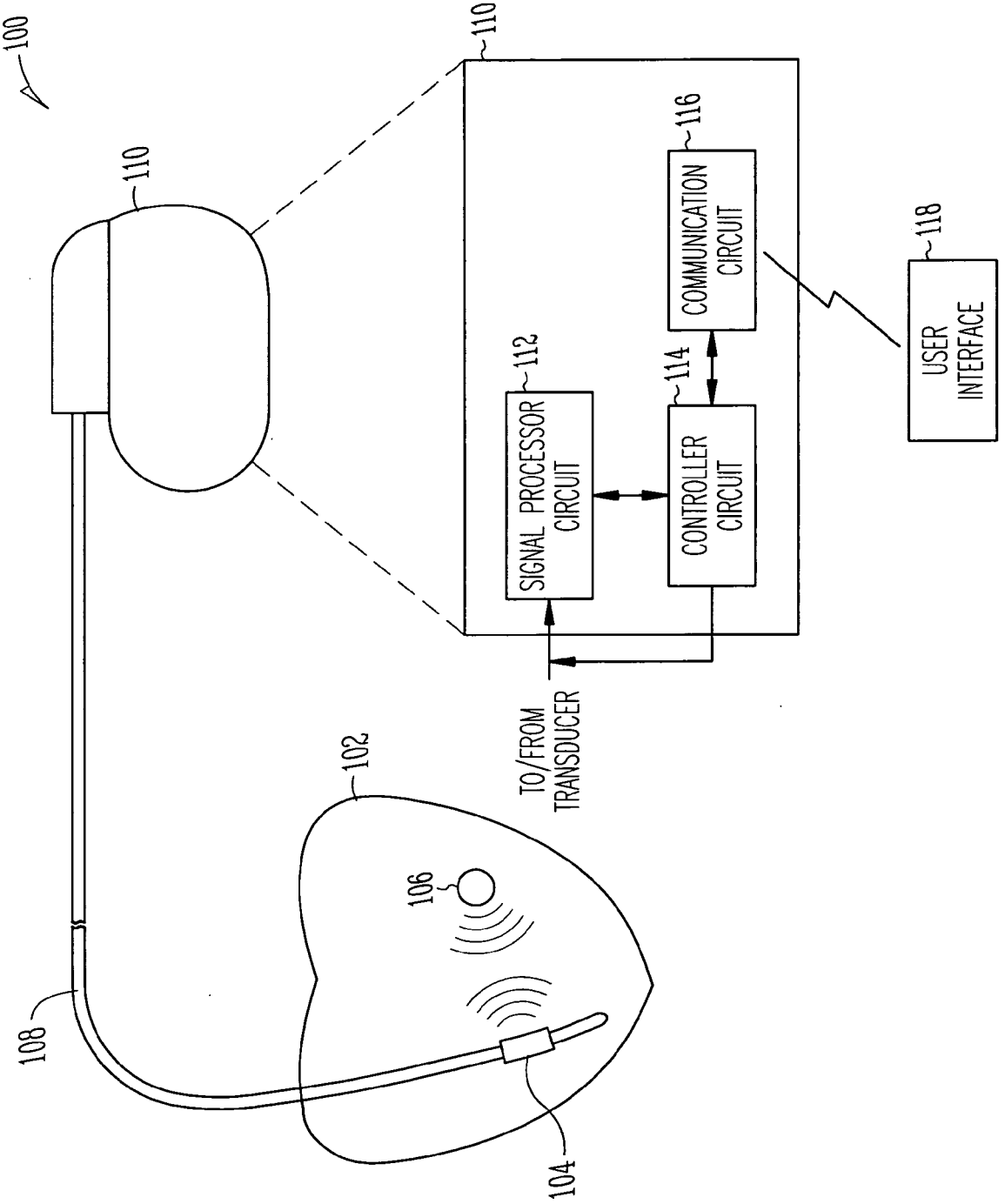

100
110
110
116
COMMUNICATION CIRCUIT
118
USER INTERFACE
112
SIGNAL PROCESSOR CIRCUIT
114
CONTROLLER CIRCUIT
TO/FROM TRANSDUCER
102
106
108
104

