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(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

[Continued on next page]

(54) **Title**: WIRELESS PRESSURE WIRE SYSTEM WITH INTEGRATED POWER

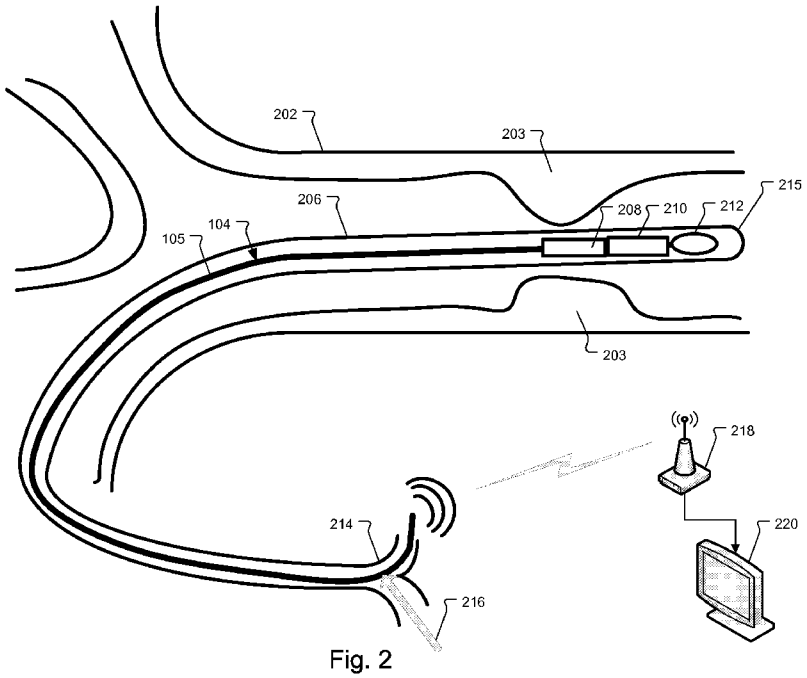

Fig. 2

(57) **Abstract**: A sensor wire system with an integrated power source and wireless transmission is provided. A sensor wire includes a distal end that is inserted into a blood vessel of a patient's body. A sensor that is mounted at the distal end of the sensor wire and an electronics unit of the distal end of the sensor wire transmit information generated by the sensor to a receiver unit outside of the patient's body wirelessly. The system further includes a power source, which in one example is mounted to the distal end of the sensor wire, that supplies power to the electronics unit. Preferably the wire body functions as an antenna for the wireless broadcasting.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

WIRELESS PRESSURE WIRE SYSTEM WITH INTEGRATED POWER

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Patent Application No. 13/364,972, filed on February 2, 2012, which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] Heart disease is a leading cause of death for men and women in the United States. Consequently, there are numerous medications, medical procedures, and medical devices aimed at diagnosing and treating heart disease.

[0003] One type of medical procedure aimed at diagnosing heart disease is angiography. The procedure requires injecting a contrast agent into the blood stream and then taking x-rays to determine if there is a blockage within the blood vessel. A problem with an angiography is that the procedure can only determine if a blockage exists, but not whether the blockage is actually affecting the blood flow within the blood vessel. As a result, many patients elect to have unnecessary procedures to treat the blockage without confirming the severity of the blockage.

[0004] Another procedure for assessing heart disease is fractional flow reserve (FFR). FFR is a technique used in coronary catheterization to measure the pressure difference and thus blood flow across a partially blocked or constricted artery. Using a guidewire system, measurements are taken on both sides of a blockage within a blood vessel to determine if there is a pressure gradient or reduced blood flow due to the blockage. If there is no drop in pressure (or a nominal drop), then there may be no need for further medical intervention because the blockage is not significantly impeding the flow of blood. Conversely, if there is a significant drop across the blockage, then the blockage may need to be removed or treated because the blood flow is impaired by the blockage.

[0005] Generally, the FFR procedure is performed by inserting a guidewire system into the femoral or radial artery of the patient. The guidewire is maneuvered into position within a partially blocked blood vessel, and a sensor at the distal end of the guidewire is used to measure pressure, temperature, and/or blood flow to determine the severity of the blockage. The sensor is connected to a display device such as a monitor of a computer screen to display the patient's readings during the procedure.

SUMMARY OF THE INVENTION

[0006] A problem with some sensor devices is that they must be physically connected to both a power source and display device during the procedure. These requirements limit the range and mobility during the procedure and create wire management challenges. They require the operator to manipulate the sensor devices so that they are properly located in the patient. The electrical connectors must be uncovered or cleaned for connection to display and data processing devices. This adds extra steps and may involve breaches of the procedure's sterile field.

[0007] The present invention is directed to a preferably single-use sensor wire system and method that can have both an integrated power source and integrated antenna for wireless transmission.

