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(54) **STEERABLE GUIDE WIRE WITH PRESSURE SENSOR AND METHODS OF USE**

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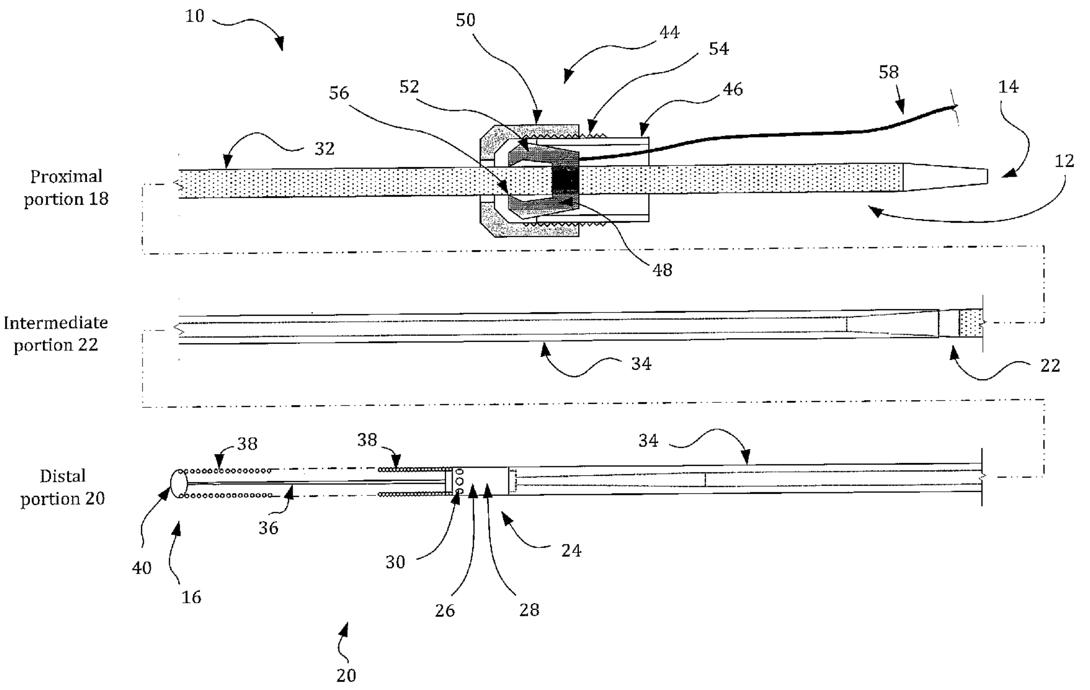
(52) **U.S. Cl.**

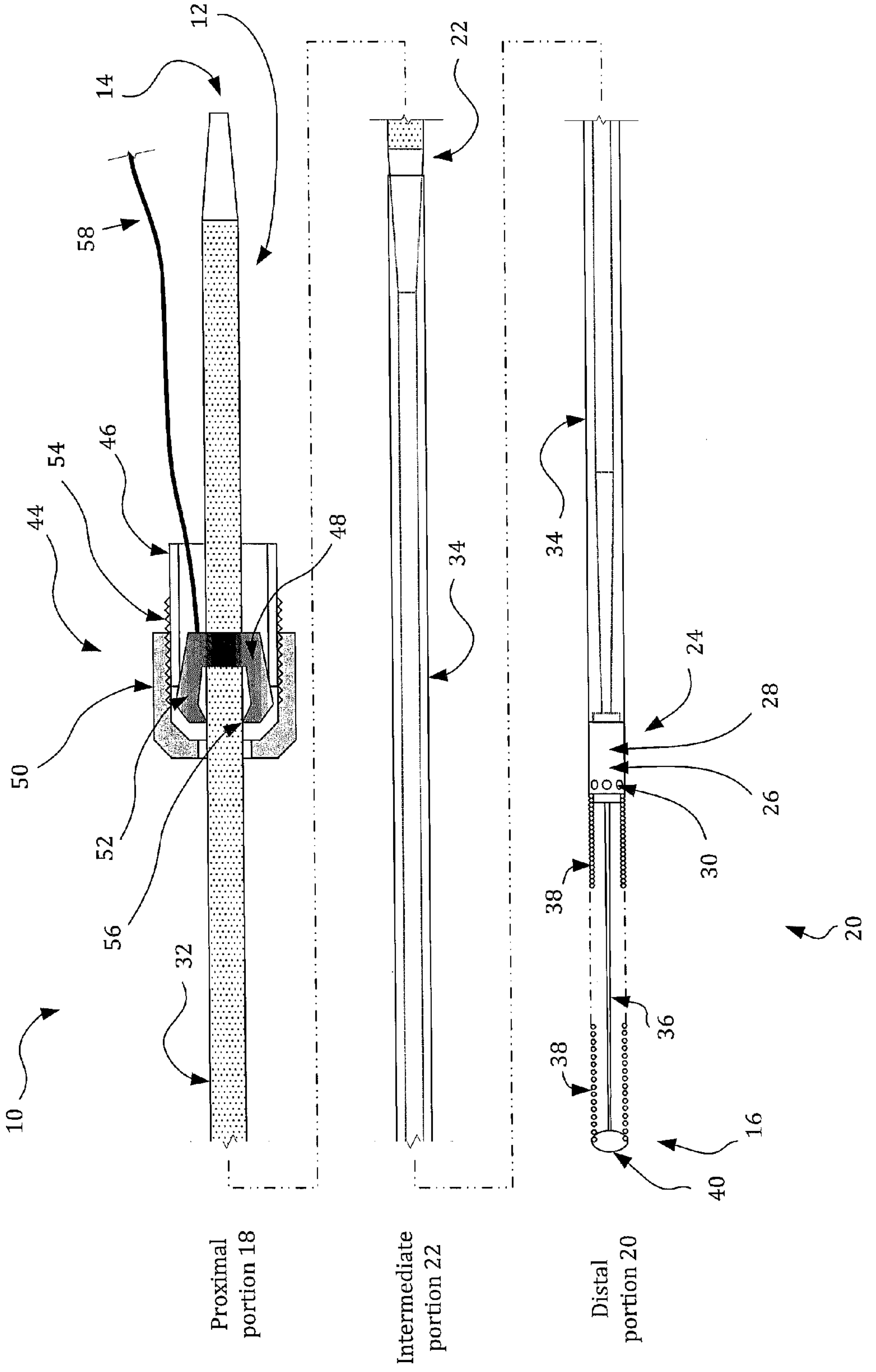
CPC ***A61B 5/6851*** (2013.01); ***A61B 5/0215*** (2013.01); ***A61B 5/02141*** (2013.01)

USPC **600/488**; 600/585

(57) **ABSTRACT**

A high performance guide wire with a pressure sensor for measuring blood pressure, may utilize a single electrical lead connected to the guide wire. An integrated circuit, powered by the single electrical connection on the guide wire, may interface with the pressure sensor, and may convert pressure information to an encoded signal. The encoded signal may be detectable in the electrical circuit, and can be used to display a pressure waveform as detected by the pressure sensor. For example, when utilized for percutaneous coronary interventions, such a guide wire can provide high quality blood pressure measurements (e.g., for fractional flow reserve), while also possessing excellent steerability and handling characteristics for navigating tortuous anatomy.




10
12
14
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54
46
48
50
52
56
32
22
34
34
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28
26
30
38
36
38
16
40
20
Proximal portion 18
Intermediate portion 22
Distal portion 20

FIG. 1

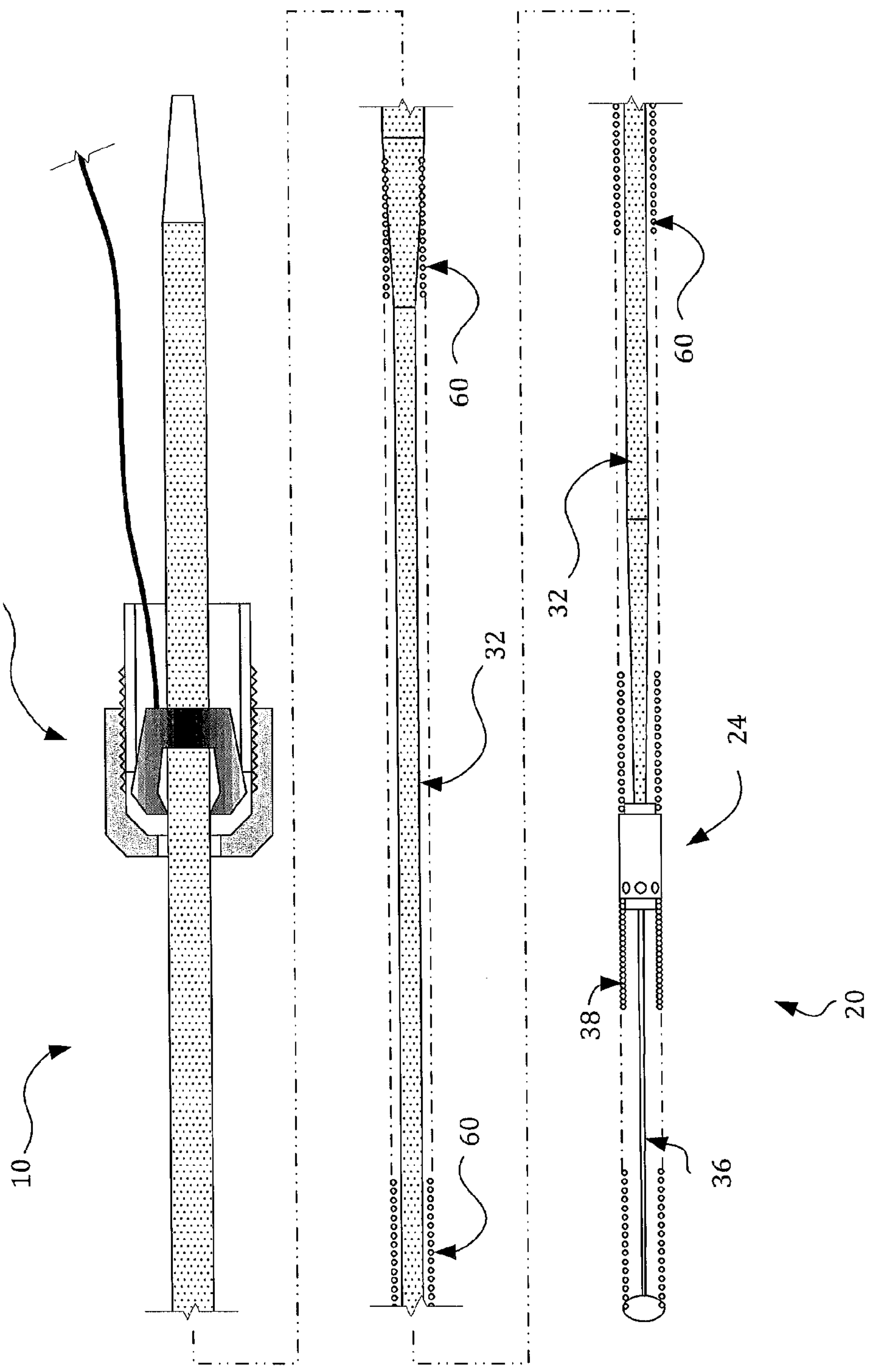


FIG. 2

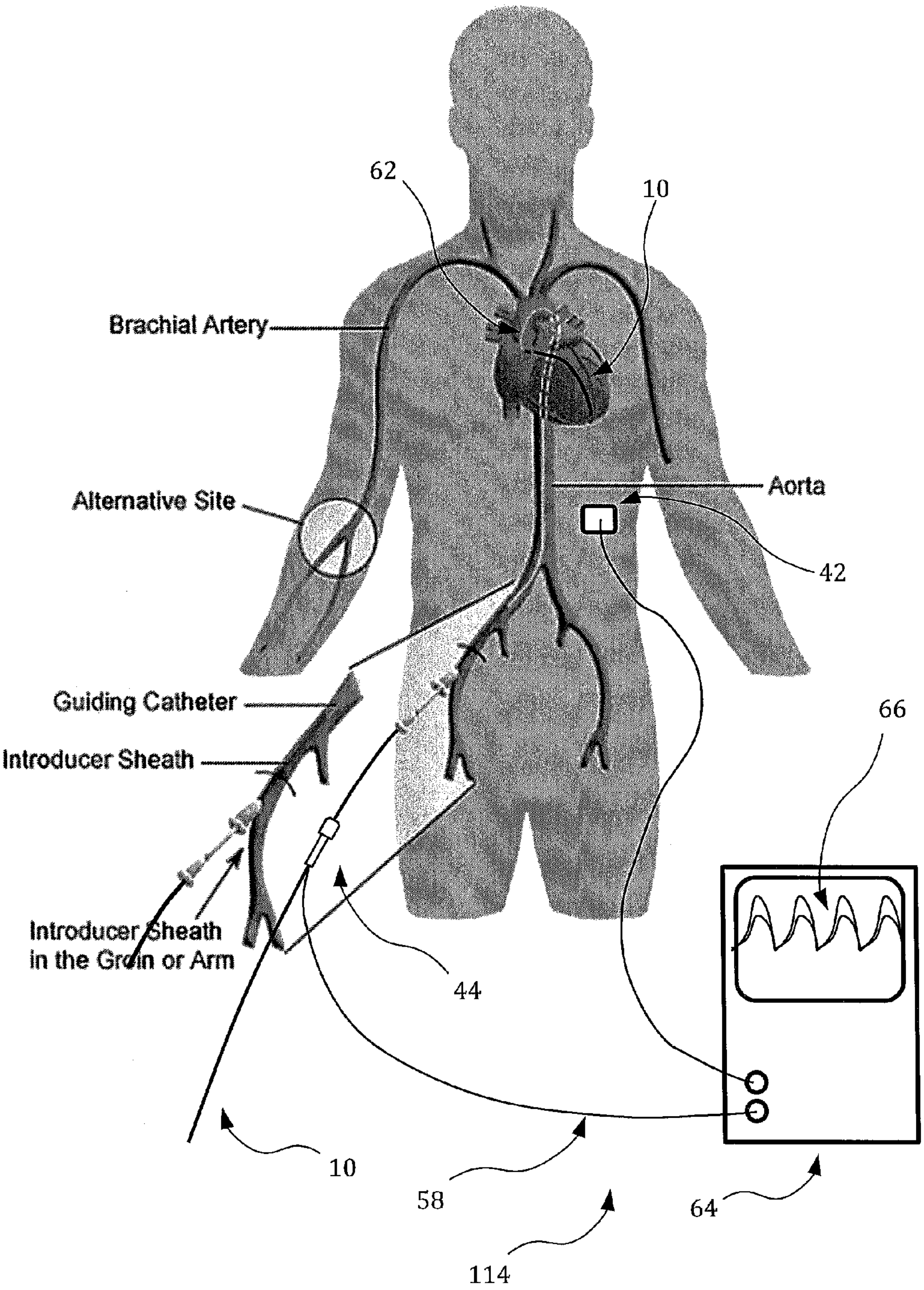

62
10
Brachial Artery
Alternative Site
Aorta
42
Guiding Catheter
Introducer Sheath
66
Introducer Sheath in the Groin or Arm
44
10
58
64
114