Fig. 1

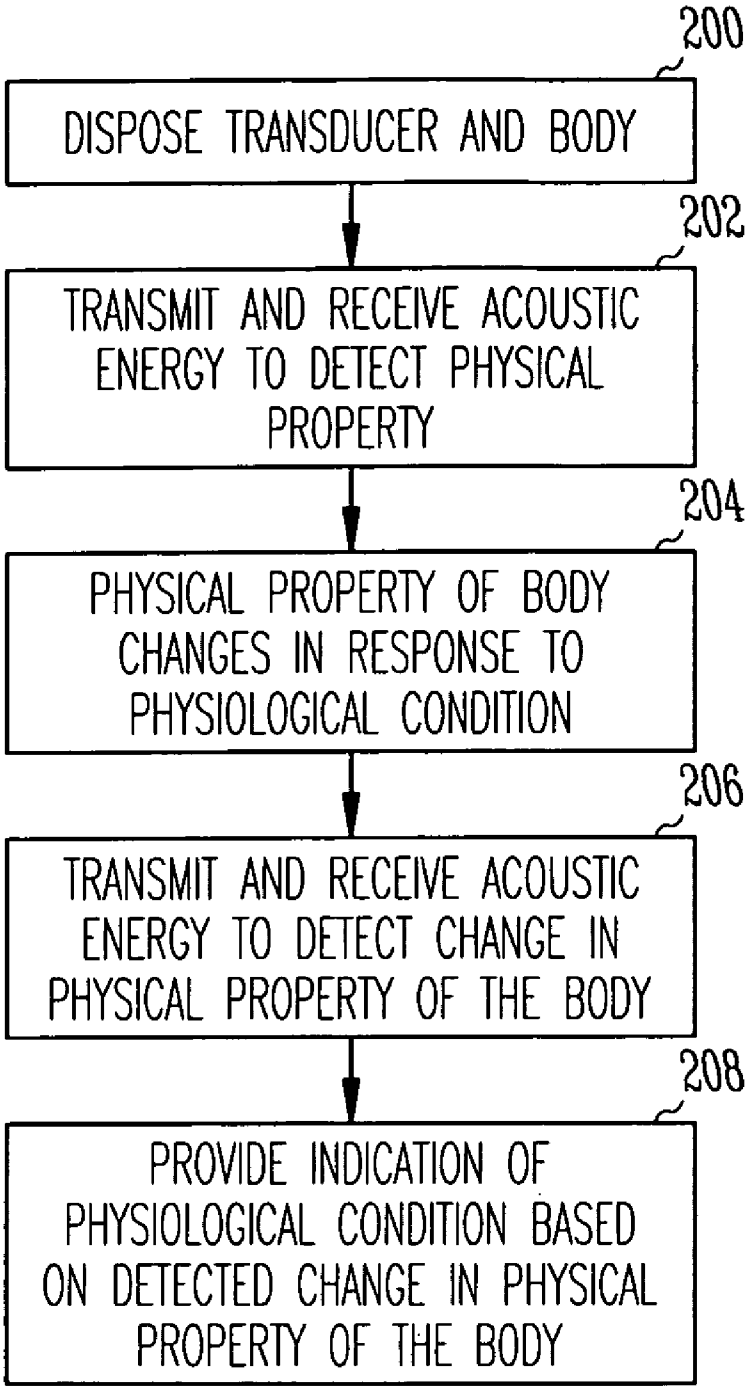

200
DISPOSE TRANSDUCER AND BODY
202
TRANSMIT AND RECEIVE ACOUSTIC ENERGY TO DETECT PHYSICAL PROPERTY
204
PHYSICAL PROPERTY OF BODY CHANGES IN RESPONSE TO PHYSIOLOGICAL CONDITION
206
TRANSMIT AND RECEIVE ACOUSTIC ENERGY TO DETECT CHANGE IN PHYSICAL PROPERTY OF THE BODY
208
PROVIDE INDICATION OF PHYSIOLOGICAL CONDITION BASED ON DETECTED CHANGE IN PHYSICAL PROPERTY OF THE BODY