[0008] In general according to one aspect, the invention features a sensor wire system. It comprises a sensor wire body having a distal end that is inserted into a blood vessel of a patient, a sensor that is mounted at the distal end of the sensor wire body, an electronics unit of the distal end of the sensor wire body that wirelessly transmits information generated by the sensor to a receiver unit outside of the patient, and a power source that supplies power to the electronics unit.

[0009] In preferred embodiments, the sensor is a pressure sensor, a temperature sensor, and/or a blood flow sensor. In other examples, it is an imaging device, such as an IVUS, FLIVUS, OCT, spectroscopic, ICE, or forward looking ICE analysis device, with encoded images from the imaging device being broadcast to the receiver unit.

[0010] In one embodiment, the power source is a power harvesting device, such as one that converts the cyclic pressure changes of surrounding blood into power to the electronics unit. In other cases, the power source is a battery, such as a battery that is activated upon insertion into the patient and that powers the electronics unit until the power source is depleted.

[0011] In general according to another aspect, the invention features a method of using a sensor wire. This comprises inserting a sensor wire body having a distal end into a blood vessel of a patient, mounting a sensor to the distal end of the sensor wire body, supplying power to an electronics unit, and transmitting information generated by the sensor to a receiver unit via the electronics unit.

[0012] The above and other features of the invention including various novel details of construction and combinations of parts, and other advantages, will now be more particularly described with reference to the accompanying drawings and pointed out in the claims. It will be understood that the particular method and device embodying the invention are shown by way of illustration and not as a limitation of the invention. The principles and features of this invention may be employed in various and numerous embodiments without departing from the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] In the accompanying drawings, reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale; emphasis has instead been placed upon illustrating the principles of the invention. Of the drawings:

[0014] Fig. 1 is a schematic illustration showing a sensor wire inserted into a patient's body.

[0015] Fig. 2 is a schematic cross-sectional view showing a sensor wire within a partially blocked blood vessel of a patient that is wirelessly transmitting information to a receiver.

[0016] Fig. 3 is a schematic cross-sectional view showing the distal end of a sensor wire with a protective sheath.

[0017] Fig. 4 is a block diagram of the electronics unit in the distal end of the sensor wire.

[0018] Fig. 5 is a block diagram of the electronics unit in the distal end of the sensor wire according to another embodiment using a reserve battery power source.

[0019] Fig. 6 is a block diagram of the electronics unit in the distal end of the sensor wire with a battery power source at the proximal end.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0020] Fig. 1 is an illustration of a sensor wire 104 that is inserted into a patient's body 102.

[0021] In operation, the sensor wire system 104 is inserted into the artery, such as the femoral artery, of a patient 102 and guided through the blood vessels until arriving at a potentially partially blocked blood vessel of interest within the patient's body 102, such as

a coronary artery. In alternative embodiments, the sensor wire 104 is inserted via the radial or other artery, or vein. In other applications, other arteries or veins are the vessels of interest.

[0022] Fig. 2 illustrates the sensor wire system 104 within a partially blocked blood vessel of a patient 102 that is wirelessly transmitting information to a receiver 218. In one embodiment, the sensor wire 104 measures pressure, blood flow, and/or temperature within the blood vessel 202 of the patient 102. Typically, the distal end 215 of the sensor wire system 104 is inserted through the femoral artery and guided to the blocked blood vessel 202 by holding the sensor wire body. Steering the sensor wire 104 within the blood vessels is often performed by manually manipulating the proximal end 214 of the sensor wire body 105 or using a separate guide wire.

[0023] Once in position, the sensor 212 measures pressure, blood flow and/or temperature and encodes the information in the form of electrical signals. In a preferred embodiment the sensor 212 includes a pressure transducer, a flow detector, and a temperature transducer.

[0024] In other embodiments, the sensor 212 further includes an imaging system. In one example, the sensor 212 included an intravascular ultrasound (IVUS) device. In another variant, the sensor 212 includes a forward-looking IVUS (FLIVUS) device. In still other embodiments, the sensor 212 includes optical coherence tomography (OCT), near infrared spectroscopic, intracardiac echocardiography (ICE), and forward looking ICE devices.

[0025] The electrical signals generated by the sensor 212 are relayed to the electronics unit 210, which processes the signals. The information is then wirelessly transmitted to an external receiver 218. The sensor wire body 105 is preferably fabricated from conductive materials such that the sensor wire body 105 operates as a radio frequency antenna capable of broadcasting the information to the external receiver 218.

[0026] Depending on the implementation, the sensor signals broadcast from the antenna are the encoded time-varying pressure, flow, and temperature detected by the sensor 212.