FIG. 3

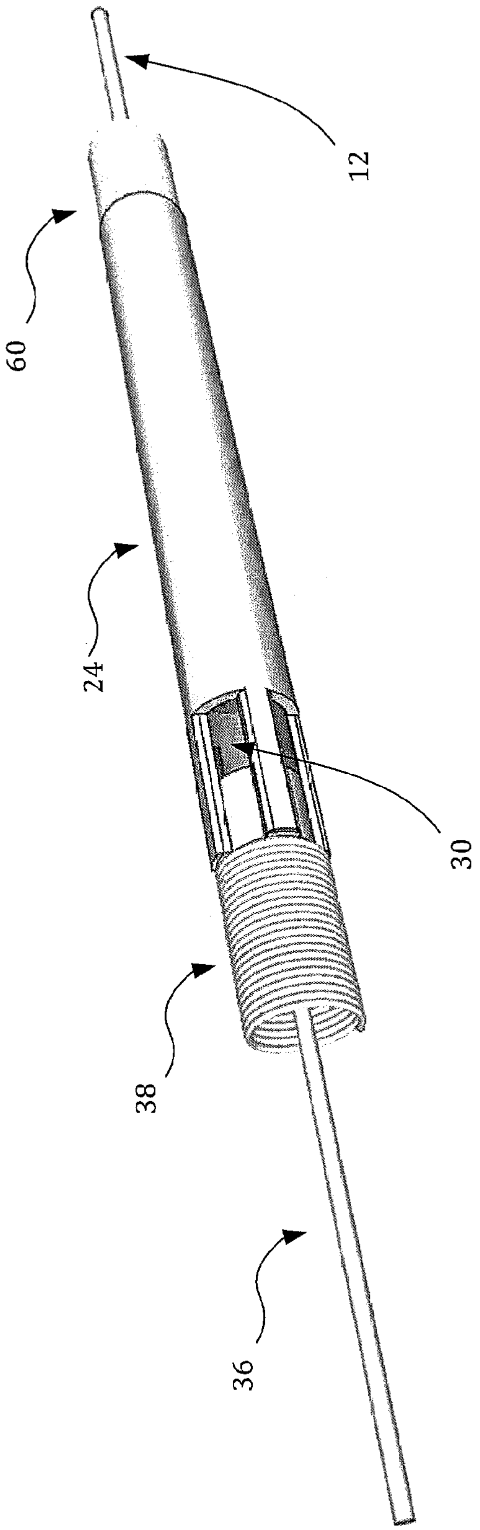


FIG. 4

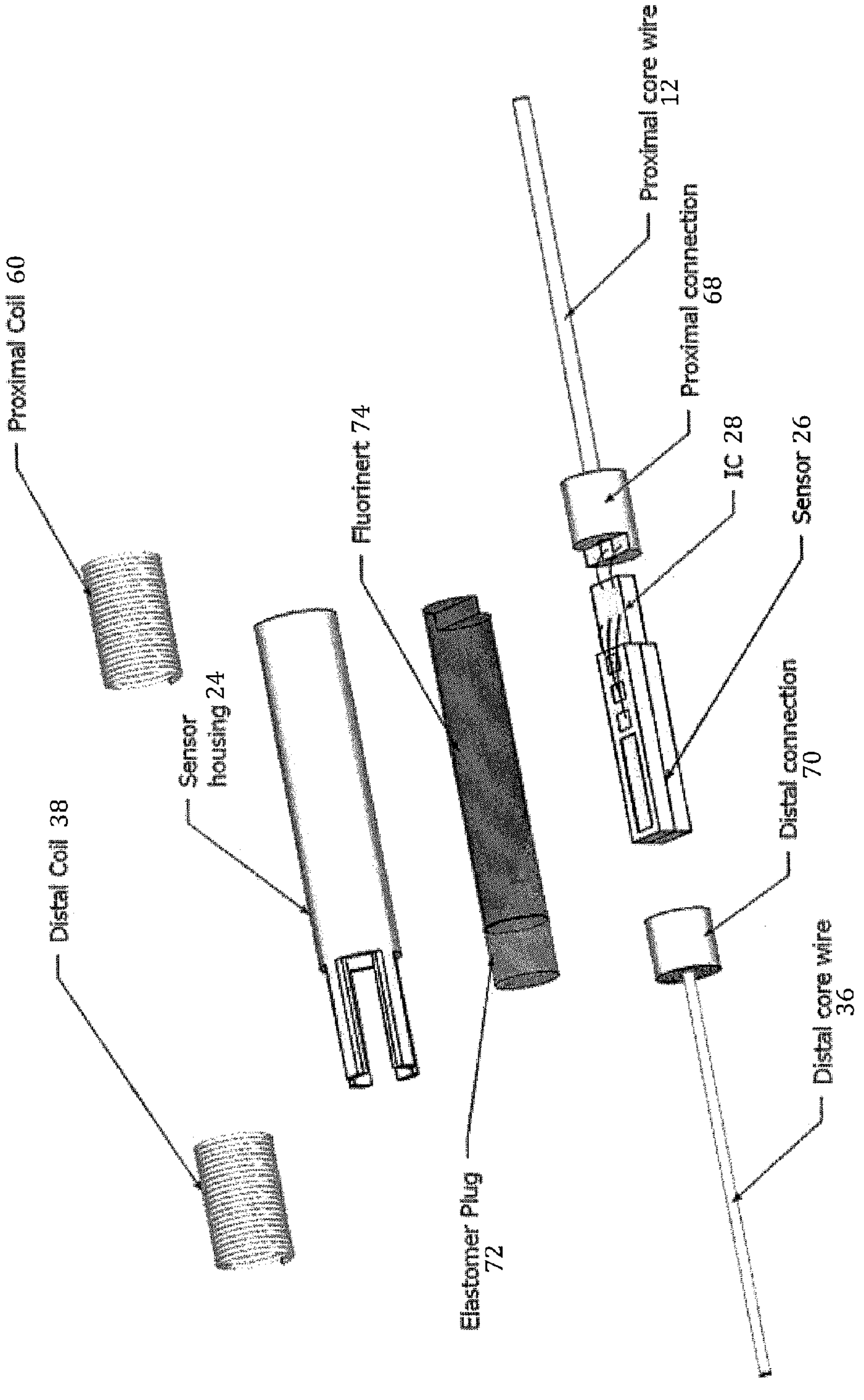

Proximal Coil 60
Distal Coil 38
Sensor housing 24
Fluorinert 74
Elastomer Plug 72
Proximal core wire 12
Proximal connection 68
IC 28
Sensor 26
Distal connection 70
Distal core wire 36

FIG. 5

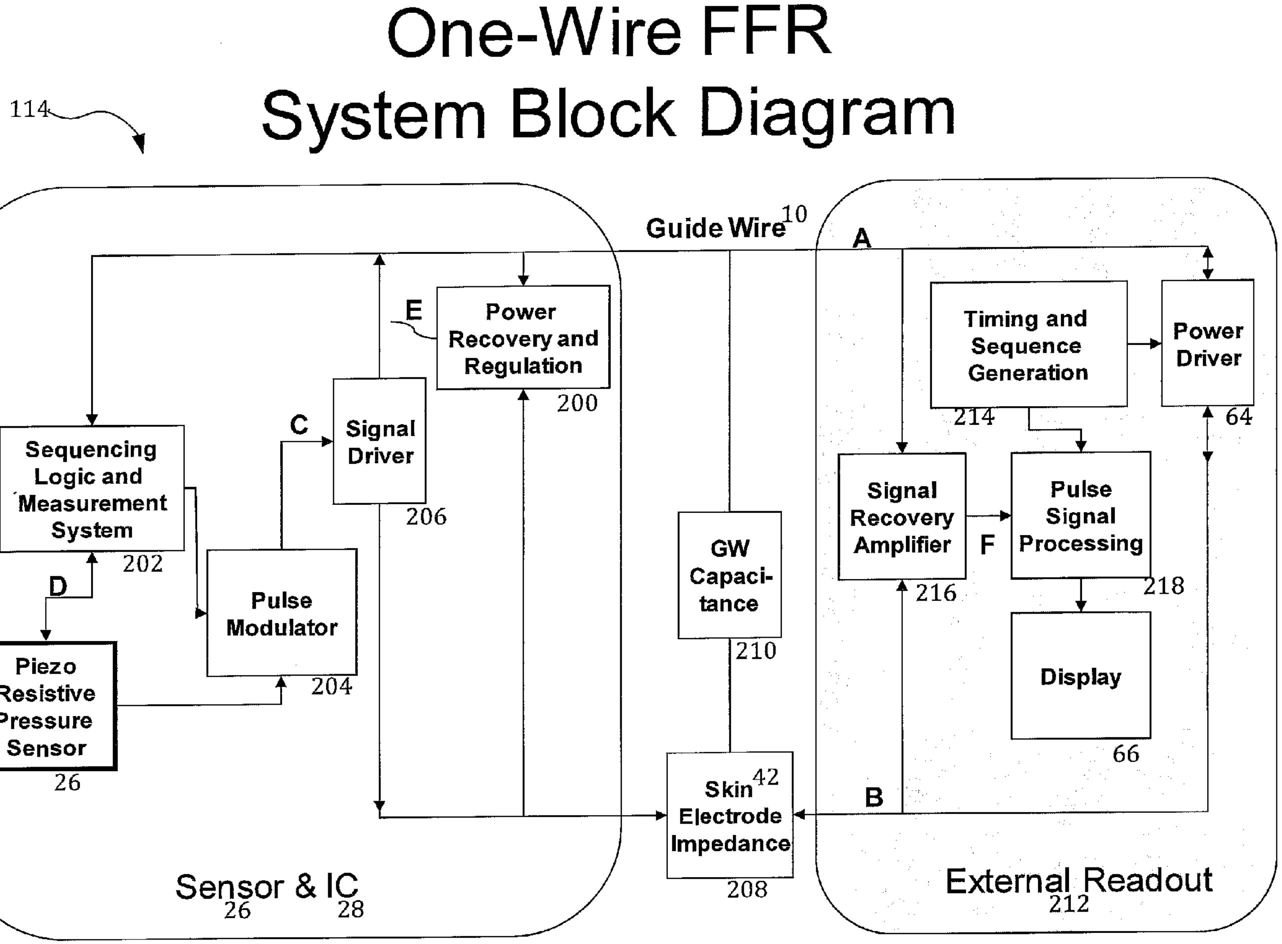

One-Wire FFR
System Block Diagram
114
Guide Wire
10
A
B
C
D
E
F
Sequencing Logic and Measurement System
202
Piezo Resistive Pressure Sensor
26
Pulse Modulator
204
Signal Driver
206
Power Recovery and Regulation
200
Sensor & IC
26
28
GW Capaci-tance
210
Skin Electrode Impedance
42
208
Timing and Sequence Generation
214
Power Driver
64
Signal Recovery Amplifier
216
Pulse Signal Processing
218
Display
66
External Readout
212