Fig. 2

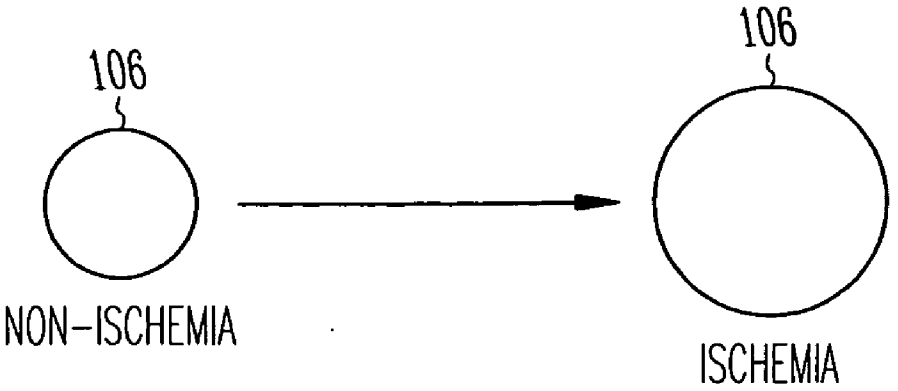

106
106
NON-ISCHEMIA
ISCHEMIA

Fig. 3

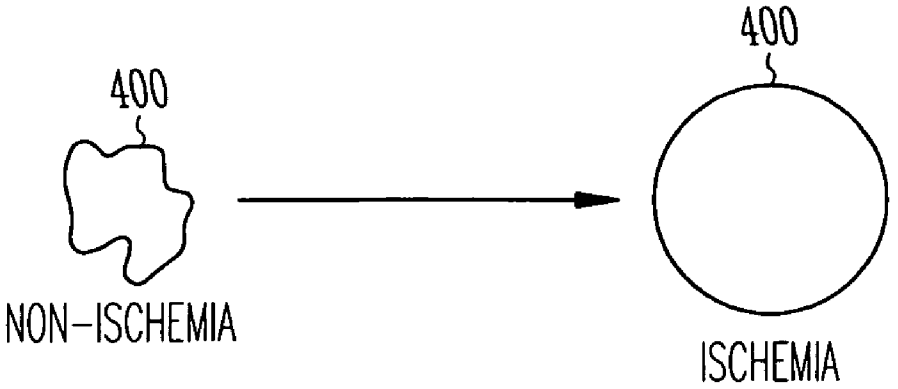

400
400
NON-ISCHEMIA
ISCHEMIA

Fig. 4

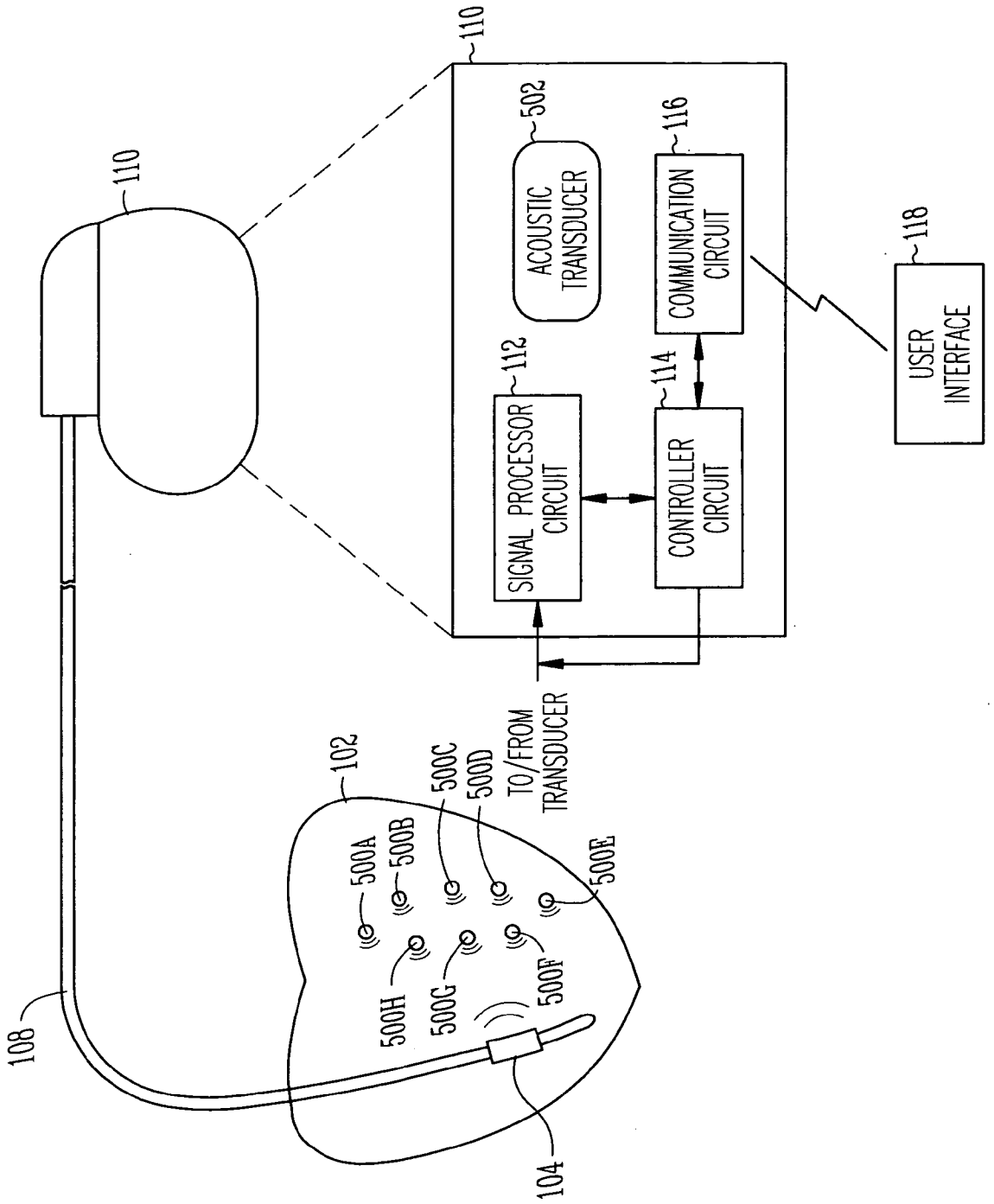

110
110
102
108
104
500A
500B
500C
500D
500E
500F
500G
500H
TO/FROM TRANSDUCER
SIGNAL PROCESSOR CIRCUIT
112
CONTROLLER CIRCUIT
114
ACOUSTIC TRANSDUCER
502
COMMUNICATION CIRCUIT
116
USER INTERFACE
118