[0027] In the cases where the sensor 212 includes an imaging modality, the broadcast sensor signals are encoded images from the IVUS, FLIVUS, OCT, spectroscopic, ICE, or forward looking ICE analysis.

[0028] Additionally, a power source 208 of the sensor wire system 104 supplies power to the electronics unit 210 and possibly the sensor 212 depending on the sensor technology used. In a typical implementation, the power source is a battery. However, in other embodiments, one or more storage capacitors supply the power requirements.

[0029] In a one embodiment, the battery power source 208 includes an anode and a cathode, but initially lacks the necessary electrolyte needed to complete a battery. In operation, the power source 208 is activated by injecting an electrolyte 216 into the sensor wire 104 or between the sensor wire 104 and a surrounding protective sheath. The electrolyte reacts with the anode and cathode to create a battery. Once the power source 210 is activated, the sensor wire system 104 wirelessly transmits the information generated by the sensor 212 until the power source 208 is exhausted.

[0030] In still another embodiment, the power for the electronics unit 210 is provided by a power harvesting system that converts the biological motion of the patient into power. In one example, the power source 208, or possibly the sensor wire body 105 itself, includes a piezo-electric power source that converts the cyclic pressures changes of the surrounding blood into electricity that powers the electronics unit 210.

[0031] The receiver 218 is connected to a display device 220 that displays the information on a screen. The display device is part of a computer system or medical workstation that includes a storage medium and printer to generate a printout of the information as well as to store a copy for future analysis.

[0032] Fig. 3 is an illustration of the distal end of a sensor wire 104 with a protective sheath 206.

[0033] In a preferred embodiment, the sensor wire 104 is contained within a protective sheath 206. The sheath 206 isolates the sensor 212, electronics unit 210 and power source 208, and wire body 105 from the patient's body 102. In alternative embodiments, however, the sensor wire 104 will not have a protective sheath.

[0034] Fig. 4 is a block diagram of the electronics unit 210 in the distal end 215 of the sensor wire system 104.

[0035] In a preferred embodiment, the sensor 212 is located in the tip of the distal end of the sensor wire 104. The sensor 212 generates pressure, blood flow and/or temperature information, usually in the form of electrical signals generated by a transducer. The electrical signals from the sensor 212 are sent to the electronics unit 210. The electrical signals are processed by the sensor control circuit 224 and encoded for transmission to the external receiver 218 and displayed on the screen 220.

[0036] The radio frequency (RF) circuit 226 is designed to wirelessly broadcast the information via the sensor wire body 105 at a specific frequency. In an alternative embodiment, the RF circuit allows the frequency to be varied so that multiple sensor wires operate at different frequencies in close spectral proximately without creating interference.

[0037] The electronics control unit 210 further includes a signal amplifier circuit 222 to amplify the signal prior to being wirelessly broadcast to the receiver 218.

[0038] An added benefit is that the sensor wire 104 can be used as a guidewire. Catheters can be threaded over the sensor wire 104. This process is facilitated by the fact that there are no electrical connections to the external receiver.

[0039] Fig. 5 is a block diagram of the electronics unit 210 in the distal end 215 of the sensor wire system 104 according to another embodiment.

[0040] In this example, the power source 208 is a reserve battery. These are devices that are commonly used in ordinance, for example. Reserve batteries are activated by addition of material or a change in temperature, the activator 250. With this addition or change, then the reserve battery 208 delivers current for several minutes to hours.

[0041] In one example, the activator 250 is water or other fluid that functions as an electrolyte causing the battery 208 to begin delivering current and thus power the electronics unit 210. The medical professional, in one example, injects the activator material 250 into the battery or breaks a bladder or capsule filled with the material, which then flows into the battery. In another example the activator is a gas that is either the active cathode material or part of the electrolyte.

[0042] Fig. 6 is a block diagram of the electronics unit 210 in the distal end 215 of the sensor wire system 104 according to another embodiment, in which the reserve battery 208 is located at the proximal end 215 of the sensor wire system 104. This embodiment has the advantage that the reserve battery 208 can be activated by the operator/surgeon only after

the wire system 104 has been placed in the patient. Wires 209 extending through the system 104 carry the current from the reserve battery 208 at the proximal end 214 to the electronics unit 210 at the distal end 215.

[0043] In another example, the reserve battery 208 is wire shaped extending through the length of the sensor wire system 104. In some examples, the wire-shaped reserve battery provides mechanical support for the system 104.

[0044] While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

CLAIMS

What is claimed is:

1. A sensor wire system, comprising:
   a sensor wire body having a distal end that is inserted into a blood vessel of a patient;
   a sensor that is mounted at the distal end of the sensor wire body;
   an electronics unit of the sensor wire body that wirelessly transmits information generated by the sensor to a receiver unit outside of the patient; and
   a power source that supplies power to the electronics unit.