FIG. 6

Waveforms 1 – Nodes A to B and C Guide Wire and Digitized Sensor Signals

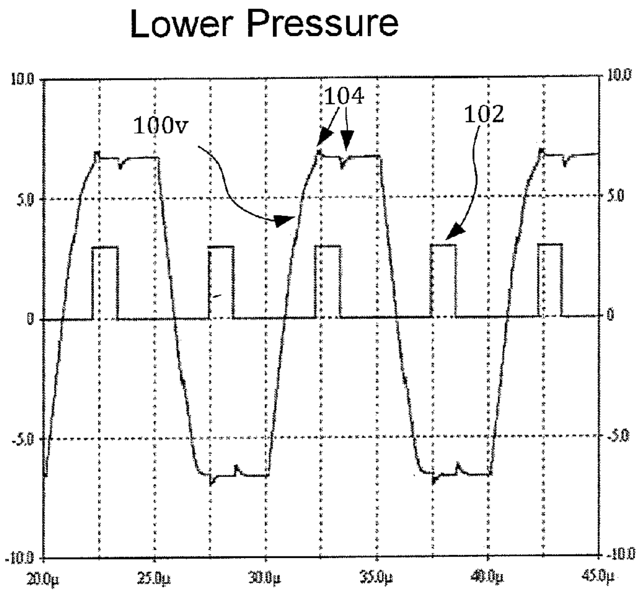


FIG. 7a

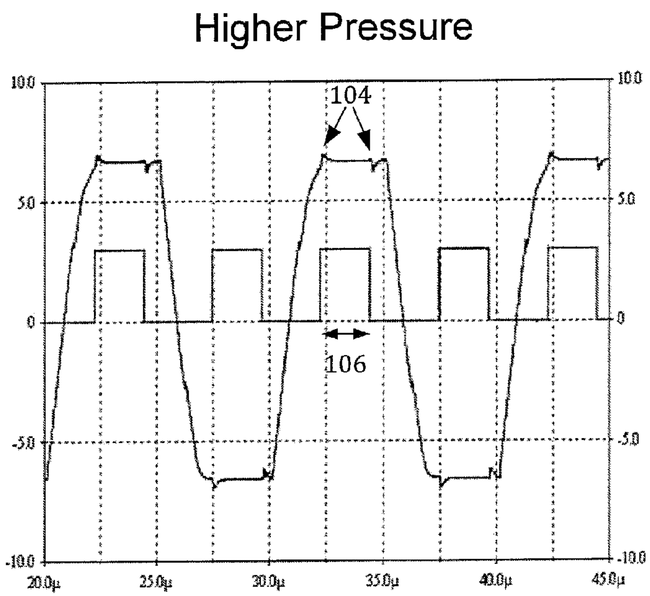


FIG. 7b

Waveforms 2 – Nodes A to B and E Guide Wire and Power Supply Voltage

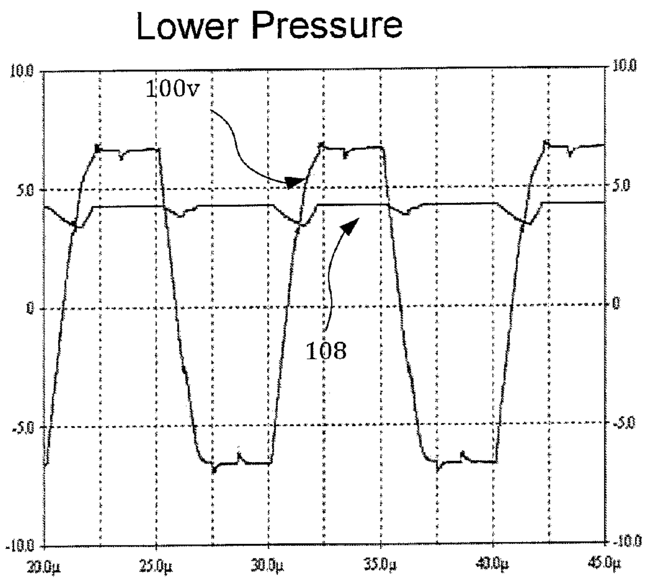


FIG. 8a

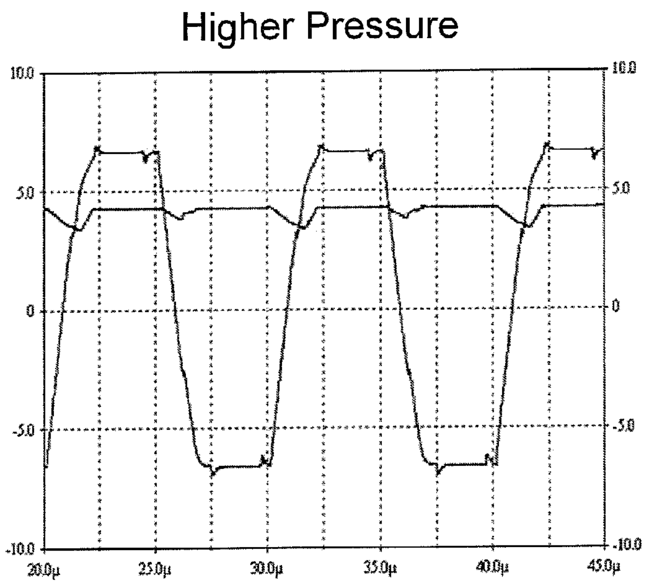


FIG. 8b

Waveforms 3 - Nodes C and D Sensor Digitizing Waveform

Lower Pressure

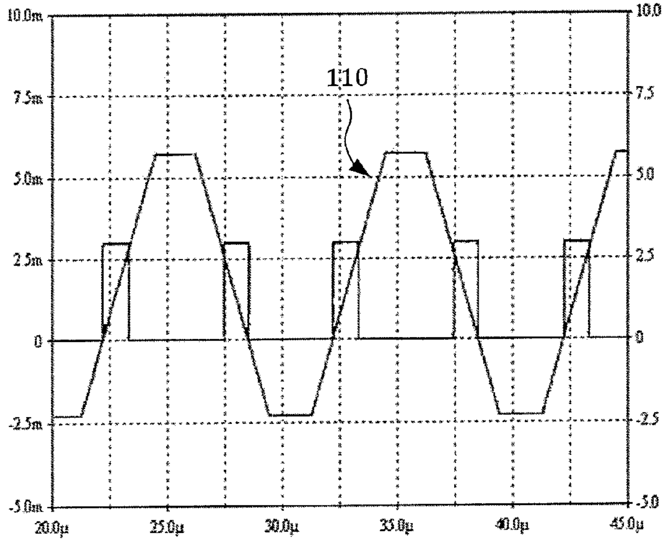


FIG. 9a

Higher Pressure

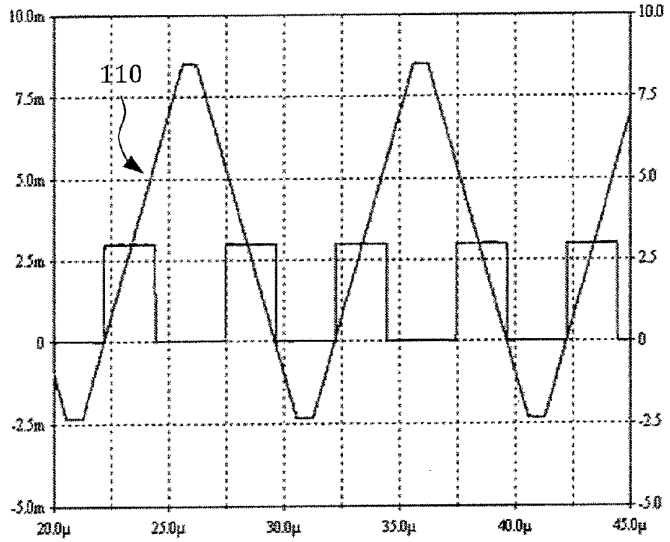


FIG. 9b

Waveforms 4 – Nodes E and F Sensor Pulse and Recovered Pulse

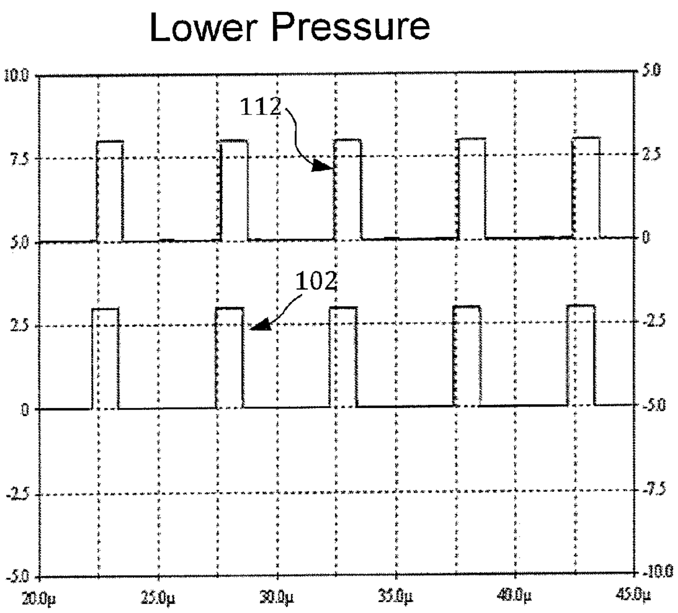

Lower Pressure

FIG. 10a

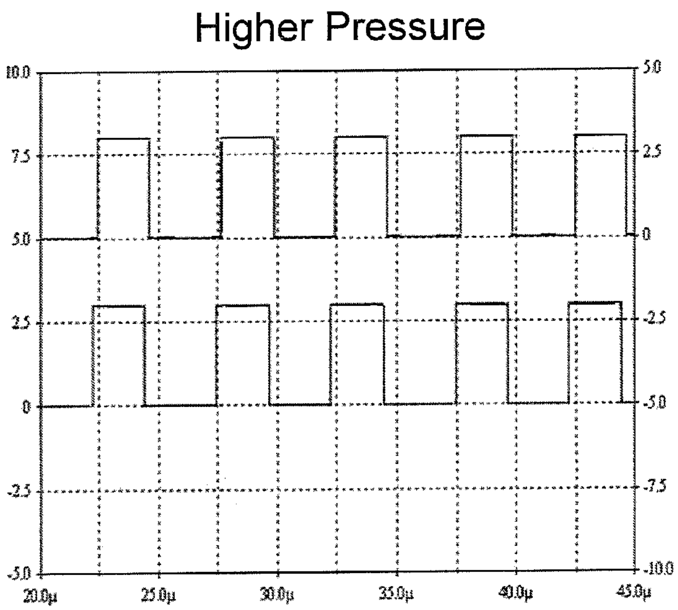

Higher Pressure

FIG. 10b

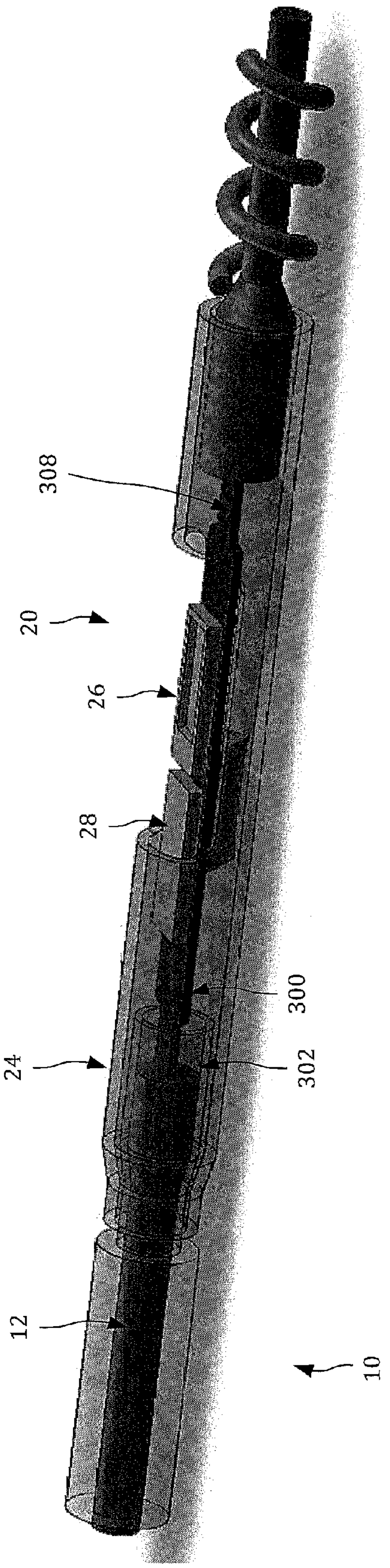


FIG. 11a

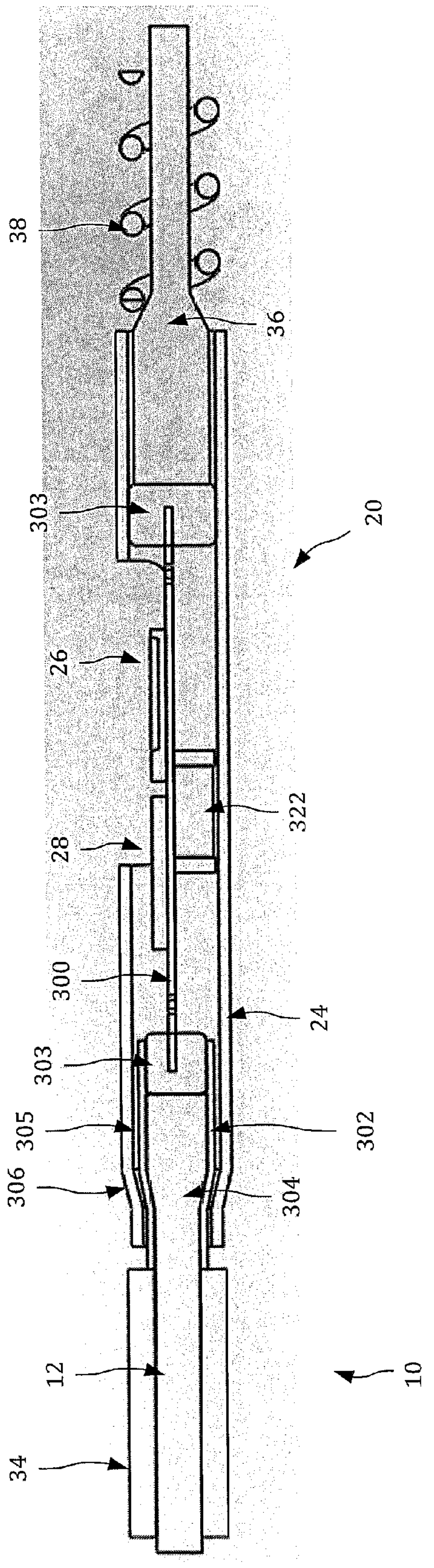


FIG. 11b

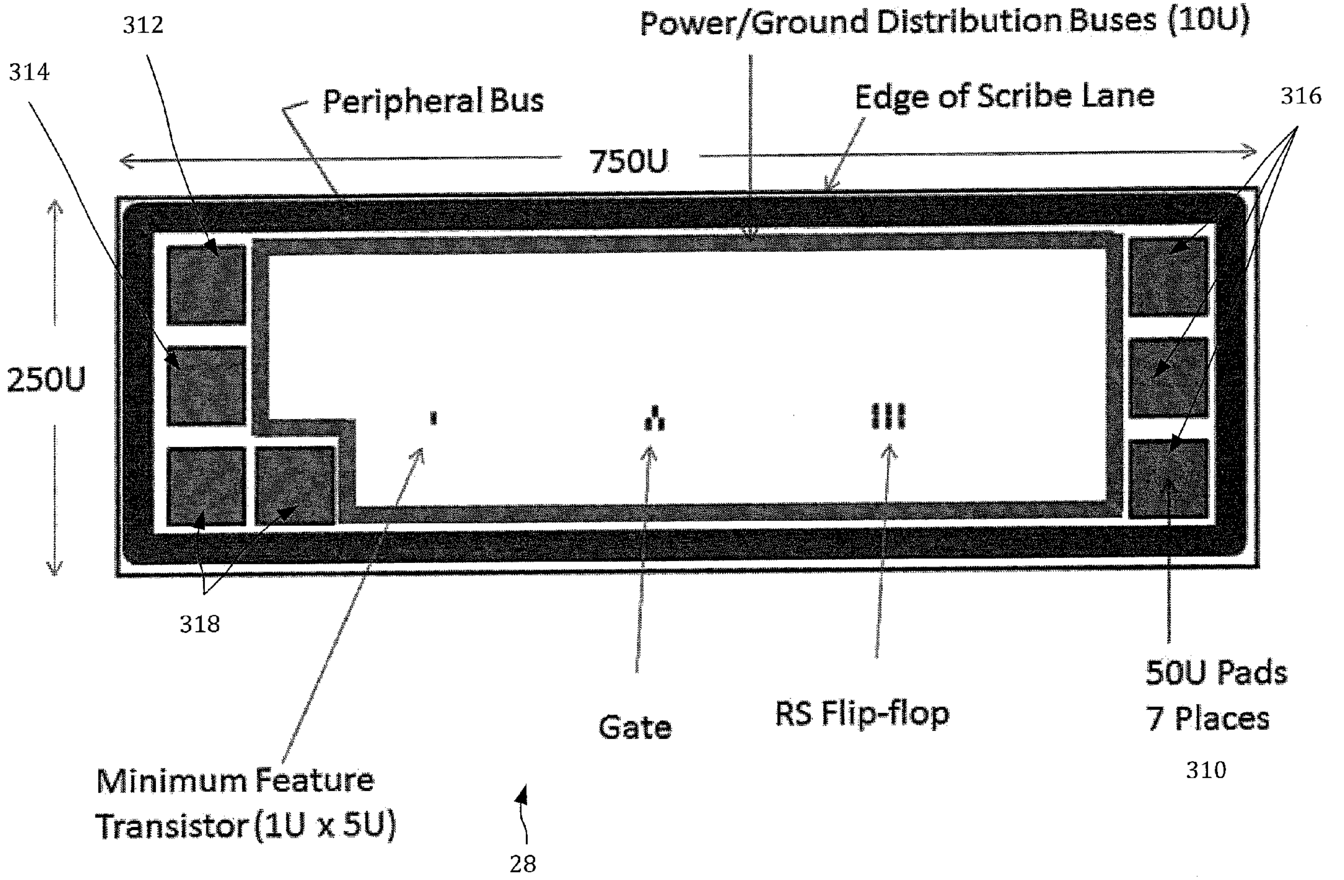

312
314
Peripheral Bus
Power/Ground Distribution Buses (10U)
Edge of Scribe Lane
316
750U
250U
318
Minimum Feature
Transistor (1U x 5U)
28
Gate
RS Flip-flop
50U Pads
7 Places
310