Fig. 5

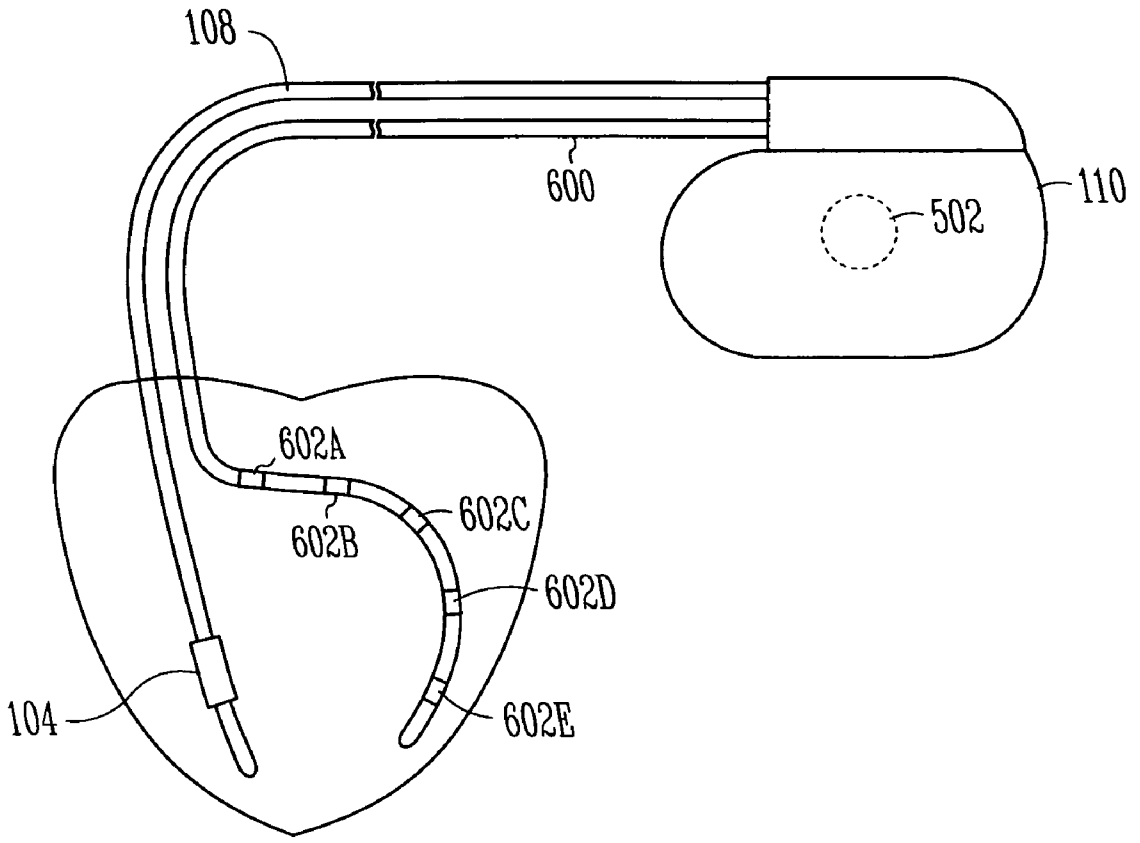


Fig. 6

ACOUSTIC PHYSIOLOGICAL SENSOR

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation of U.S. application Ser. No. 10/648,837, filed Aug. 26, 2003, which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] This document relates generally to medical systems, devices, and methods, and particularly, but not by way of limitation, to an acoustic physiological sensor.

BACKGROUND

[0003] Physiological conditions of a subject can provide useful information about the subject's health status to a physician or other caregiver. For example, portions of a heart muscle that receive inadequate blood circulation may become ischemic. There is a need for improved techniques of invasively or noninvasively measuring changes in a physiological condition indicative of ischemia.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] In the drawings, which are not necessarily drawn to scale, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

[0005] FIG. **1** is a schematic diagram illustrating generally one example of a system to detect a change in at least one physiological condition of a tissue, such as a heart.

[0006] FIG. **2** is a flow chart illustrating generally a method of providing an indication of a physiological condition, such as by using the system of FIG. **1**, or other desired system.

[0007] FIG. **3** is a conceptual schematic diagram illustrating generally a swelling of a spherical body from non-ischemic to ischemic conditions.

[0008] FIG. **4** is a conceptual schematic diagram illustrating generally a swelling of a body that changes its physical property of morphology, shape, or stiffness from non-ischemic to ischemic conditions.

[0009] FIG. **5** is a schematic diagram, similar to FIG. **1**, but illustrating a plurality of spherical or other bodies positioned at desired myocardial locations, such as described above.

[0010] FIG. **6** is a schematic diagram, similar to FIG. **5**, but illustrating an example of a second intravascular lead catheter.

DETAILED DESCRIPTION

[0011] In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments, which are also referred to herein as "examples," are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that the embodiments may be combined, or that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents.

[0012] In this document, the terms "a" or "an" are used, as is common in patent documents, to include one or more than one. In this document, the term "or" is used to refer to a "nonexclusive or," unless otherwise indicated. Furthermore, all publications, patents, and patent documents referred to in this document are incorporated by reference herein in their entirety, as though individually incorporated by reference. In the event of inconsistent usages between this documents and those documents so incorporated by reference, the usage in the incorporated reference(s) should be considered supplementary to that of this document; for irreconcilable inconsistencies, the usage in this document controls.

[0013] FIG. **1** is a schematic diagram illustrating generally, by way of example, but not by way of limitation, one example of a system **100** to detect a change in at least one physiological condition of a tissue, such as tissue of a heart **102**. In this example, the system includes an ultrasound or other acoustic transducer **104**, which is disposed within or near the heart **102**, or any other region of interest. In this example, a sphere or other body **106** is also disposed within or near the heart **102** or other region of interest, such as near the transducer **104**. In this example, but not by way of limitation, the transducer **104** is located on an intracardiac lead **108**, which is coupled to an implantable cardiac rhythm management (CRM) or other device **110**. In one example, the spherical body **106** includes a diameter approximately between 1 micrometer and 50 micrometers, such as about 20 micrometers.