2. The system according to claim 1, wherein the sensor is a pressure sensor.

3. The system according to claim 1, wherein the sensor is a temperature sensor.

4. The system according to claim 1, wherein the sensor is a blood flow sensor.

5. The system according to claim 1, wherein the sensor is an imaging device.

6. The system according to claim 1, wherein the electronics unit further comprises a signal amplifier, sensor control circuit, and radio frequency circuit.

7. The system according to claim 1, wherein the power source is a power harvesting device.

8. The system according to claim 1, wherein the power source converts the cyclic pressure changes of surrounding blood into power to the electronics unit.

9. The system according to claim 1, wherein the power source is a battery.

10. The system according to claim 1, wherein the power source is a battery that is activated upon use.

11. The system according to claim 1, wherein the electronics unit transmits the information until the power source is depleted.

12. A sensor wire system, comprising:

a sensor wire body having a distal end that is inserted into a blood vessel of patient;

a sensor that is mounted at the distal end of the sensor wire body;

an electronics unit that transmits information generated by the sensor, via the sensor wire body that functions as a radio frequency antenna, to a receiver unit outside of the patient; and

a power source that supplies power to the electronics unit.

13. The system according to claim 12, wherein the sensor is a pressure sensor.

14. The system according to claim 12, wherein the sensor is a temperature sensor.

15. The system according to claim 12, wherein the sensor is a blood flow sensor.

16. The system according to claim 12, wherein the sensor is an imaging device.

17. The system according to claim 12, wherein the electronics unit further comprises a signal amplifier, sensor control circuit, and radio frequency circuit.

18. A method of using a sensor wire, comprising:

inserting a sensor wire body having a distal end into a blood vessel of a patient in which a sensor is mounted to the distal end of the sensor wire body;

supplying power to an electronics unit; and

transmitting information generated by the sensor to a receiver unit via the electronics unit.

19. The method according to claim 18, wherein the sensor is a pressure sensor.

20. The method according to claim 18, wherein the sensor is a temperature sensor.

21. The method according to claim 18, wherein the sensor is a blood flow sensor.

22. The method according to claim 18, further comprising displaying the information generated by the sensor on a display device.

23. The method according to claim 18, further comprising the sensor generating images of the blood vessel.

24. The method according to claim 18, further comprising harvesting power from the patient.

25. The method according to claim 18, further comprising converting cyclic pressure changes of surrounding blood into power to the electronics unit.

26. The method according to claim 18, further comprising supplying power to the electronics unit from a battery.

27. The method according to claim 18, further comprising activating the battery upon use, with the electronics unit transmitting the information until the battery is depleted.