FIG. 12

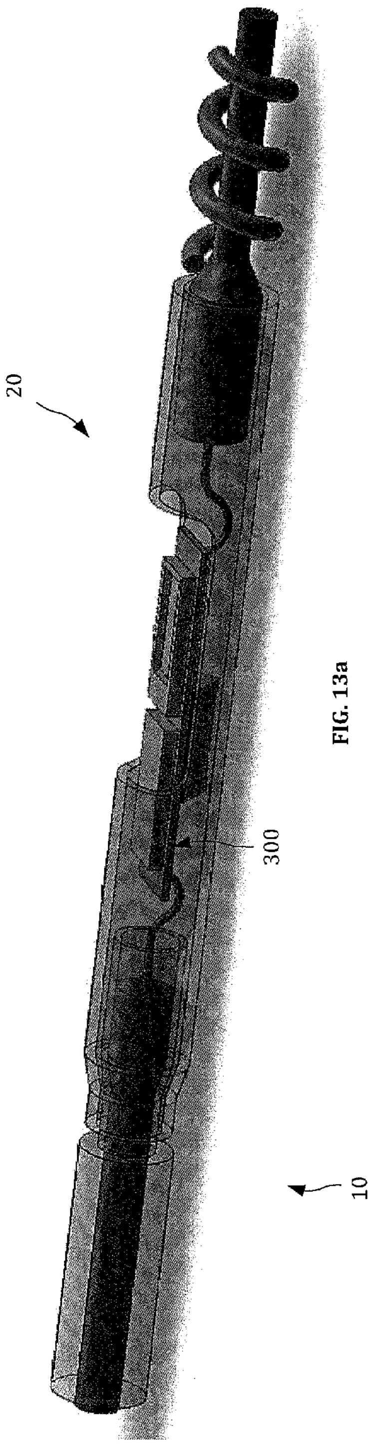


FIG. 13a

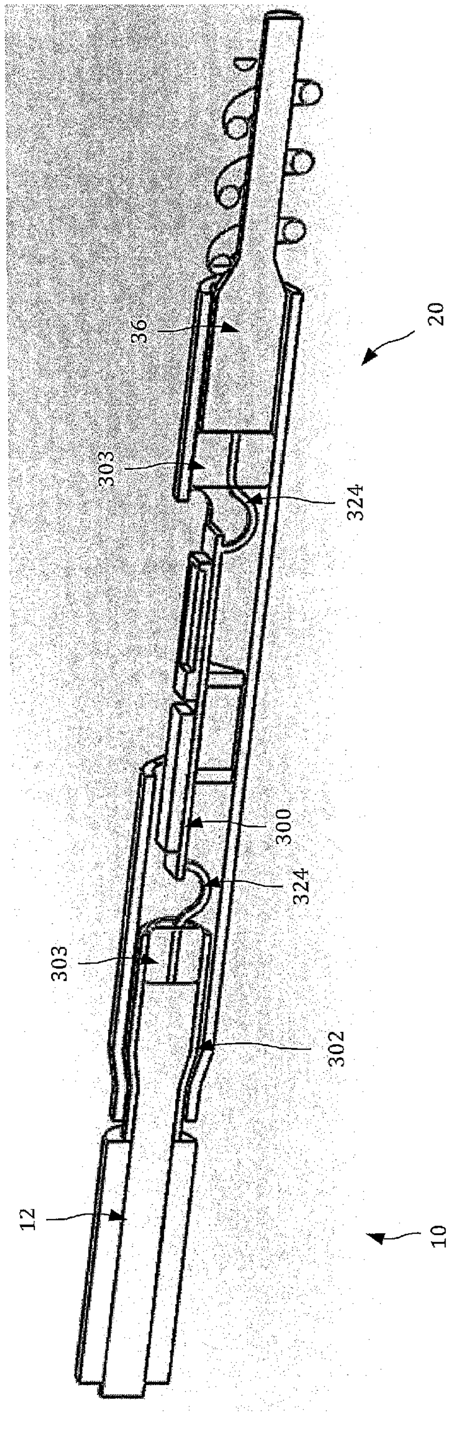


FIG. 13b

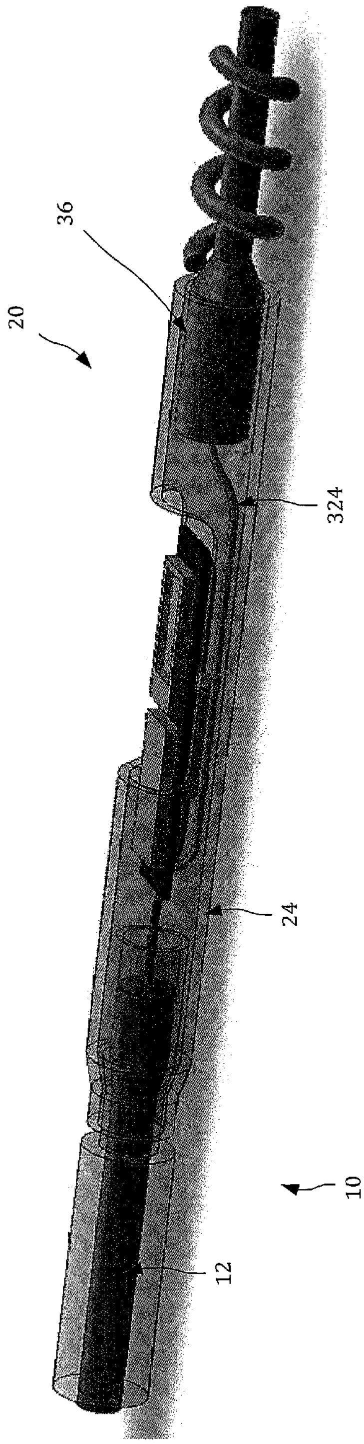


FIG. 14a

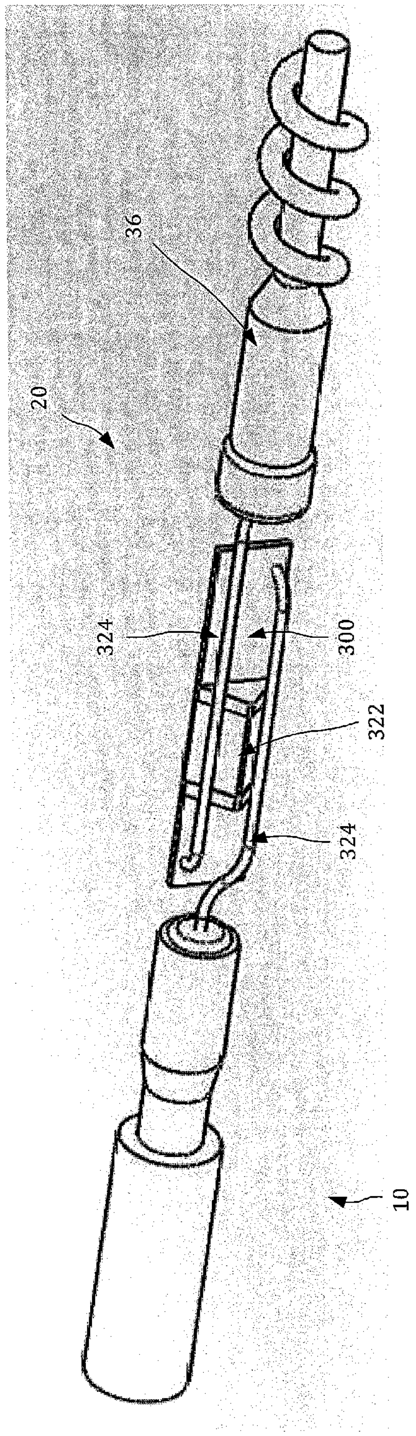


FIG. 14b

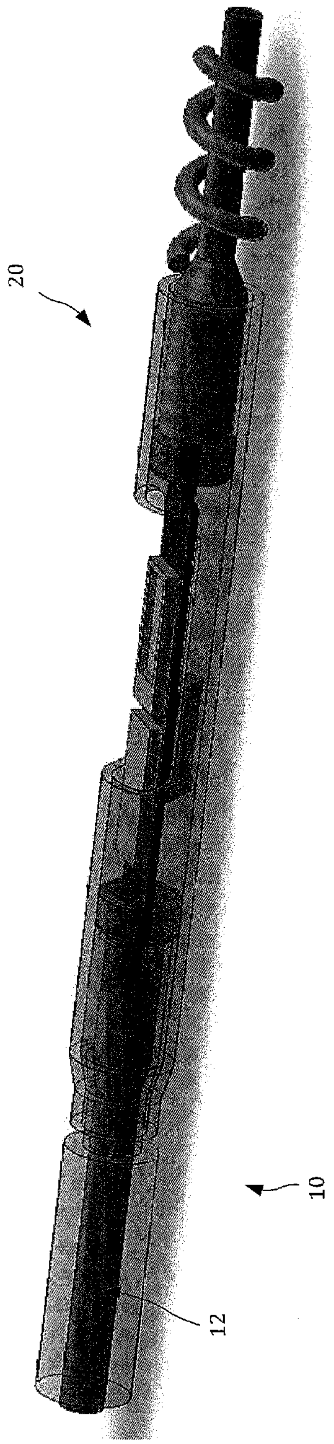


FIG. 15a

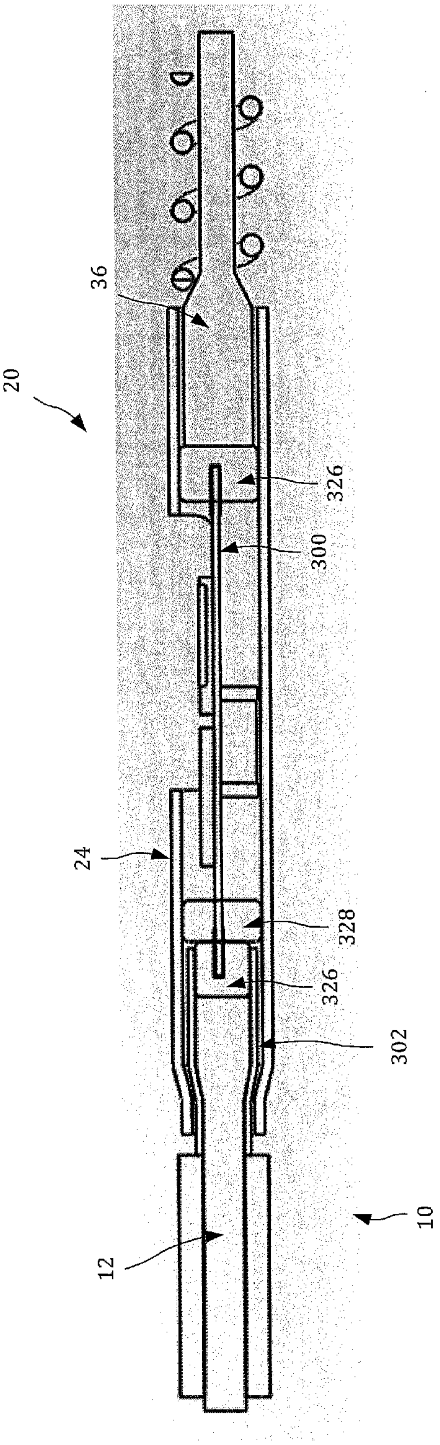


FIG. 15b

FIG. 16a

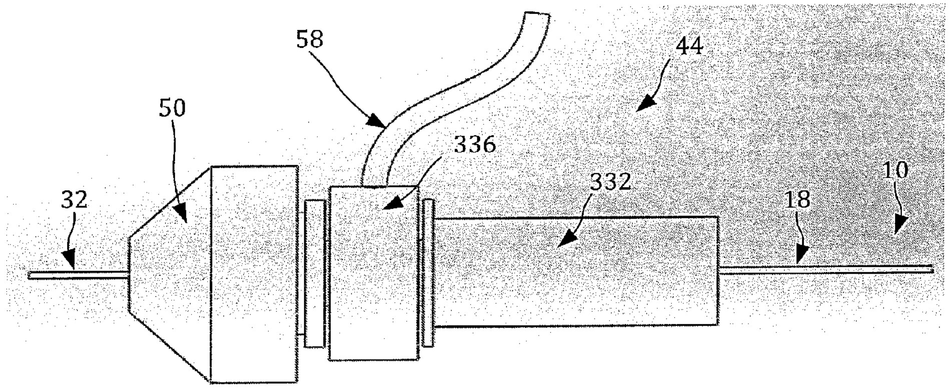
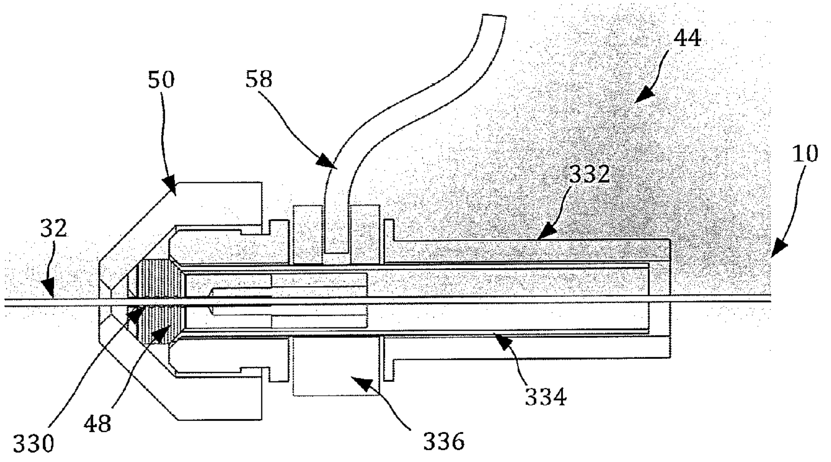


FIG. 16b



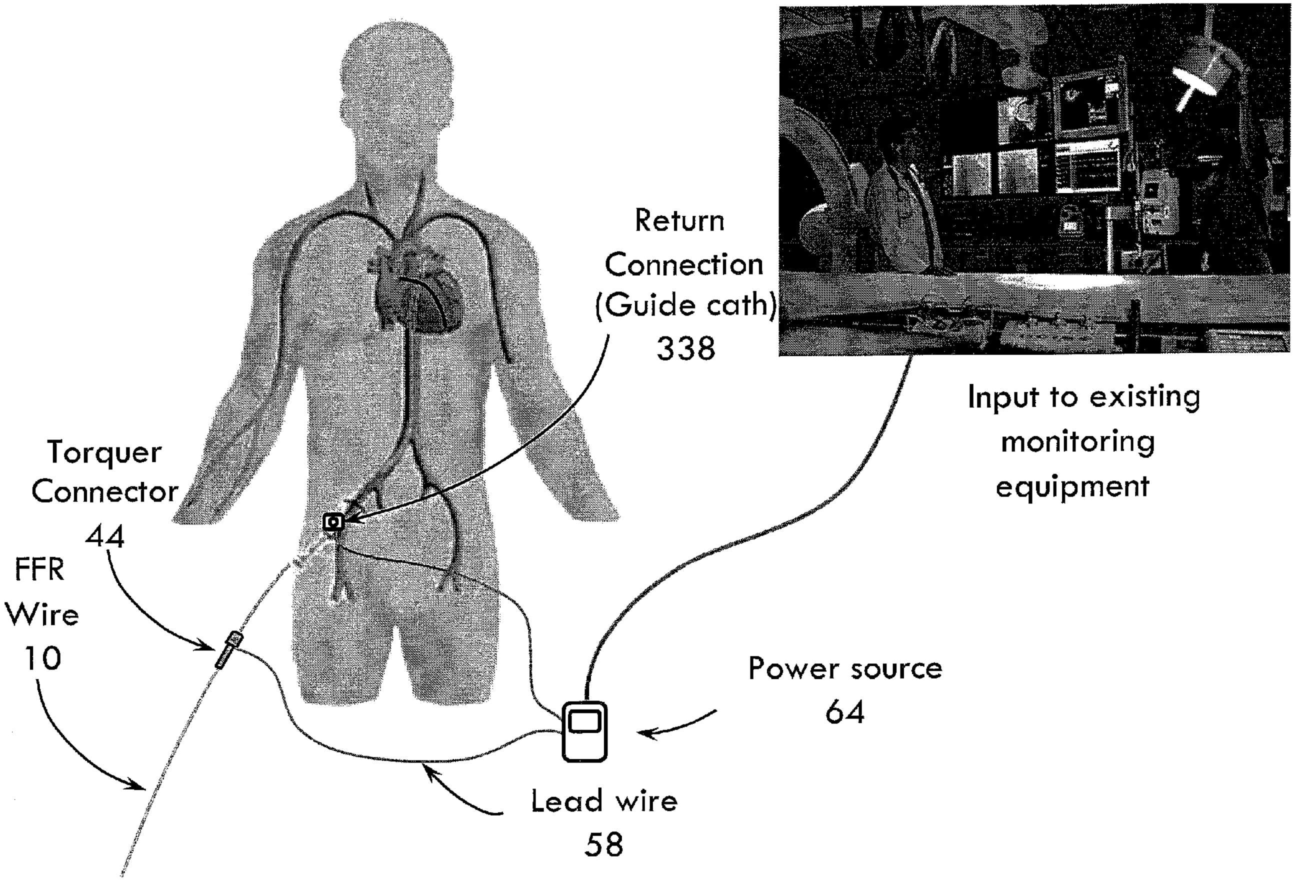

Return
Connection
(Guide cath)
338
Input to existing
monitoring
equipment
Torquer
Connector
44
FFR
Wire
10
Power source
64
Lead wire
58

FIG. 17

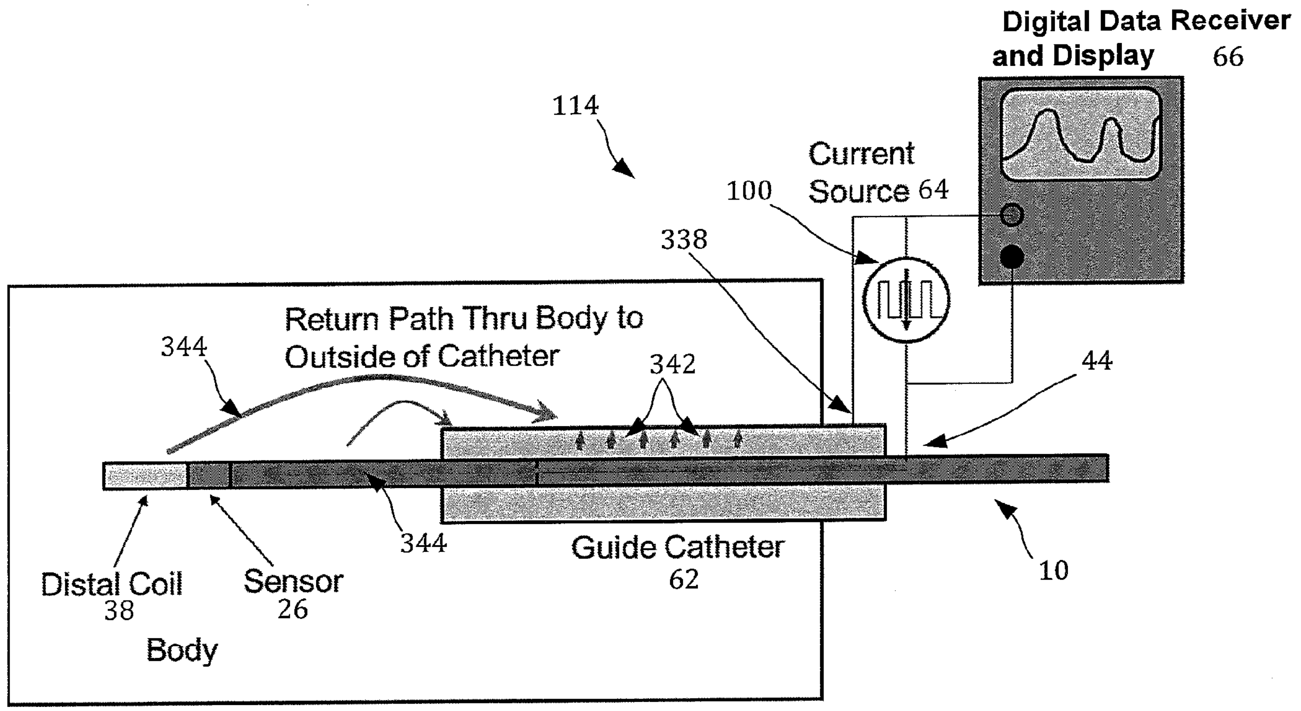

Digital Data Receiver
and Display 66
114
Current
Source 64
100
338
Return Path Thru Body to
Outside of Catheter
344
342
44
344
Guide Catheter
62
10
Distal Coil
38
Sensor
26
Body

FIG. 18

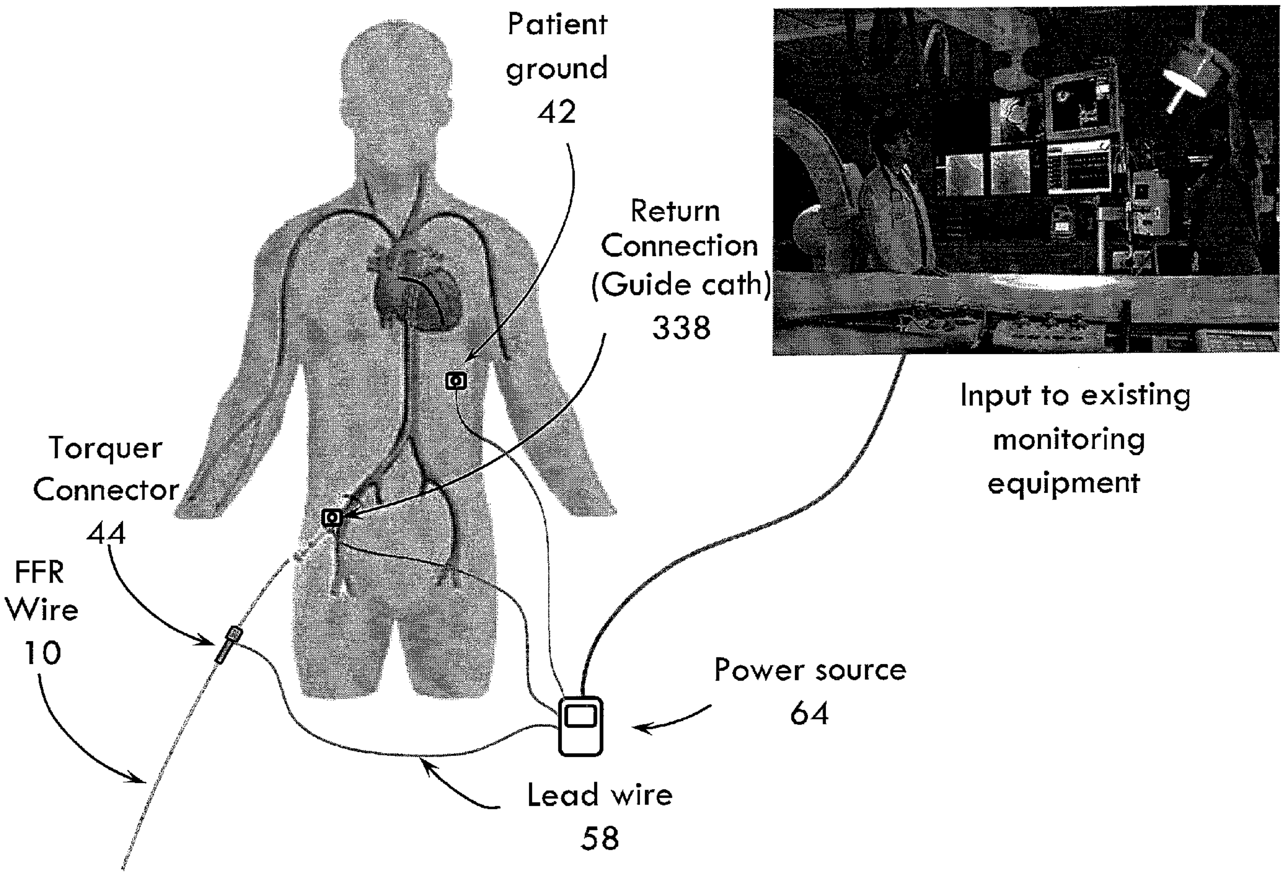

Patient
ground
42
Return
Connection
(Guide cath)
338
Input to existing
monitoring
equipment
Torquer
Connector
44
FFR
Wire
10
Power source
64
Lead wire
58