[0014] In this example, the device **110** includes a signal processor circuit **112**. The signal processor circuit **112** is coupled to the transducer **104** to process an ultrasound or other acoustic signal received from the transducer **104**. In this example, the device **110** also includes a controller circuit **114**. The controller circuit **114** is coupled to the transducer **104** to provide at least one control signal to the transducer **104**. In this example, the controller circuit **114** is also coupled to the signal processor circuit **112**, such as to digitally perform additional processing on the acoustic signal. In this example, the device **110** includes a telemetry or other communication circuit **116**. The communication circuit **116** is coupled to the controller circuit **114**, such as to receive information about a change in at least one physiological condition of the heart **102** or other tissue or region of interest, where the change in the physiological condition is detected using an acoustic determination of a change in a physical property of the body **106**. The communication circuit **116** is communicatively couplable to an external user interface **118**, such as for transmitting an indication of the physical property, the change in the physical property, the physiological condition, or the change in the physiological condition for display to a user and/or recording. In one example, the external user interface **118** includes a nearby external programmer. In another example, the external user interface **118** includes an a computer network-linked (e.g., internet linked) and/or telephone network-linked more distant advanced patient management system capable of storing and/or displaying patient data and/or performing other functions. In one example, the external user interface **118** includes a short range communication circuit for communication with the implantable device **110** and an internet-linked or other long range communication circuit to communicate with an patient management computer server.

[0015] FIG. **2** is a flow chart illustrating generally, by way of example, but not by way of limitation, a method of providing an indication of a physiological condition, such as by using the system of FIG. **1** or other desired system. In the example of FIG. **2**, at **200**, the transducer **104** and the body **106** are disposed near the local region of tissue for which the indication of the physiological condition is desired. In one example, this includes intravascularly introducing an ultrasound transducer **104** into a right ventricular chamber of the heart **102**, such as by using an intracardiac lead **108**. In one example, this also includes intravascularly introducing a small spherical or other body **106** into coronary vasculature, such as via the coronary arteries or veins, to position the body **106** into contact with a local region of a microcirculatory myocardial tissue bed for which an ischemia determination is desired.

[0016] At **202**, the transducer **104** transmits acoustic energy. In this example, the transmitted acoustic energy is reflected by the body **106**. The reflected acoustic energy is received at the same (or different) transducer **104**. The received acoustic energy is processed to obtain a first reading of a physiological condition using a physical property of the body **106**.

[0017] At **204**, a physical property of the body **106** changes in response to a physiological condition. In one illustrative example, the size of a spherical body **106** changes in response to the physiological condition of ischemia. Ischemia results from a decreased blood flow to the heart tissue. This reduced blood flow produces several physiological effects in the extracellular portion of the ischemic tissue. For instance, the extracellular space would undergo a slight decrease in sodium (Na+) ions, a substantial increase in potassium (K+) ions, an increase in calcium (Ca++) ions, and a decreased pH due to accumulation of metabolic waste (e.g., particularly an increase in percentage carbon dioxide (pCO_2) and a decreased percentage oxygen (pO_2). In one example, the spherical or other at least one body **106** responds to the change in pH, and is constructed using a pH sensitive polymer. As a result of the decreased pH during ischemia, the body **106** adsorbs water or other bodily fluids and swells, such as illustrated in FIG. **3**. This change in a physical property of the body **106** is acoustically detectable. It is believed that a 10% change in diameter of the spherical body **106** will increase the frequency of reflected acoustic energy by about 10% (e.g., from 20 MHz to 22 MHz).

[0018] At **206**, the transducer **104** transmits and receives acoustic energy to obtain a second reading of a physiological condition (e.g., ischemia) using this change in a physical property (e.g., size and acoustic reflectance) of the body **106**. A difference between the first and second readings permits the detection of any change in the physiological condition.

[0019] At **208**, the system provides an indication of the physiological condition and/or a change in the physiological condition using any detected change in the physical property of the body **106**.

[0020] FIG. **3** is a conceptual schematic diagram illustrating generally, by way of example, but not by way of limitation, a swelling of a spherical body **106** from non-ischemic to ischemic conditions, thereby increasing the frequency at which acoustic energy is reflected from the spherical body **106**.