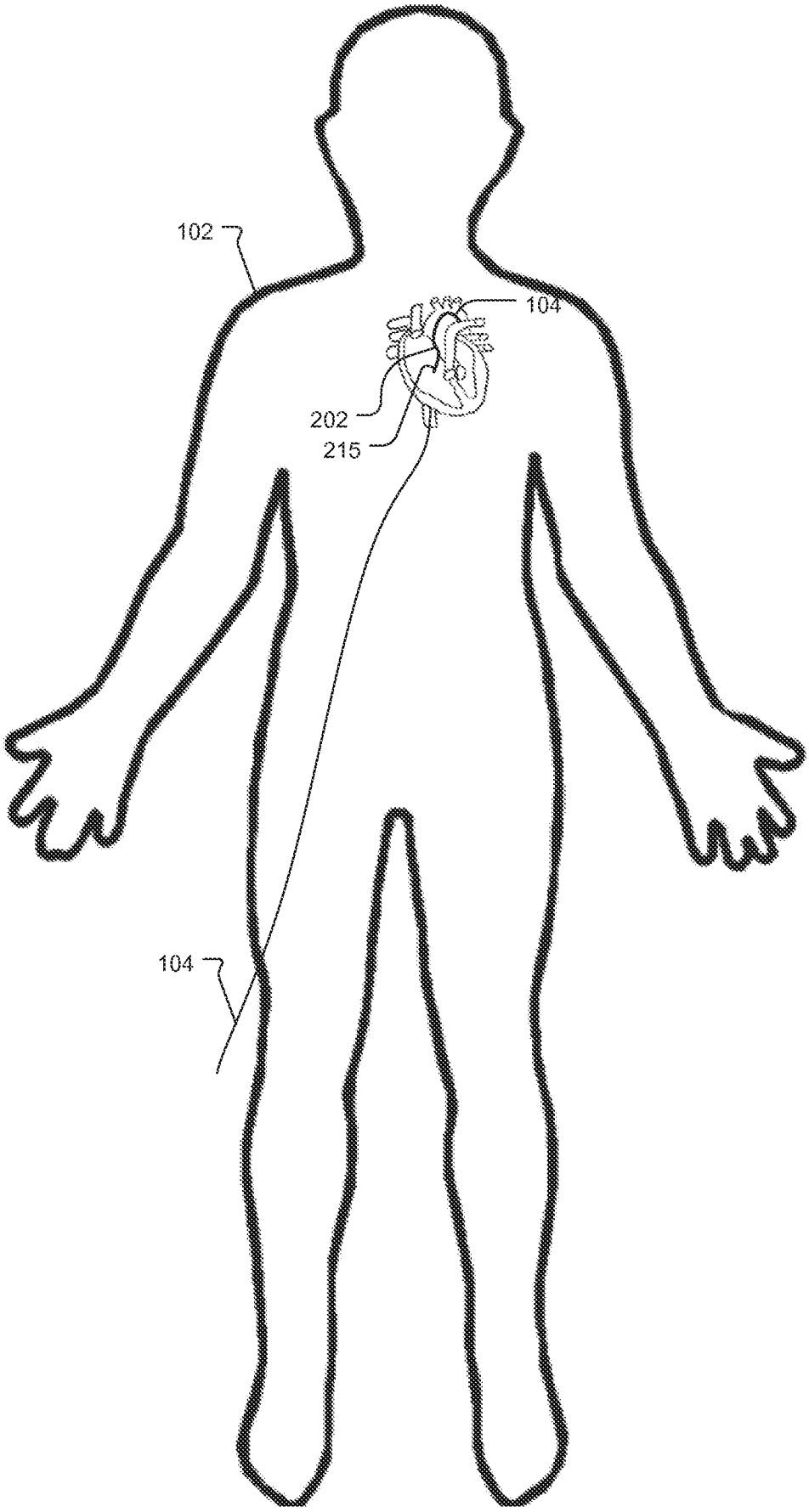

Fig. 1

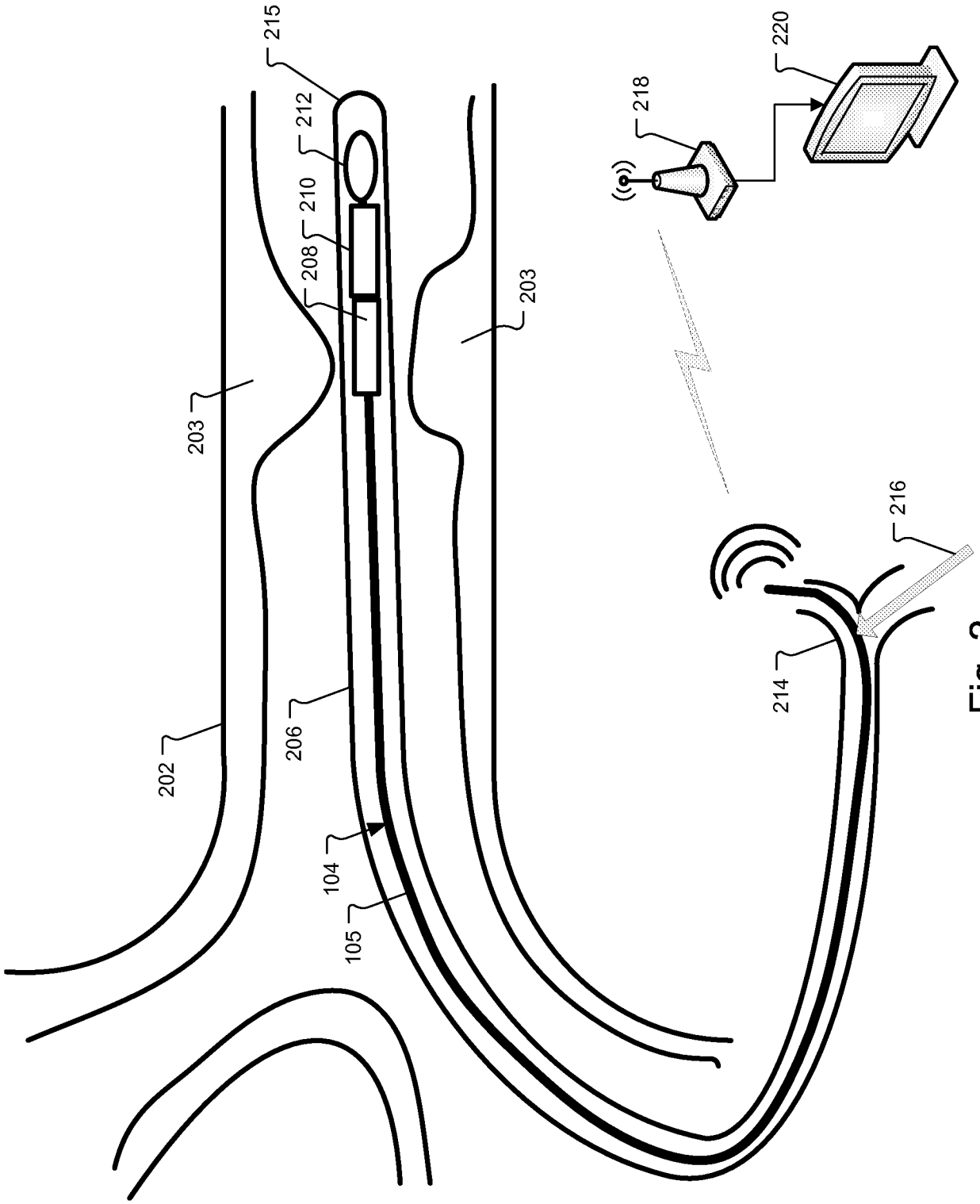

Fig. 2

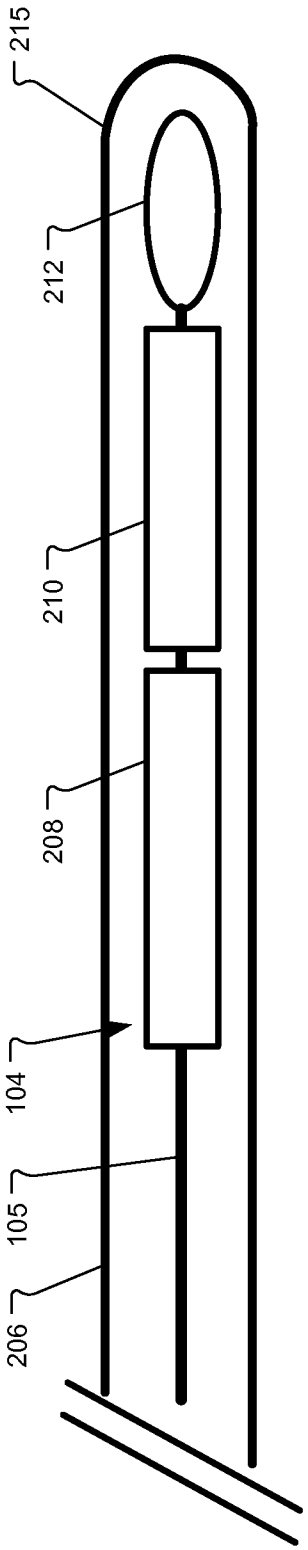

Fig. 3