FIG. 19

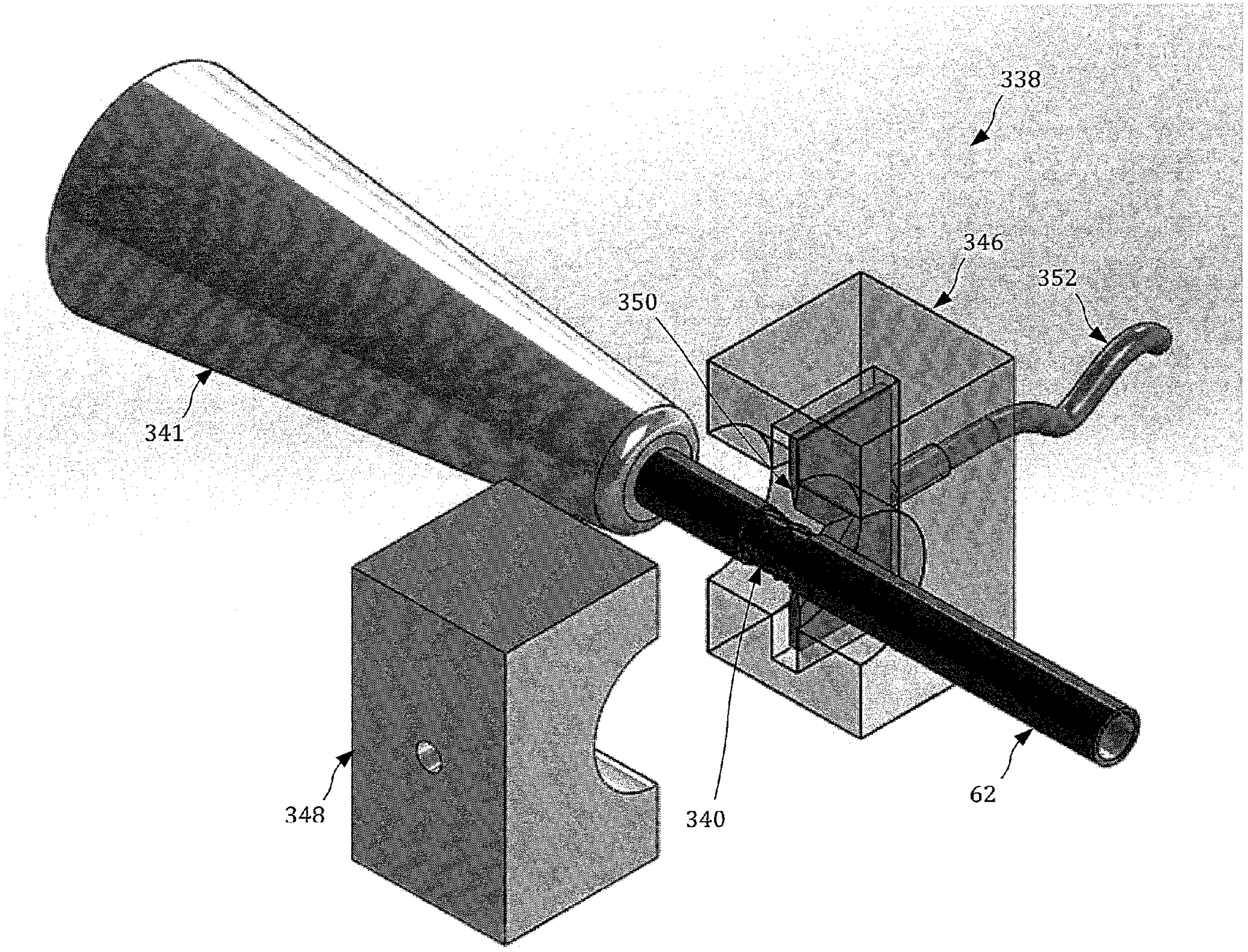


FIG. 20A

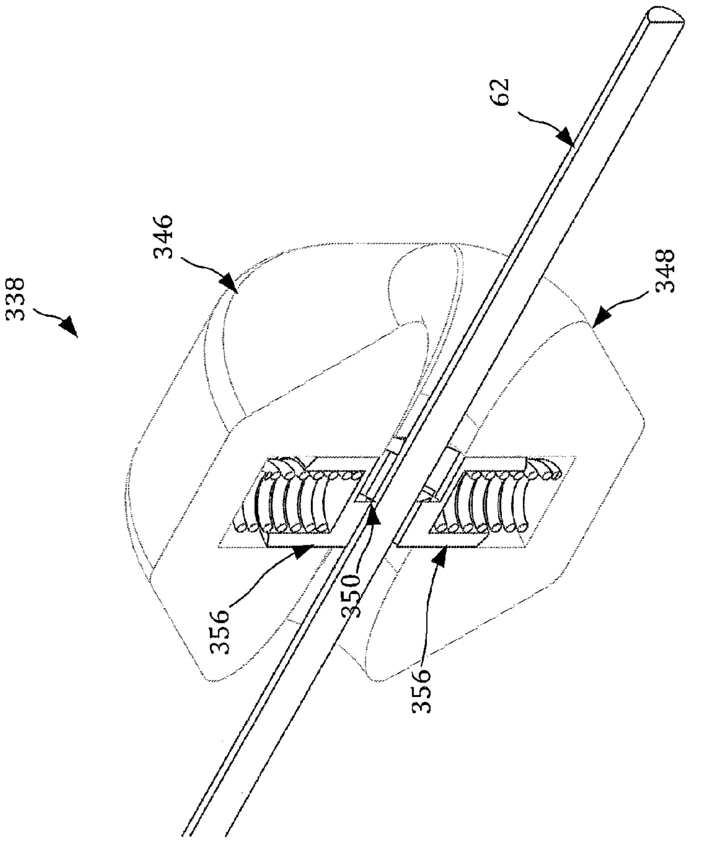


FIG. 20C

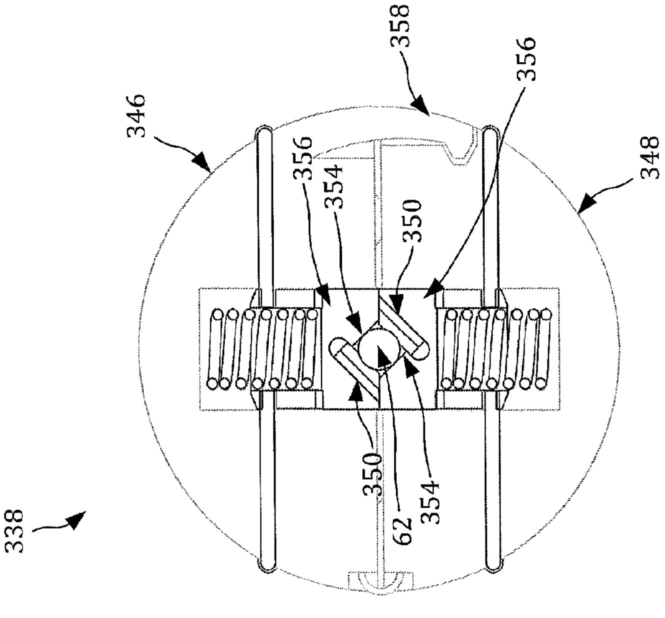


FIG. 20B

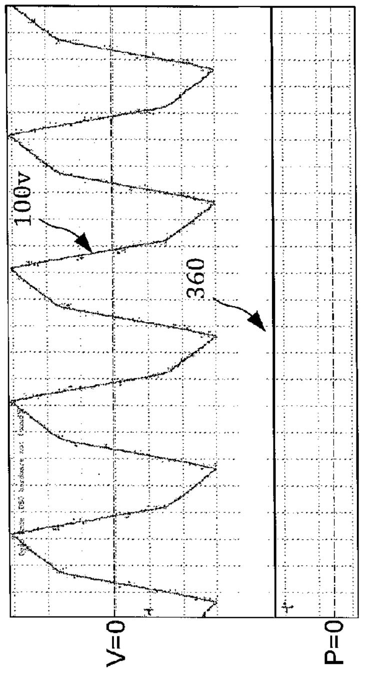


FIG. 21A

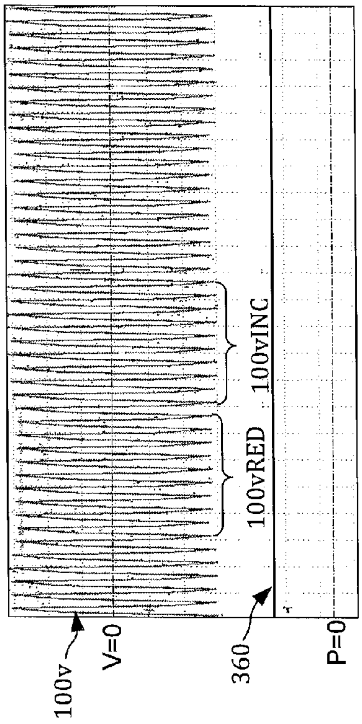


FIG. 21B

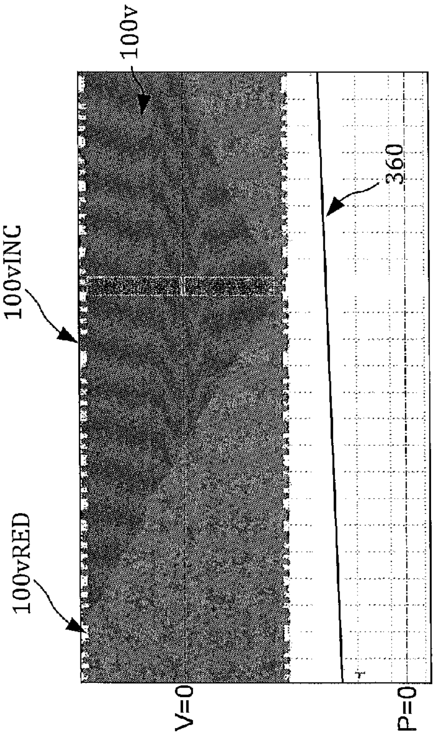


FIG. 21C

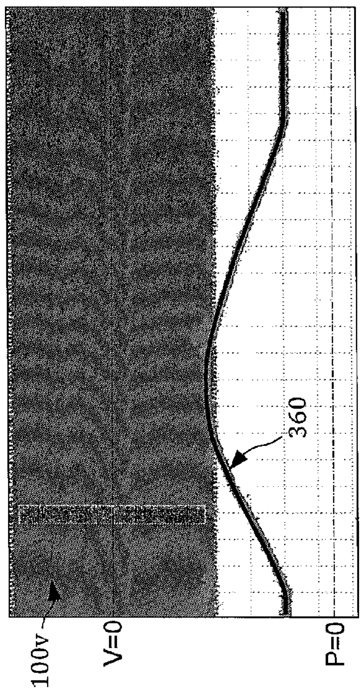


FIG. 21D

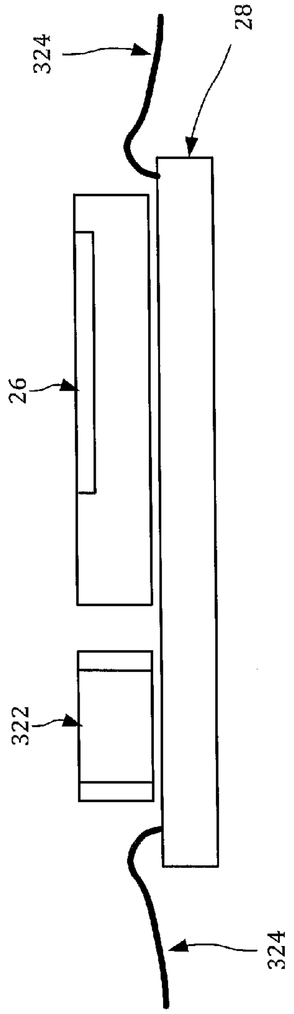


FIG. 22A

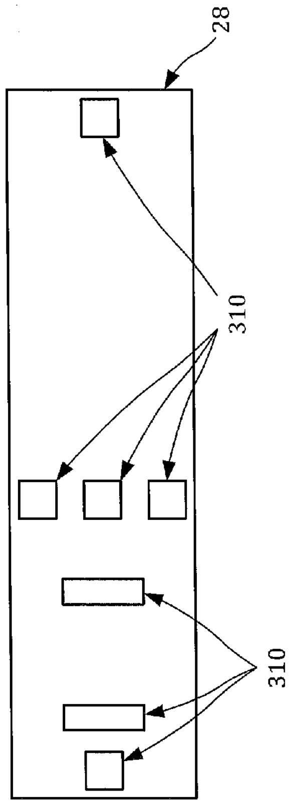


FIG. 22B

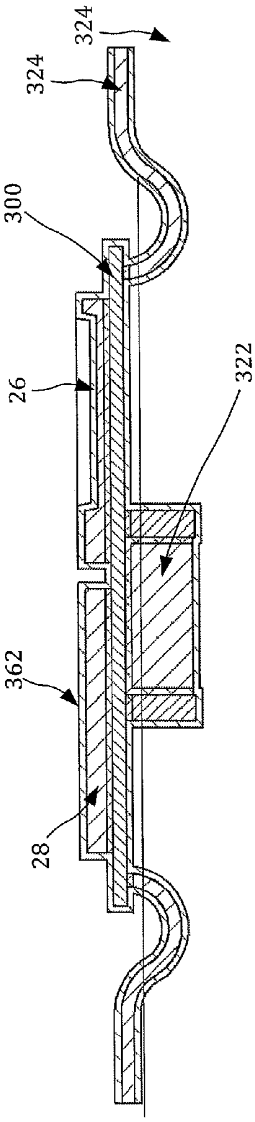


FIG. 22C

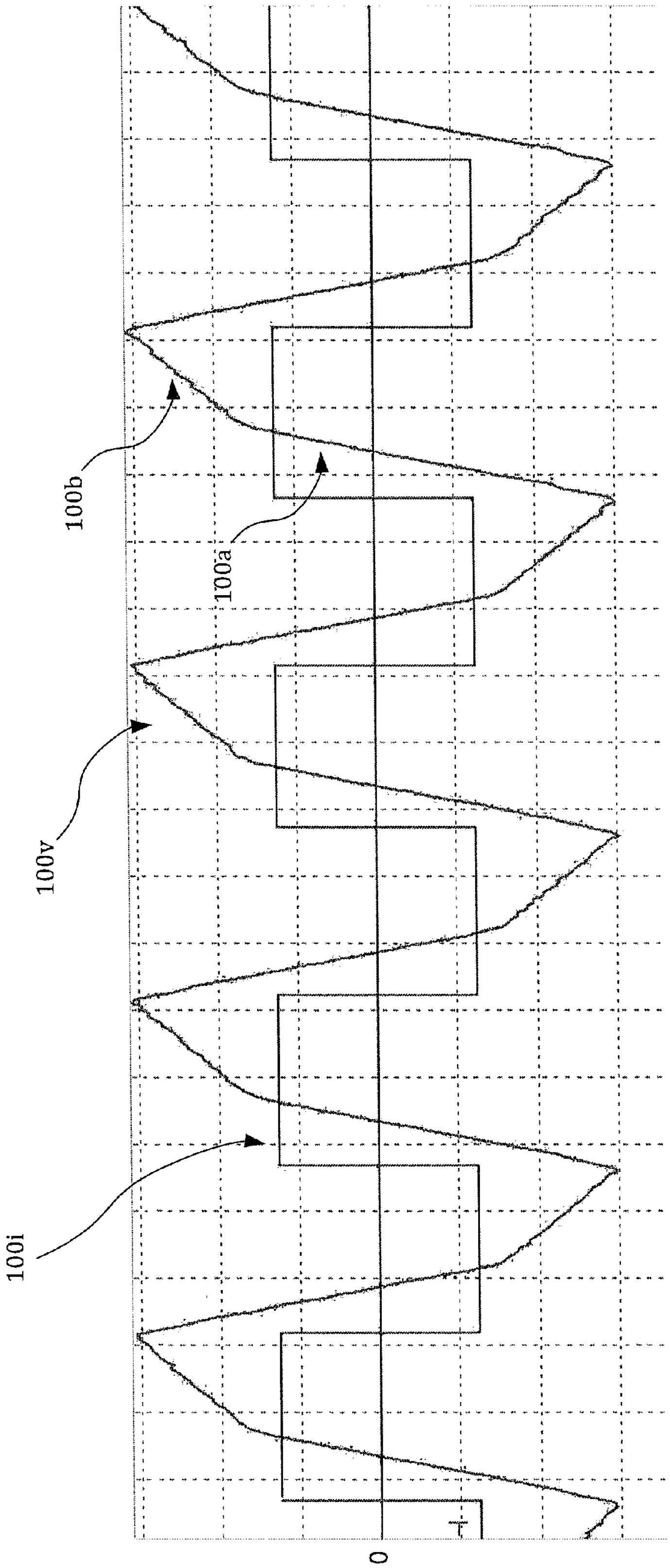


FIG. 23

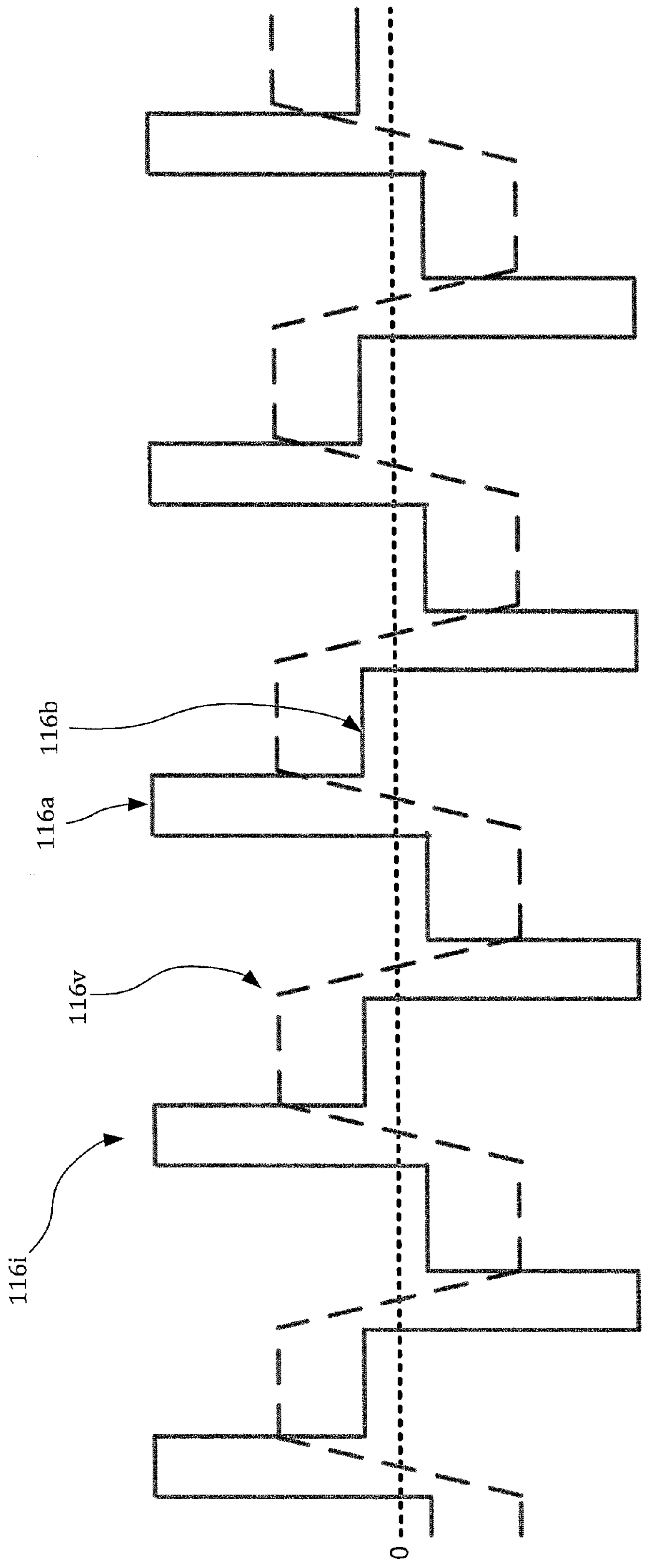


FIG. 24

STEERABLE GUIDE WIRE WITH PRESSURE SENSOR AND METHODS OF USE

[0001] This application claims the benefit of priority under 35 U.S.C. §119(e) of U.S. Provisional Application No. 61/564,151, filed Nov. 28, 2011, the entire contents of which are incorporated herein by reference.

TECHNICAL FIELD

[0002] Various embodiments of the present disclosure relate generally to medical devices and related methods. More specifically, particular embodiments of the present disclosure relate to a guide wire with a variable resistance pressure sensor and methods of use.

BACKGROUND

[0003] Guide wires have become common tools in a number of medical applications. They may be used to access portions of the internal anatomy by being externally manipulated and advanced by the user to a desired position in the body. As the guide wire is manipulated, it is often visualized with the aid of x-ray fluoroscopy, endoscopy, MRI, or other imaging modalities. This visualization helps to position the guide wire. Once the guide wire is in position, other medical devices such as balloon catheters, stents, and diagnostic catheters, can be guided to a desired location by incorporation of a lumen that is advanced over the previously placed guide wire. The guide wire therefore becomes a rail to facilitate placement of the larger device within a target anatomy.

[0004] For example, in vascular applications such as angioplasty and stenting, the guide wire may first be manipulated down a vessel beyond a constricted portion of the vessel. The angioplasty/stent catheter may then be advanced over the guide wire until the working portion of the device (stent and dilation balloon) is at the constriction. Fluoroscopy combined with radiopaque portions on the guide wire and catheter may be used to view the placement of each. The balloon may be inflated to place the stent inside the blood vessel to permanently enlarge the constriction and improve blood flow.

[0005] Quite often, these blood vessels are tortuous, so the guide wires may be steerable and trackable. Steerability may be facilitated by having a "J" bend at the distal end, such that rotation imparted on the proximal end controls the orientation of the "J", allowing for navigation through curves and branches. For rotation to be transmitted effectively, the guide wire may be nearly perfectly straight (when in its unstressed condition). Any pre-existing curvature could cause the guide wire to whip when it is rotated, rather than smoothly rotate. Further, the guide wire may be resilient to resist permanent deformation when it is flexed by being in tortuous vessels, as well as during routine handling of the guide wire. Any permanent deformation may eliminate the initial straightness qualities, again leading to whipping.

[0006] Trackability may be facilitated by having a guide wire that gradually becomes more flexible near its distal end. For example, a 0.014 inch diameter guide wire suitable for coronary artery applications may be formed with a solid core wire, with gradual tapers in the core wire near the distal end to impart greater flexibility. A highly flexible coil or sleeve extends over the distal tapered region to maintain a relatively uniform diameter while minimizing added stiffness. The resulting guide wire has significantly greater flexibility the further distal on the guide wire one measures it, when compared to the proximal portion.

[0007] A commonly used material for the core wire is 300 series stainless steel, such as type 304. This type of material has tremendous work hardening potential as it is drawn into the wire form. It is also highly biocompatible. Because it work hardens during the wire drawing process, tensile strengths in excess of 300,000 psi are often achieved. The resulting hard wire becomes highly resilient (for durability and steerability) and has a good modulus of elasticity to result in a desirable flexibility profile (for trackability) once the tapers are formed.

[0008] Recently, for some vascular applications, it has been observed that measuring blood pressure at various locations in the blood vessel prior to the treatment of the constriction can be helpful in determining if a particular constriction warrants treatment with angioplasty/stenting. Constrictions that are not severe enough to substantially impact the blood flow are best left untreated. The measurement of blood pressure upstream and downstream of the constriction can aid in this determination (to determine "fractional flow reserve" or FFR). Therefore, various pressure sensors have been incorporated into certain guide wires near their distal ends, adding functionality to those guide wires.

[0009] Certain pressure sensing guide wires use a piezoresistive pressure sensor in either a Wheatstone bridge configuration or a half Wheatstone bridge configuration near the distal end of the guide wire. Multiple insulated lead wires may be needed to connect to the various nodes on the sensor. To facilitate multiple lead wires, the guide wire may be hollow, allowing lead wires to occupy the hollow space. The lead wires may then be connected between the sensor and a connector on the opposing end of the guide wire. Wiring and circuitry within the guide wire may be insulated, as any current leakage could be erroneously interpreted as a change in pressure.

[0010] The proximal, stiffer portion of these pressure sensing guide wires may be formed with a hypotube with the lead wires extending inside. Using a hypotube, a readily available component, greatly compromises guide wire steerability. Hypotubes are not nearly as resilient, and have different flexibility, than guide wires made from solid wire.

[0011] Furthermore, to facilitate electrical connection to the multiple lead wires running inside the hypotube, a series of connecting rings may be fabricated at the proximal end. A proximal connector may be connected to these rings to connect the guide wire to an external power source and monitor. Whenever pressure data is being measured, this connector may be in place. However, the presence of this connector inhibits the rotation and advancement of the wire needed during navigation within the body. Quite often it may be removed during the vascular navigation steps, further complicating the procedure.

[0012] There is a need for guide wires that are capable of measuring pressure, but possess higher performance characteristics than other designs.

SUMMARY

[0013] According to one aspect of the presently disclosed embodiments, an elongate intravascular guide wire may include an electrically conductive core wire connected to a sensor housing. The guide wire may also include a pressure sensor and an integrated circuit located within the sensor housing. The guide wire may also include at least one return electrode connected to the integrated circuit. The integrated circuit, pressure sensor, and return electrode may be electrically connected to form part of a primary electrical circuit. The guide wire may also include an electrical connector disposed on a proximal portion of the core wire. The electrical connector may be electrically connected to the core wire. The core wire may be configured to deliver electrical power to the integrated circuit from the connector. The integrated circuit may be configured to transmit electrical information.

[0014] According to another aspect of the presently disclosed embodiments, a system for measuring intravascular blood pressure within a mammal may include an elongate guide wire. The elongate guide wire may include a pressure sensor at a distal portion of the core wire, the pressure sensor being configured to sense blood pressure. The guide wire may also include an integrated circuit at the distal portion of the core wire, the integrated circuit being electrically connected to the core wire. The system may also include a steering device in electrical communication with the core wire. The system may also include a power source connected to the steering device. The system may also include a guiding catheter surrounding at least a portion of the guide wire. The integrated circuit may operate with the pressure sensor to convert the sensed pressure to an information encoded signal sent along the guide wire.

[0015] According to another aspect of the presently disclosed embodiments, a pressure sensor circuit for an electrically conductive guide wire may include a piezo-resistive pressure sensor having at least one resistance element that changes resistance in response to changes in applied pressure. The circuit may also include an integrated circuit electrically connected to the pressure sensor and powered by alternating electrical current delivered via the guide wire. The integrated circuit may be configured to convert the resistance to a pulse. The pulse may cause a signal driver to impose a first voltage change on the guide wire at a time corresponding to a first pulse transition and to impose a second voltage transition on the guide wire at a time corresponding to a second pulse transition. The circuit may also include a data processor external to the guide wire. The data processor may be configured to convert timing between the first voltage transition and second voltage transition into a recovered time interval, and convert the recovered time interval into an indication of pressure.