[0021] FIG. **4** is a conceptual schematic diagram illustrating generally, by way of example, but not by way of limitation, a swelling of a body **400** (which need not be spherical). In this example, the swelling changes its physical property of morphology, shape, or stiffness from non-ischemic to ischemic conditions, thereby increasing the frequency at which acoustic energy is reflected from the body **400**. In one example, the body **400** is constructed from a pH sensitive polymer or other pH sensitive material, as discussed above, to obtain the change in morphology, shape, or stiffness. In another example, the body **400** is constructed of an ion-selective membrane enclosure defining its shape. Ischemia results in an altered local concentration of sodium (Na+), potassium (K+), and calcium (Ca++). During ischemia, one or more of these variety of ions are accepted from the local environment across the membrane enclosure to within the body **400**. The resulting swelling of the body **400** causes an acoustically detectable change in shape.

[0022] FIG. **5** is a schematic diagram, similar to FIG. **1**, but illustrating generally, by way of example, but not by way of limitation, a plurality of spherical or other bodies **500** positioned at desired myocardial locations, such as described above. This permits detection of a change in physiological condition over a broader region. Moreover, although the above description has generally emphasized detecting a change in physiological condition by using a change in acoustic reflectance due to a change in a physical property (e.g., size and/or shape) of the body, other techniques could rely on a change in acoustic transmission, acoustic attenuation, and/or acoustic transit time, and/or any other acoustic technique. In one example, the device **110** includes a second acoustic transducer **502** (e.g., carried within a hermetically-sealed housing enclosure of the implantable device **110**, or disposed on a second intravascular catheter). In this example, acoustic energy is transmitted from the first transducer **104** and received at the second transducer **502** (or vice versa). The bodies **500** are positioned acoustically in between the transducers **104** and **502**. A change in physiological condition (e.g., ischemia) alters the acoustic transmission and/or attenuation between the transducers. This is measured by the signal processor circuit **112** and the controller circuit **114**.

[0023] FIG. **6** is a schematic diagram, similar to FIG. **5**, but illustrating generally, by way of example, but not by way of limitation, a second intravascular lead catheter **600**. The second intravascular lead catheter **600** includes one or more bodies **602** that swell or otherwise alter an acoustically detectable physical property in response to a change in a physiological condition, such as described above. In one example, the catheter **600** is introduced into a coronary sinus and/or great cardiac vein, such as to position the bodies **602** in contact with a myocardial tissue region of interest. Acoustic detection is performed either using the single transducer **104**, as described above, or by using two transducers **104** and **502**, as also described above. Alternatively, the second intravascular lead catheter provides an appropriate electrical connection to the one or more bodies **602** that swell or otherwise alter a physical property, thereby changing an electrical property (e.g., a bridge or other resistance, capacitance, etc.) incorporated within the one or more bodies **602**. In this example, the ischemia or other physiological condition is detected electrically instead of acoustically.

[0024] In one example, a change in physiologic condition (e.g., ischemia) is determined from the acoustic response of the spherical or other body or bodies **602** to a change in the physiologic condition. The acoustic response is compared to a baseline acoustic response. If the acoustic response deviates from the baseline acoustic response by an amount that is

greater than a predetermined threshold value, then a detected change in the physiologic condition (e.g., ischemia) is declared. In one example, the detected change in the physiologic condition is stored and/or communicated to the remote user interface **118** for storage and/or display or other presentation to the user. In one example, the detected change in the physiologic condition is used in conjunction with an alarm to alert the physician and/or the clinician (e.g., that the patient is undergoing an ischemic episode).

[0025] In another example, the detected change in the physiologic condition is used to initiate or modify therapy being delivered by the implantable cardiac rhythm management device **110**. For example, if a detected ischemia episode was preceded by a time period during which pacing pulses were delivered at a relatively higher average rate, then, in one example, the pacing rate is reduced. In another example, such as where multiple pacing electrodes are disposed at different locations about the heart, the locations or sequence of delivery of pacing pulses from such locations is altered, such as to shift blood toward the ischemic area of the heart tissue. In a further example, the change in the physiologic condition is used as a factor that is predictive of the occurrence of a future episode of cardiac arrhythmia, such as fibrillation. One example of using factor(s) predictive of future arrhythmias (as well as taking preventative measures) is described in Robert J. Sweeney et al. U.S. Pat. No. 6,272,377 entitled CARDIAC RHYTHM MANAGEMENT SYSTEM WITH ARRHYTHMIA PREDICTION AND PREVENTION, which is assigned to Cardiac Pacemakers, Inc., and which is incorporated by reference herein in its entirety, including its disclosure of devices and methods for predicting and preventing future arrhythmias. In one example, the detected change in the physiologic condition is used to alter the state of the cardiac rhythm management device **110** in anticipation of a future physiologic event. For example, the device **110** could monitor the subject with greater time resolution during an ischemia episode, or could pre-charge defibrillation capacitors to more readily deliver a defibrillation pulse.