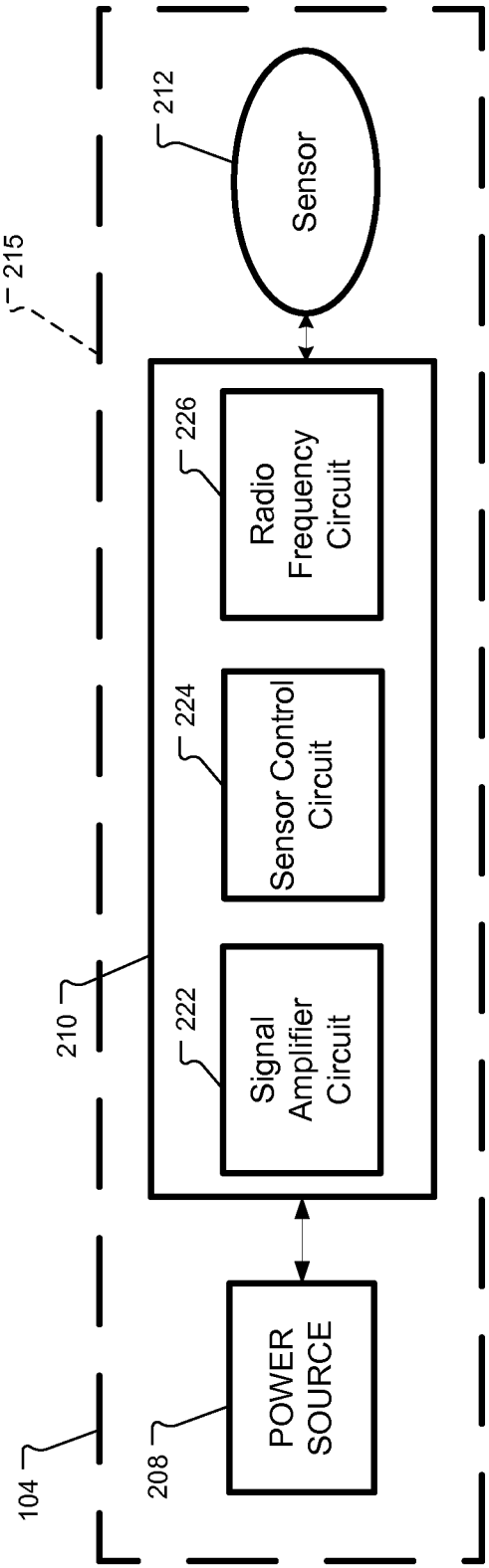
104
208
POWER SOURCE
210
222
Signal Amplifier Circuit
224
Sensor Control Circuit
226
Radio Frequency Circuit
215
212
Sensor