[0016] According to another aspect of the presently disclosed embodiments, a method for measuring blood pressure in a patient may include advancing a guide wire to a desired position in the patient's blood vessel. The guide wire may include a pressure sensor and an integrated circuit at a distal portion of the guide wire. The integrated circuit may be configured to send an information encoded signal representative of blood pressure through the guide wire. The method may also include operating a power source electrically connected to a connector in electrical communication with the guide wire, to send electrical current along the guide wire. The method may also include measuring the pressure at the desired position.

[0017] According to another aspect of the present disclosed embodiments, a system for measuring blood pressure may include a power supply. The system may also include a guide wire assembly operatively coupled to the power supply. The guide wire assembly may include an electrically conductive core wire connected to a sensor housing. The guide wire assembly may also include a pressure sensor and an integrated circuit located within the sensor housing. The guide wire assembly may also include at least one return electrode connected to the integrated circuit. The integrated circuit, pressure sensor, and return electrode may be electrically connected to form part of a primary electrical circuit. The guide wire assembly may also include an electrical connector disposed on a proximal portion of the core wire. The electrical connector may be electrically connected to the core wire and the power supply. The core wire may be configured to deliver electrical power to the integrated circuit from the connector. The integrated circuit may be configured to transmit electrical information. The system may also include a guide catheter configured to receive at least a portion of the guide wire assembly. The guide catheter may include a conductive braid configured to receive the electrical information from the integrated circuit. The guide catheter may also include a guide catheter connector operatively coupled to the braid. The guide catheter connector may be configured to receive the electrical information from the braid, and deliver the electrical information to an output device.

[0018] According to another aspect of the presently disclosed embodiments, a method for determining intracorporeal pressure in a patient may include inserting a transducer, and an integrated circuit operatively coupled to the transducer, into a portion of a body for detecting the pressure in the portion of the body. The conductor may be operatively coupled to the integrated circuit. The method may also include directing power from a power supply to the conductor. The power may be in the form of an alternating current. The method may also include delivering the alternating current to the integrated circuit and the transducer through the conductor. The method may also include modulating the alternating current with at least one of the transducer and the integrated circuit, in response to the pressure detected.

[0019] According to another aspect of the presently disclosed embodiments, a connector configured to steer a guide wire may include an elongate body defining a lumen. The lumen may be configured to receive the guide wire. The connector may also include a clamp configured to mechanically grip the guide wire. The connector may also include an electrical connection coupled to the clamp. The electrical connection may be configured to deliver power from a power source through the clamp and to the guide wire.

[0020] According to another aspect of the present disclosed embodiments, a pressure sensing guide wire assembly, for sensing blood pressure in a patient's body, may include a guide wire including a distal portion and a proximal portion. The guide wire assembly may also include a sensor assembly operatively coupled to the distal portion of the guide wire. The sensor assembly may include an integrated circuit operatively coupled to the guide wire. The sensor assembly may also included a sensor operatively coupled to the integrated circuit. The sensor may be configured to sense pressure, and the integrated circuit may be configured to convert the sensed pressure into encoded information. The sensor assembly may also include a sensor housing configured to receive the integrated circuit and the pressure sensor.

[0021] Additional objects and advantages of the disclosed embodiments will be set forth in part in the description that follows, and in part will be apparent from the description, or may be learned by practice of the disclosed embodiments. The objects and advantages of the disclosed embodiments will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

[0022] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the disclosed embodiments, as claimed.

BRIEF DESCRIPTION OF THE FIGURES

[0023] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate various exemplary embodiments and together with the description, serve to explain the principles of the disclosed embodiments.

[0024] FIG. **1** is a side view illustration of an exemplary pressure sensing guide wire, consistent with embodiments of the present disclosure.

[0025] FIG. **2** is a side view illustration of another exemplary embodiment of a pressure sensing guide wire, consistent with embodiments of the present disclosure.

[0026] FIG. **3** is a schematic view illustration of an exemplary system including a pressure sensing guide wire, in use within a patient, consistent with embodiments of the present disclosure.

[0027] FIG. **4** is a perspective view illustration of a portion of an exemplary pressure sensing guide wire, in a region of a pressure sensor, consistent with embodiments of the present disclosure.

[0028] FIG. **5** is an exploded perspective view illustration of an exemplary pressure sensing guide wire, in a region of a pressure sensor, showing internal electrical components, consistent with embodiments of the present disclosure.

[0029] FIG. **6** is a block diagram illustration showing electrical functional elements of an exemplary pressure sensing guide wire, consistent with embodiments of the present disclosure.

[0030] FIGS. **7***a* and **7***b* are graphical illustrations showing exemplary waveforms of portions of the block diagram shown in FIG. **6**, consistent with embodiments of the present disclosure.

[0031] FIGS. **8***a* and **8***b* are graphical illustrations showing exemplary waveforms of other portions of the block diagram shown in FIG. **6**, consistent with embodiments of the present disclosure.

[0032] FIGS. **9***a* and **9***b* are graphical illustrations showing waveforms of other portions of the block diagram shown in FIG. **6**, consistent with embodiments of the present disclosure.

[0033] FIGS. **10***a* and **10***b* are graphical illustrations showing waveforms of other portions of the block diagram shown in FIG. **6**, consistent with embodiments of the present disclosure.

[0034] FIG. **11***a* is a perspective view illustration of a portion of an exemplary pressure sensing guide wire, in a region of a pressure sensor, consistent with embodiments of the present disclosure.

[0035] FIG. **11***b* is a longitudinal section side view illustration of the portion of the exemplary pressure sensing guide wire, in the region of the pressure sensor, shown in FIG. **11***a*, consistent with embodiments of the present disclosure.

[0036] FIG. **12** is a top view illustration of an integrated circuit, consistent with embodiments of the present disclosure.

[0037] FIG. **13***a* is a perspective view illustration of a portion of an exemplary pressure sensing guide wire, in a region of a pressure sensor, consistent with embodiments of the present disclosure.

[0038] FIG. **13***b* is a perspective longitudinal section view illustration of a cross-section of the portion of the exemplary pressure sensing guide wire, in the region of the pressure sensor, shown in FIG. **13***a*, consistent with embodiments of the present disclosure.

[0039] FIG. **14***a* is a perspective view illustration of a portion of an exemplary pressure sensing guide wire, in a region of a pressure sensor, consistent with embodiments of the present disclosure.

[0040] FIG. **14***b* is another perspective view illustration of a portion of the exemplary pressure sensing guide wire, in the region of the pressure sensor, shown in FIG. **14***a*, consistent with embodiments of the present disclosure.

[0041] FIG. **15***a* is a perspective view illustration of a portion of an exemplary pressure sensing guide wire, in a region of a pressure sensor, consistent with embodiments of the present disclosure.

[0042] FIG. **15***b* is a longitudinal section side view illustration of the portion of the exemplary pressure sensing guide wire, in the region of the pressure sensor, shown in FIG. **15***a*, consistent with embodiments of the present disclosure.

[0043] FIG. **16***a* is a side view illustration of an exemplary connector, consistent with embodiments of the present disclosure.

[0044] FIG. **16***b* is a side view illustration of a cross-section of the exemplary connector, shown in FIG. **16***a*, consistent with embodiments of the present disclosure.