[0026] Although the above examples have emphasized use of an implantable device **110**, such as for obtaining chronic measurements, alternatively, each of these examples is implemented with an external device, operating similarly.

[0027] It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, aspects of the above-described embodiments may be used in combination with each other. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Moreover, in the following claims, the terms "first," "second," and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

What is claimed is:

1. An apparatus comprising:

a physiological sensor including a biocompatible body sized and shaped to be implanted within a subject to contact tissue, at least a portion of the body including a material having at least one physical property that changes in response to a physiological condition predictive or indicative of a tachyarrhythmia when that portion of the body is implanted in contact with the tissue, wherein the change in the at least one physical property occurs because of the contact between that portion and the tissue, wherein the portion of the body is sized and shaped such that the change in the physical property is detectable using acoustic energy to provide an indication of the physiological condition.

2. The apparatus of claim **1**, wherein the change in the physical property of the body includes a change in size of the body.

3. The apparatus of claim **1**, wherein the change in the physical property of the body includes a change in an acoustic property of the body.

4. The apparatus of claim **1**, comprising an implantable transducer configured to supply the acoustic energy for providing the indication of the physiological condition.

5. The apparatus of claim **1**, wherein the body includes at least a portion of a catheter.

6. The apparatus of claim **1**, wherein the body includes a sphere.

7. The apparatus of claim **1**, wherein the change in the physical property of the body is responsive to a change in pH.

8. A method comprising:

introducing a physiological sensor including a biocompatible body into contact with a tissue, wherein the body includes at least one physical property that changes as a result of the contact with the tissue in response to a physiological change associated with the tissue, the physiological change predictive or indicative of a tachyarrhythmia;

transmitting acoustic energy to the body and the tissue;

receiving transmitted acoustic energy for detecting the change in the physical property of the body; and

detecting and providing an indication of the physiological change by detecting the change in the physical property of the body.

9. The method of claim **8**, wherein introducing the physiological sensor includes introducing a pH sensitive biocompatible body.

10. The method of claim **8**, wherein introducing the physiological sensor includes introducing an ion sensitive biocompatible body.

11. The method of claim **8**, wherein introducing the physiological sensor includes introducing a catheter.

12. The method of claim **8**, wherein introducing the physiological sensor includes introducing a sphere.

13. The method of claim **8**, comprising introducing a device for transmitting the acoustic energy.

14. The method of claim **8**, comprising introducing a device for receiving the transmitted acoustic energy.

15. The method of claim **8**, wherein transmitting the acoustic energy includes transmitting the acoustic energy using an implantable transducer.

16. An apparatus comprising:

a physiological sensor including a biocompatible body, the body sized and shaped to be implanted within a subject to contact tissue, at least a portion of the body including a material having at least one physical property that changes in response to a physiological condition of the tissue when that portion of the body is implanted in contact with the tissue, the change in the physiological condition being predictive or indicative of ischemia,

wherein the change in the at least one physical property occurs because of the contact between that portion and the tissue, wherein the portion of the body is sized and shaped such that the change in the physical property is detectable using acoustic energy to provide an indication of the physiological condition.

17. The apparatus of claim **16**, comprising an implantable transducer configured to supply the acoustic energy for providing the indication of the physiological condition.

18. The apparatus of claim **16**, wherein the change in the physical property of the body includes a change in size of the body.

19. The apparatus of claim **16**, wherein the change in the physical property of the body includes a change in an acoustic property of the body.

20. The apparatus of claim **16**, wherein the change in the physical property of the body is responsive to a change in pH.

* * * * *