Fig. 4

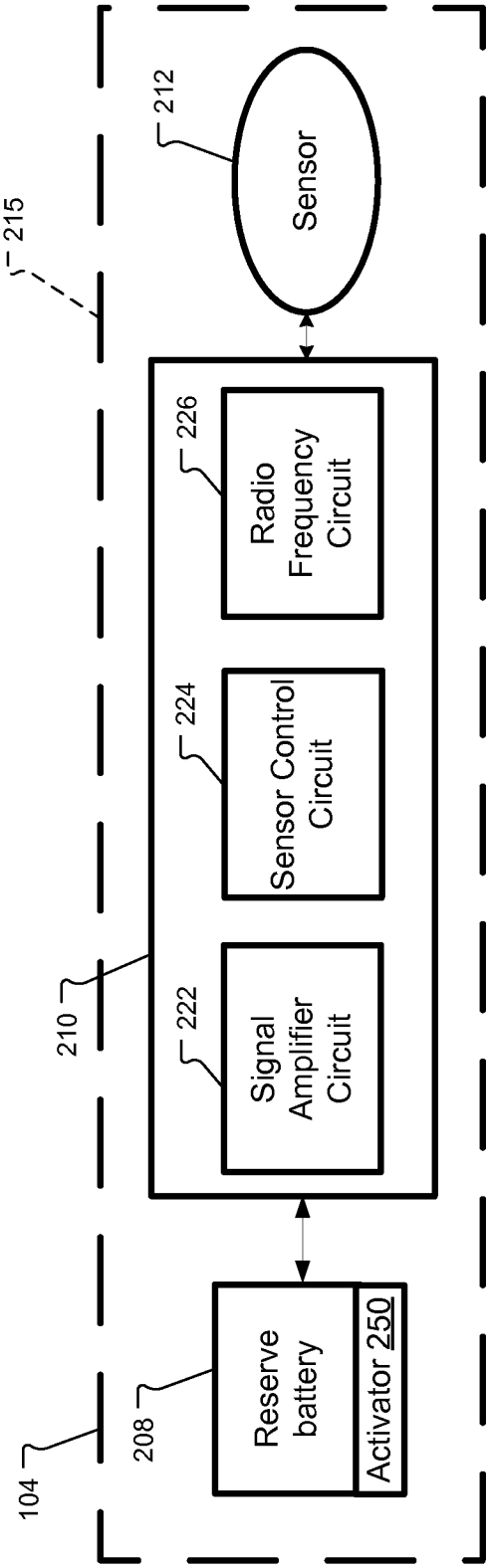
104
208
Reserve battery
Activator 250
210
222
Signal Amplifier Circuit
224
Sensor Control Circuit
226
Radio Frequency Circuit
215
212
Sensor