[0045] FIG. **17** is a schematic view illustration of an exemplary system including a pressure sensing guide wire, in use within a patient, consistent with embodiments of the present disclosure.

[0046] FIG. **18** is a schematic view illustration of an exemplary system including a pressure sensing guide wire, consistent with embodiments of the present disclosure.

[0047] FIG. **19** is a schematic view illustration of an exemplary system including a pressure sensing guide wire, in use within a patient, consistent with embodiments of the present disclosure.

[0048] FIG. **20**A is a perspective view illustration of an exemplary guide catheter clip, consistent with embodiments of the present disclosure.

[0049] FIG. **20**B is an axial section front view illustration of an exemplary guide catheter clip, consistent with embodiments of the present disclosure.

[0050] FIG. **20**C is a longitudinal section perspective view illustration of the exemplary guide catheter clip, shown in FIG. **20**B, consistent with embodiments of the present disclosure.

[0051] FIGS. **21**A-**21**D are graphical illustrations showing exemplary resistance modulation and digital encoding, consistent with embodiments of the present disclosure.

[0052] FIG. **22**A is a side view illustration of exemplary electronic components, consistent with embodiments of the present disclosure.

[0053] FIG. **22**B is a top view illustration of exemplary electronic components, consistent with embodiments of the present disclosure.

[0054] FIG. **22**C is a side view illustration of a cross-section of exemplary electronic components, consistent with embodiments of the present disclosure.

[0055] FIG. **23** is a graphical illustration showing exemplary waveforms, consistent with embodiments of the present disclosure.

[0056] FIG. **24** is a graphical illustration showing exemplary waveforms, consistent with embodiments of the present disclosure.

DETAILED DESCRIPTION

[0057] Reference will now be made in detail to the exemplary embodiments of the disclosure, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0058] Exemplary features of one embodiment of the guide wire **10** of the present disclosure is shown in FIG. **1**. This embodiment may be a steerable coronary guide wire, however the same principles described in connection with this and all embodiments herein could be applied to other guide wire embodiments as well.

[0059] Guide wire **10** includes a core wire **12**. Core wire **12** may be a solid wire, and may be fabricated from a conductive material such as stainless steel (e.g., hard drawn type 304) or other biocompatible conductive materials. A preferred material is type 304 that is hardened from the drawing process to a tensile strength of 300,000 psi or greater. This results in a core wire which is resilient, contributing to steerability and durability of the guide wire during a medical procedure. Alternative materials are also contemplated, such as nickel titanium alloy (nitinol), cobalt chromium alloys, other grades of stainless steel, or other resilient high strength biocompatible materials, as well as various combinations thereof. While a solid wire is preferred for the core wire **12**, a hollow tube is also contemplated as other features can still be realized with a hollow tube as the core wire **12**.

[0060] Guide wire **10** has a proximal end **14** and a distal end **16**, between which are three portions: (i) a proximal portion **18** which extends from proximal end **14** to a (ii) tapering intermediate portion **22**, where the core wire **12** has reduced diameter to impart greater flexibility for navigating curves such as the curves in coronary blood vessels; and (iii) a distal portion **20**. At the distal end of the intermediate portion **22** is the sensor housing **24**. Distal to the sensor housing **24** is the distal portion **20**. Distal portion **20** is formed of a distal core wire **36**, surrounded by a distal coil **38**, and a distal tip **40**.

[0061] Core wire **12** terminates at the proximal end of the sensor housing **24**, freeing up space within the sensor housing **24** for a transducer or sensor **26** and an integrated circuit (IC) **28** inside (not visible in this view). One or more access windows **30** formed in sensor housing **24** allow for blood pressure to be conveyed to the sensor **26**.

[0062] Core wire **12** may have a tapering feature adjacent the proximal end **14**, to facilitate adding an extension wire to extend the length of the guide wire, if "over the wire" catheters are needed to be exchanged over the guide wire **10**. For substantially the entire length of the proximal portion **18** of core wire **12**, a lubricious coating **32** such as PTFE may be applied. Such lubricious coating **32** further provides an electrical insulation to the core wire **12**.

[0063] As mentioned, the intermediate portion **22** may have diametric tapering of the core wire **12** to impart greater flexibility. Such tapering may be formed by centerless grinding. To maintain a uniform outer diameter, a sleeve **34** may surround the core wire **12** in the reduced diameter regions. Such sleeve **34** may additionally serve to insulate the core wire **12** in this portion.

[0064] Core wire **12** is attached to the proximal end of the sensor housing **24** in a manner that mechanically connects them, but does not allow for electrical communication to the sensor housing **24**. Sensor housing **24** could be formed of a non-conductive material such as ceramic or rigid polymer. In this case, any suitable mechanical bonding, such as adhesive bonding, can be used. Alternatively, sensor housing **24** could be metallic (and conductive). In this case, an insulating bonding layer, such as a ceramic coating, could be applied to the outside of the core wire **12** to facilitate mechanical bonding, such as adhesive bonding, without electrical communication to the sensor housing **24**.

[0065] Inside sensor housing **24**, the distal end of the core wire **12** is electrically connected to the IC **28**, as will be described in further detail below. The IC **28** is powered by current delivered down the core wire **12** near the proximal end, from an external power source via a connector **44**, also described in more detail below. The distal core wire **36** is mechanically secured to the distal end of the sensor housing **24**, using similar techniques as the attachment of the distal end of the core wire **12** to the proximal end of the sensor housing **24**.

[0066] To form a complete primary electrical circuit **114**, the IC **28** is in electrically connected to the distal core wire **36** and/or the distal coil **38**. If the distal tip **40** of the guide wire **10** is a weld, solder, or braze joint, then distal coil **38** and distal core wire **36** will both be in electrical communication with the IC **28**. Since the distal portion **20** of the guide wire **10** is in the electrically conductive bloodstream, the distal coil **38** serves as a return electrode. A grounding pad **42**, such as an EKG pad affixed to the patient, can be wired back to an external power source, thus completing the primary circuit **114**.

[0067] The input power required to operate the sensor and IC circuitry will be relatively small, and current leakage concerns into the patient will be mitigated. This is particularly true if an alternating current waveform at relatively high frequency is utilized to power the IC and sensor circuitry.

[0068] Electrical power is delivered to the guide wire **10** via a connector **44**. Connector may operate as the torque device or steering device which may be used to manipulate steerable guide wire **10**.

[0069] One embodiment of connector **44** includes a finger grip **46**, a clamp **48**, and a nut **50**. The clamp **48** includes tangs **52** that compress onto the guide wire **10** when the nut **50** is tightened against the finger grip **46** via threads **54**. To deliver electrical power, tangs **52** further include one or more sharpened tips **56**, which can penetrate the insulative lubricious coating **32** to make contact with the conductive core wire **12**. Clamp **48** is conductive, and is connected to a lead wire **58** which is connected to the power source. Lead wire **58** may be connected to the clamp **48** directly by means such as solder, or may be connected via rotary connection, which allows the connector **44** to rotate and steer the guide wire **10** without causing the lead wire to twist around the guide wire **10** proximal of the connector **44**.

[0070] In an alternative embodiment of the connector **44**, the tangs **52** do not include sharpened tips, but rather may be simply compressed against the lubricious coating until they are in close proximity to the conductive core wire **12**. The lubricious coating acts as a dielectric, and the close proximity of the conductive tangs **52** to the core wire **12** results in a capacitive coupling. As long as the input drive signals on the guide wire **10** are alternating, these signals can pass through to the core wire **12** capacitively without direct electrical contact. This embodiment avoids the mechanical piercing and disruption to the lubricious coating **32**.

[0071] FIG. **2** illustrates an alternative embodiment, in which a proximal coil **60** is utilized as the return electrode, instead of or in addition to the distal coil **38** of the embodiment of FIG. **1**.

[0072] Rather than a sleeve, metallic proximal coil **60** is utilized to maintain the uniform diameter of the guide wire **10**. In this embodiment, an insulative coating such as PTFE or ceramic may be applied to the surface of the reduced diameter portions of the intermediate portion **22** of guide wire **10**. The proximal coil **60** and core wire **12** are secured to the proximal end of the sensor housing in such a way as to provide for electrical connection between the IC **28** and the proximal coil **60**, described in further detail below. This embodiment provides for greater surface area for the return electrode, as proximal coil **60** can typically be longer than distal coil **38**. This is because in certain embodiments, it may be desirable for the sensor **26** to be near the distal tip **40** of guide wire **10**, thus resulting in a relatively short length of the distal portion **20**.

[0073] FIG. **3** depicts an embodiment of the guide wire **10** in use in a human patient, and illustrates the primary circuit **114**. In this embodiment, guide wire **10** is a steerable coronary guide wire used in conjunction with a potential stent implantation. A guiding catheter **62** is present in the patient, extending from an access site (in this case, the femoral artery), through the aorta, and engaging the ostium of a coronary blood vessel. The guide wire **10** extends through the guiding catheter **62** and is advanced and steered down the desired coronary artery, beyond one or more narrowed or constricted areas that may be targets for angioplasty and stenting. In addition to establishing a conduit from the femoral artery access site, the guiding catheter **62** further insulates the guide wire **10** from the patient's body, and greatly minimizes capacitive losses along the length of the guide wire **10**. The guiding catheter **62** may also include a pressure sensor (not shown) for measuring pressure upstream from the narrowed or constricted area. For example, the guiding catheter **62** may measure aortic blood pressure in the aorta using a pressure sensor at a distal end of the guiding catheter **62**.

[0074] The guide wire **10** is connected via the connector **44** and lead wire **58** to the power source **64**. A grounding pad **42**, like an EKG type pad, attached to the patient, is also connected to the power source **64** to complete the primary electrical circuit **114**. Power source **64** may also include a display **66**. Electrical signals travel down the guide wire **10** and are converted into a pressure waveform as will be further described below. Additional signal inputs can be traced as well on the display **66** such as the aortic blood pressure, typically measured via the guiding catheter **62**. Display **66** may also be a separate component.

[0075] As the guide wire **10** is positioned in various locations, the blood pressure can be measured and compared to the aortic blood pressure. For example, if the blood pressure as measured by the guide wire **10** at a location distal to a narrowing is significantly lower than the aortic blood pressure, the narrowing may be determined to be critical enough to warrant dilation and stenting. However, if the distal blood pressure is not substantially lower than the aortic blood pressure, the narrowing may not be dilated and stented, thus saving substantial costs and avoiding unnecessary risks to the patient of having a permanent stent positioned in that narrowing. One way to compare the aortic blood pressure to the distal blood pressure is to determine a fractional flow reserve ("FFR"). FFR may be a ratio of distal pressure to aortic pressure. If FFR crosses a predetermined threshold value, it may indicate that a critical narrowing or constriction is present.

[0076] If stent placement is desired, the connector **44** is removed, and the stent delivery catheter (not shown) is advanced over the guide wire **10** to the site of narrowing. Because the connector **44** is also the steering device, and not a separate device as in other pressure guide wires, only this one device needs to be removed from the guide wire **10** to facilitate loading and advancement of the stent delivery catheter.

[0077] FIG. **4** is an enlarged view of the part of the guide wire **10** incorporating the sensor **26** and IC **28**. A portion of the distal core wire **36**, a portion of the distal coil **38**, a portion of the proximal core wire **12** and a portion of the proximal coil **60** are shown, all connected to the sensor housing **24**.

[0078] FIG. **5** is an exploded view of FIG. **4**, showing an embodiment of the guide wire **10** showing the sensor **26** and IC **28**, which would reside within the sensor housing **24**. Sensor **26**, which may be a piezo-resistive sensor with at least one or more resistors etched in a deflectable silicon wafer, as well as one or more resistors etched in a non-deflectable portion of sensor (which may serve as calibration resistors), is electrically connected the IC **28**, and will be further described below. The variable resistors change their resistance in response to mechanical deformations caused by changes in local pressure applied to the sensor **26**. IC **28**, which is powered by the power source **64**, sends electrical signals to the sensor **26**. The IC **28** incorporates a logic module which essentially responds to the variations in resistance by converting the resistance changes to time based voltage impulses that are applied back onto the guide wire **10** and received and relayed by the display **66**. A similar "resistance to time" logic circuit is described in Jeong, et al., "A low-cost resistance-to-time converter for resistive bridge sensors", in *The* 23rd *International Technical Conference on Circuits/Systems, Computers and Communications* (*ITC-CSCC* 2008), pp. 1137-1140.

[0079] The one or more resistors that are incorporated into the sensor **26** are electrically connected to the IC **28**. The IC **28**, which is powered via the core wire **12**, has an electrical connection as shown. If the proximal coil **60** serves as the return electrode, another electrical connection to the proximal connection **68** provides electrical continuity to the proximal coil **60**. An insulative coating on the outside of the distal end of the core wire **12** prevents a short from the core wire **12** to the proximal coil **60**, while providing for a mechanical joining means between the core wire **12**, proximal coil **60** and proximal end of sensor housing **24**. A distal connection **70** provides for a mechanical joining or joint between the distal end of sensor housing **24** and the distal core wire **36** and distal coil **38**.

[0080] To minimize mechanical artifact to the sensor, due to bending forces acting on the guide wire, the sensor **26** resides within the sensor housing **24**. In one embodiment, and as shown in FIG. **5**, the sensor **26** and IC **28** are not mounted to the core wire **12**, but essentially float within the housing. This arrangement further minimizes artifactual stresses induced by mounting the sensor to a substrate. Alternative embodiments may extend the core wire **12** or some other mechanical structure into the sensor housing **24** for attachment of the sensor **26**.

[0081] To further isolate the sensor **26** from external influences other than fluid pressure, the interior of the housing may be fluid filled, with a highly wettable priming fluid **74** such as Fluorinert. To keep the priming fluid **74** in place, a gel or soft elastomeric plug **72** is positioned within the access windows **30**. Pressure transmits through the soft plug **72** and priming fluid to the sensor **26**.

[0082] In an alternative embodiment, the interior of the sensor housing **24** is kept open and dry until guide wire **10** is to be used. At that time, the interior can be prepped using a liquid such as saline, which can be applied via the access window(s) **30**. To further facilitate priming, one or more additional access window(s) can be positioned closer to the proximal end of the sensor housing **24**. To prevent shorting of the sensor **26** and IC **28**, the internal components within the sensor housing **24** may be insulated, such as with a parylene coating.

[0083] The electrical components of one embodiment of the present disclosure are shown in FIG. **6**, and further described in detail below. The large box on the left (sensor and IC **26** and **28**) includes the pressure sensor **26** which includes the variable resistance element(s) and the control resistance element(s), as well as the functional components that are part of the IC **28**. The sensor **26** and IC **28** are located within the sensor housing **24**.

[0084] The large box on the right (external readout **212**) includes the power source **64** which sends alternating current down the guide wire **10** to power the IC **28**, a display **66** which displays the desired output, e.g. a pressure waveform, after the impulses imparted to the wire **10** by the IC **28** are processed back into pressure information.

[0085] The primary circuit **114** is driven by the power source **64**, which sends an input drive signal down the guide wire **10**. The input drive signal may be current driven, in which case the drive signal will have a drive signal current waveform **100***i*. The impedance characteristics of all the electrical components in the primary circuit **114** will influence the resultant voltage waveform **100***v* that can be measured at the power source **64**. Various alterations or modulations to the voltage **100***v* as controlled by the IC **28** may be encoded as pressure data from the sensor **26**, and then decoded to result in a processed pressure waveform **360**, as will be further described below.

[0086] The IC **28** includes components **200** that recover power delivered through the guide wire **10** in the form of a symmetrically oscillating current square wave **100***i* to provide regulated voltage to internal sensor components. Recovered power operates sequencing logic **202**, a piezo resistive pressure sensor **26** and pressure sensor measurement circuits, a pulse modulator **204** and a signal driver **206**. A function of IC **28** is to convert piezo resistive pressure sensor output into pulses of a duration related to the pressure and to transmit those pulses to external readout **212** by signal driver **206**. The pulses can represent pressure sensor output in a number of forms. For example, the pulses may be pulse width modulated in relation to pressure. Alternatively, sensor signals may be digitized and the pulses may represent the digitized data bits.

[0087] The power recovery and regulation block **200** may include a bridge rectifier and two stages of regulation. The first stage of regulation is a shunt regulator that clamps the peak voltage output from the rectifier. A clamped voltage may be used since parasitic resistance in the return path requires the external power driving source to be a current source. A current source will drive current by allowing voltage to vary until some externally imposed voltage limit is reached, possibly even to the point of delivering excess voltage to electrical components. In this case, that limit is defined by a shunt regulator.

[0088] The output of the shunt regulator feeds a small capacitance at the input of a second stage of regulation. The second stage regulator is a series regulator that smooths any remaining voltage variations from the shunt regulator and capacitor.

[0089] Power is delivered to the sensor as a constantly reversing current. The current is set by an external power driving source and is at a frequency and amplitude that are compliant with the AAMI ES1 electrical safety standard for what the standard refers to as risk current. To make as much current available to the sensor as possible and to minimize the size of the filter capacitor across the shunt regulator, a high frequency driving current is preferred. In this case, a 100 KHz square wave is used to drive the sensor power recovery and regulation circuit allowing up to 1 mA peak current at the sensor.