Fig. 5

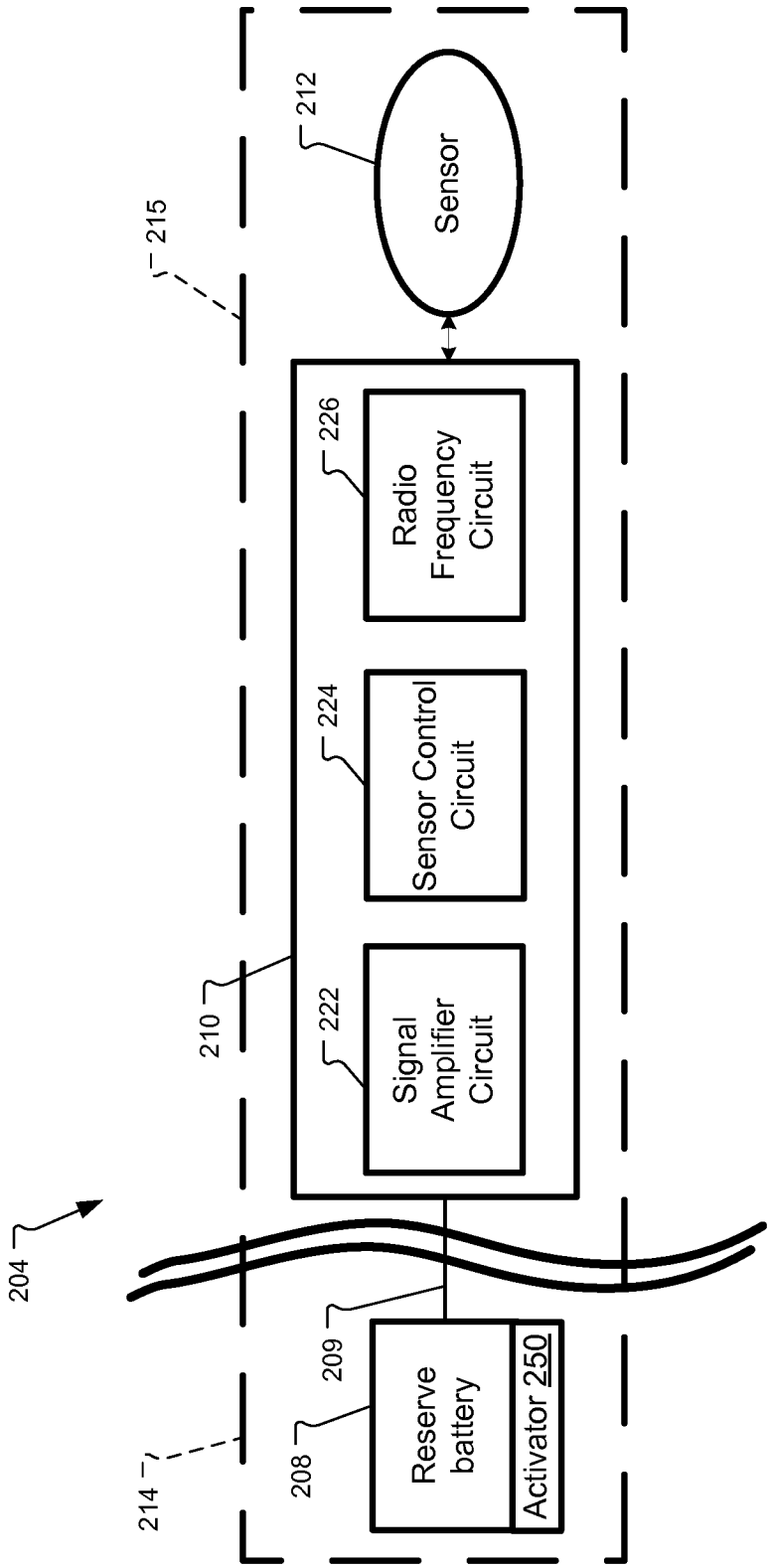
204
214
215
208
209
210
212
222
224
226
Reserve battery
Activator 250
Signal Amplifier Circuit
Sensor Control Circuit
Radio Frequency Circuit
Sensor

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/022863

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/01 A61B5/021 A61B5/0215 A61B5/026
ADD.

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

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)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/32105 A1 (BALL SEMICONDUCTOR INC [US]; ISHIKAWA AKIRA [US]; TAKEDA NABUO [JP]; A) 8 June 2000 (2000-06-08)	1-4,6
Y	page 1, lines 1-4; claims; figures page 4, lines 1-9 page 7, line 14 - page 14, line 12 page 21, lines 20-27	5

X	WO 2010/030882 A1 (ACIST MEDICAL SYS INC [US]; MANSTROM DALE R [US]; RAATIKKA AMY R [US];) 18 March 2010 (2010-03-18) sentences 2,12,36-37,44; claims; figures	1-6

X	WO 2008/075295 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]; PHILIPS CORP [US]; DEKKER RONALD) 26 June 2008 (2008-06-26) page 1, lines 1-3,23-28 page 2, line 17 - page 3, line 22	1-6

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[X] Further documents are listed in the continuation of Box C.

[X] 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 another 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	Date of mailing of the international search report
26 March 2013	17/06/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Mundakapadam, S

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/022863

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/082678 A1 (SMITH LEIF [SE]) 26 March 2009 (2009-03-26) paragraphs [0001], [0029], [0040] - [0042]; claims; figures	1-6
Y	WO 2006/045075 A1 (BOSTON SCIENT SCIMED INC [US]; HASTINGS ROGER N [US]; SADASIVA ANUPAMA) 27 April 2006 (2006-04-27)	5
A	page 5, lines 6-11; claims; figures page 36, lines 8-21	1-4,6

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2013/022863

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0032105 A1	08-06-2000	AU 2032400 A	19-06-2000
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		WO 2006045075 A1	27-04-2006

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6

   directed to various sensors of a sensor wire system.

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2. claims: 12-17

   directed to a sensor wire body that functions as a radio frequency antenna.

   ---

3. claims: 7-11

   directed to power sources of a sensor wire system.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/022863

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18-27
because they relate to subject matter not required to be searched by this Authority, namely:

Methods of treatment of the human body by surgery (Rule 39.1(iv) PCT)

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-6

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.