[0090] The AAMI ES1 specification limits current at DC to a value of less than 10 uA. Since the system uses the body as a return path, it may be preferable for the DC current component of the driving waveform to be symmetrical, so that the average DC current is as close to zero as possible.

[0091] Sequencing of internal processes in the sensor **26** can be based on timing derived from the drive power waveform. Both the rising and falling edge of the drive waveform can be used to initiate measurements. Sequencing logic **202** controls data conversion of the output signal from piezo resistive sensor **26**, pulse modulation timing and if needed, blanking to mask transient intermediate signals. Alternatively, timing can be derived from an oscillator in the IC **28** itself.

[0092] The sensor **26** may be a piezo resistive sensor and may include either a full Wheatstone bridge or a half Wheatstone bridge. The half Wheatstone bridge is completed by the addition of fixed resistors. For example, in a Pulse Width Modulated (PWM) embodiment, a forced bridge imbalance is used to ensure that the PWM output never reaches zero or negative pulse time. This imbalance is created either by the addition of a series resistance in one side of the bridge or a series resistance in both sides of the bridge. Forced bridge imbalance output is taken from opposing ends of the imbalance resistors or one end of a single imbalance resistor.

[0093] Regulated voltage is applied to the Wheatstone bridge and external pressure creates an output voltage imbalance in addition to any forced bridge imbalance. Other embodiments may make use of different types of sensors, for example, capacitive sensors.

[0094] Pressure data gathered by the IC **28** may be communicated in many ways, such as modulation of the power waveform. The following is but one example. Output from the Piezo Resistive Sensor **26** (PRS) is digitized in the pulse modulator **204**, also called a converter. Pulses may be generated by a Pulse Width Modulator (PWM) or other digitizing system, such as an Analog to Digital Converter (ADC).

[0095] In the case of a PWM, a pulse is generated with a time duration that is related to the PRS output. The pulse duration may include a constant time factor plus a variable time factor, where the variable time factor varies in proportion to the PRS input pressure signal. Pulses from an ADC can either be present or absent, or can be short pulses and long pulses to represent logical 1's or 0's.

[0096] In one embodiment, to generate a PWM signal, a ramp waveform is generated that is applied to the inverting inputs of two comparators. The non-inverting inputs of the comparators are respectively connected to each side of the Wheatstone bridge. As the ramp waveform increases in voltage, a first comparator will switch output state indicating a first timing edge. As the waveform continues to rise, a second comparator will switch output state indicating a second timing edge. To generate a pulse, the outputs of the comparators are exclusive OR'ed together generating a pulse that is present only when the comparator outputs differ. The process can be repeated in reverse by a downward ramping waveform of the same voltage slope as the upward ramping waveform. The pulse duration of a system using a 100 KHz power drive signal can range between 1 and 4 microseconds.

[0097] An alternative to using two comparators that may have significantly different offset voltages is to use a single comparator that is switched between each of the sides of the Wheatstone bridge. Logic would control comparator input switching and convert the comparator output into equivalent output signals as the two-comparator embodiment.

[0098] To control sensitivity, ensure bounded voltage limits on the ramp waveform and control the location of the PWM pulse signal in relation to the power drive waveform, the outputs of the comparators with small added delays can be used to control the ramp generator.

[0099] Pulses from the pulse modulator **204** may be suitable for direct modulation of the voltage on the guide wire **10** or may require additional power or wave shaping. The signal driver **206** converts logic signals from the pulse modulator **204** into signals that can be received by the external readout.

[0100] One form of signal driver **206** signal conversion is to high pass filter PM pulses, converting them into spike-like impulses. These impulses can then be separated from the drive waveform by similar high pass filtering located at the external readout equipment.

[0101] The guide wire **10** and skin electrode connection **42** form the electrical connections between the pressure sensor **26** and IC **28** located in the body and external readout equipment **212**. The metallic guide wire **10** forms a direct electrical connection to power the in-body circuitry. The return path may include, for example, the proximal coil **60** of the guide wire **10**. The proximal coil **60** may be used to reduce current density to the maximum extent possible because of its greater length compared to the distal coil **38**. Current returned through the proximal coil is **60** collected by an electrode **208** attached to the skin, which may include, for example, a small ECG electrode or a large defibrillation patch.

[0102] The guide wire **10** may include a conductive metal core **12** covered by a thin layer of insulating material **32**. When in the body, the insulation **32** forms the dielectric of a capacitor with one plate of the capacitor made of the conductive wire **12**, and the other plate made of the surrounding tissue and conductive fluids of the body.

[0103] Capacitance **210** from the guide wire **10** dielectric insulation **32** causes displacement currents to flow when driven by a square wave current. These displacement currents cause the voltage **100***v* on the guide wire **10** to have transitions with finite voltage slope (as seen, for example, in FIGS. **7***a* and **7***b*).

[0104] The Skin Electrode Connection (SEC) **208** may include an electrode placed on the skin, such as the electrode **42**. The electrode **42** may include a small ECG patch to a large defibrillation electrode. A function of the SEC **208** is to collect return current from the proximal coil **60** of the guide wire **10**. From an electrical standpoint, the SEC **208** includes a series resistance paralleled by a capacitance.

[0105] The external readout **212** may be made up of subsystems used to power the sensor **26** and IC **28** and to recover and display data measured by the sensor **26**.

[0106] Timing and sequence generation creates control waveforms that sequence a power driver **64** and aid in signal recovery. The operating frequency is set high enough that sufficient "risk current", as defined by the AAMI ES1 safety specification, is available to operate sensor circuits. A preferred frequency of operation is 100 KHz. It is also preferable that the drive current is as symmetrical as possible to minimize the DC component to a "risk current" value that meets the AAMI ES1 electrical safety specification.

[0107] The power driver (or power source) **64** is a controlled current source that supplies current to the guide wire **10**. The current source may include a high voltage compliance current source with the ability to switch polarity to form a square wave current of at least 100 KHz.

[0108] The signal recovery amplifier **216** may include a high pass filter to pass data impulses generated by the sensor/IC signal driver **206** and to block guide wire **10** voltage variations caused by the power driver **64**. The high passed signals are amplified and detected by, for example, a Schmitt trigger. The output of the Schmitt trigger represents an analog of the pulse generated by the sensor/IC **26**/**28**. The Schmitt trigger output will vary in pulse width and pulse presence in direct relation to pulses generated at the sensor/IC **26**/**28**. Alternatively, a comparator can detect the voltage variations in direct relation to pulses generated at the sensor/IC **26**/**28**.

[0109] The pulse output of the Signal Recovery Amplifier **216** can be directly measured and converted into a representation of pressure. Using either direct time measurement or a pulse integration and digitization method can provide at least 100 measurement levels or 7 bits of resolution, in a pulse width modulation scheme.

[0110] The pulse output can also be processed to reduce signal noise and increase resolution by performing pulse width or signal averaging.

[0111] The benefit of signal averaging is a substantial improvement in resolution. For example, if the drive waveform has a frequency of 100 KHz, a pulse width modulator that uses both an upward and downward slope to generate a pulse will generate data at a rate of 200 k samples per second. If the end bandwidth is intended to be 200 Hz, the system over samples the sensor at by 1000 times per output reading. Noise can be reduced by the square root of the over sample rate or about 32 times. Signal averaging in this case provides an additional 5 bits of signal resolution in addition to the at least 7 bits of resolution from pulse to pulse signal measurements.

[0112] The display **66** can include any of a number of common display apparatuses and methods. Exemplary display methods can be any combination of a digital or analog display, peak, average or valley pressures, pressure over time as a graph, or other statistic, or an on-off binary indication if certain statistical measures have been met or exceeded.

[0113] Pressure waveform signals can be further processed to detect certain specific changes in pressure statistics such as a drop in peak, average or valley pressures and provide a binary user indication.

[0114] To further illustrate how the various functional components operate, signal or voltage waveforms from several nodes are illustrated in the graphs described below.

[0115] FIGS. **7***a* and **7***b* illustrate voltage waveforms of an embodiment of the present disclosure, as shown in FIG. **6**. Between nodes A and B, waveform **100***v*, represents the voltage signal on the guide wire **10**, near its proximal end by or at the connector **44** and the electrode or grounding pad **42**. This waveform represents a square wave alternating current driven by the power source **64**. Because of capacitive coupling losses along the insulated guide wire **10**, the voltage plot is not a true square wave, and has a reduced slew rate. This waveform also serves to drive the IC **28**. For illustration purposes, this waveform is shown as a 100 KHz current limited and balanced drive signal, however alternative parameters are contemplated as well.

[0116] Node C waveform **102** represents the digitized voltage signal used to drive the guide wire **10** from the IC **28** after receiving sensor data. This square wave **102** is then superimposed on the drive signal by the signal driver **206**. The resulting signal **100***v* is seen to incorporate impulses **104**. The pressure data from the sensor **26** is encoded in this signal **102** as a time increment **106** in the square wave. The time increment between the impulses **104** corresponds to the width of the square wave in this embodiment. Again, other sensing and logic schemes defining the IC **28** and sensor **26** circuit are contemplated in the presently disclosed embodiments.

[0117] The waveforms in FIG. **7***a* represent those when the sensor **26** is exposed to a lower pressure, while the waveforms in FIG. **7***b* represent those when the sensor **26** is exposed to a higher pressure. As can be seen the time increment of the square wave and impulse spacing are longer at the higher pressure than at the lower pressure.

[0118] FIGS. **8***a* and **8***b* illustrate the IC power supply voltage **108** (power recovery and regulation function **200**) at low pressure and high pressure. A drive signal is rectified and filtered to a substantially steady DC voltage, regardless of the pressure applied to the sensor **26**. Droops seen in the IC power supply voltage result from drive transitions and are further regulated for smooth sensor DC power.

[0119] FIGS. **9***a* and **9***b* show the interaction between elements of the IC **28** and sensor **26** in one embodiment of the present disclosure. A ramping voltage **110** is applied to the sensor **26** to scan from the voltage imbalance of one arm of the Wheatstone bridge to the voltage on the other. Note the scale for this signal is millivolts. As the voltage applied to comparators is increased, logic gates in the IC **28** determine how large of a resistance imbalance (and therefore pressure) is present within the variable resistance elements of the sensor **26**. The greater the resistance imbalance, the higher the voltage ramp **110** must go in order to detect the greater imbalance. Once the imbalance is determined, the square wave **102** signal is returned to zero. The same sequence is applied during the ramp down **110** of the voltage.

[0120] As discussed above, the width of the square wave within the IC **28** is applied to the guide wire **10** by the signal driver **206** to encode the pressure sensed by the sensor **26**. The width shown in FIG. **9***a* is lower, due to the lower pressure on the sensor **26**, and the width in FIG. **9***b* is greater at the higher pressure. Other digitization methods of converting pressure signals can be used, but pulse width modulation is show here for illustration purposes.

[0121] FIGS. **10***a* and **10***b* illustrate the waveforms of the square waves **102** generated by the signal driver **206** in the IC **28**, and the square waves **112** generated by the signal recovery amplifier **216** in the external readout **212** (which may be part of or operatively coupled to the external power source **64**). The scale on the left of the graph is for signal **102**, and the scale on the right of the graph is for signal **112**. The pulse widths of each are substantially identical in time duration, with only a slight transmission delay. The signal **112** is what goes into the pulse signal processor **218** for conversion to a desirable output, such as a pressure waveform on display **66**.

[0122] These waveforms demonstrate an embodiment that has an increase in time increment of about 1.1 micro second time for a 0.1% bridge imbalance, which is more than suitable pressure sensitivity for accurate monitoring of blood pressure (certain piezo-resistive sensors exhibit about 2% imbalance at maximum pressure). As with the other electrical components in this guide wire circuit, the system sensitivity can be tailored for specific sensor sensitivity by design.

[0123] FIGS. **11***a* and **11***b* illustrate one embodiment of a distal portion **20** of guide wire **10**. Core wire **12** terminates within the proximal end of the sensor housing **24**. A portion of the distal end of the core wire **12** may taper **304** up to facilitate a mechanical interlock in a cooperative fashion with a subsequent taper **306** within the proximal end of the sensor housing **24** to enhance the mechanical integrity of the joint therebetween. Other mechanical interlock designs are contemplated as well, such as spiral or circumferential grooves, or other partially or fully interlocking shapes for the core wire **12** and/or the sensor housing **24**. Alternatively, a redundant mechanical connection could incorporate the use of a non-conductive tether extending between the core wire **12** and distal core wire **36**, bonded by suitable mechanical bonding, such as adhesive.

[0124] The core wire **12** conducts electrically with one or more electrical traces (not shown) on a substrate **300** by, for example, a conductive adhesive **303**. However, the core wire **12** does not conduct to the sensor housing **24**. To facilitate this, a non-conductive proximal insulating sleeve **302** surrounds the core wire **12**. Suitable non-electrically conductive adhesive **305** may be used to mechanically join the core wire **12**, insulating sleeve **302**, and sensor housing **24**. Alternatively, the sensor housing **24** could be fabricated of a non-conductive material, such as ceramic, alumina or zirconia, a polymer such as polyimide, PEEK, Vectran, or other rigid polymer, anodized aluminum, oxidized titanium, or similar materials.

[0125] Substrate **300** may further include narrowed portions **308** where they are connected to the core wire **12** and distal core wire **36**. Narrowed portions **308** serve to mechanically isolate the substrate **300** from mechanical stresses that may be imparted to the guide wire **10**.

[0126] One or more traces (not shown) electrically connect the distal end of the substrate **300** to the distal core wire **36** by suitable mechanical bonding, such as conductive adhesive, solder, braze, ultrasonic weld, or resistance weld. The mechanical joint at the distal end of the housing **24** may be a solder or braze joint, thereby electrically connecting the distal core wire **36**, distal coil **38**, and the sensor housing **24**. As described above, the relatively small electric current then emanates from these components to the patient to complete the primary circuit **114**.

[0127] As shown in FIG. **12**, integrated circuit **28** is electrically mounted to the substrate **300** by electrical bonding pads **310**. IC **28** may include 7 bonding pads **310**, or more or less, depending on the electrical functionality desired. Seven bonding pads **310** provide for one power/signal input **312** (from core wire **12** via substrate electrical trace), one power/signal output **314** (to distal core wire **36** via substrate trace), three sensor interfaces **316** (typical for a half-bridge type piezo resistive sensor), and two pads **318** for connection to an optional capacitor **322** that may be mounted on the opposite side of substrate **300**. Other exemplary features (e.g. peripheral bus, power/ground distribution buses, transistors, gates, RS flip-flops, etc.) are described in FIG. **12**, as might be incorporated into the IC **28**, depending on the desired logic scheme desired. Also, typical but merely exemplary dimensions of the IC **28** and the various elements are indicated. Capacitor **322** serves to smooth out the alternating power waveform, thus providing a relatively steady DC current to operate the IC **28**. The sensor **26**, as mentioned, may have three bonding pads. The electrical connections between the IC **28** and the sensor **26** may be facilitated with electrical bonds to additional traces on the substrate (not shown), or by separate electrical wires therebetween (also not shown).

[0128] FIGS. **13***a* and **13***b* illustrate another embodiment of distal portion **20** of guide wire **10**. Here, the substrate **300** may be shorter, so as not to fully extend to the core wire **12** or distal core wire **36**. Connector leads **324** electrically connect the core wire **12**, via bonding pads on substrate (not shown), to one or more traces (not shown) in the substrate **300**, and from the substrate **300** to the distal core wire **36**. These connections are relatively short. FIG. **13***b* also shows where suitable bonding, such as conductive adhesive **303**, solder, braze, ultrasonic weld, or resistance weld, could be placed within the proximal insulating sleeve **302**, and within a distal interior portion of the sensor housing **24**. It should be noted that other embodiments described here may incorporate a conductive joining or bond, and may also make use of the alternatives described previously.

[0129] FIG. **14***a* shows a further embodiment of distal portion **20** of guide wire **10**. The electrical connector leads **324** from the core wire **12** and distal core wire **36** are substantially longer than in the embodiment shown in FIG. **13***a* and FIG. **13***b*. The connector lead **324** from the core wire **12** may extend to the distal end of the substrate **300**, while the connector lead from the distal core wire **36** may extend to the proximal end of the substrate **300**. Suitable conductive traces in the substrate may then make the proper electrical connections to the various bonding pads on the IC **28** and sensor **26**. It is contemplated that the electrical connector leads **324** can be connected to the substrate **300** at any point along the substrate **300** for purposes of ease of manufacture, assembly, or any reason. FIG. **14***b* illustrates this same embodiment from below, with the sensor housing **24** removed for clarity.

[0130] FIGS. **15***a* and **15***b* show a further embodiment of distal portion **20** of guide wire **10**. The substrate **300**, with its electrical traces may be electrically connected to the core wire **12** and distal core wire **36** by a conductive fluid **326**, rather than connector leads. A small droplet of conductive fluid **326** adjacent the distal end of the core wire **12**, and inside the proximal insulating sleeve **302** near the proximal end of the sensor housing **24**, makes this connection on the proximal end of the substrate **300**. Examples of conductive fluids include ionic solutions such as saline, conductive hydrogel, or a colloidal solution of metallic particles. Conductive fluids could be either hydrophilic or hydrophobic. A preferred conductive fluid is a silicone fluid loaded with silver particles. A similar droplet adjacent the proximal end of the distal core wire **36** makes the electrical connection for the distal end of the substrate **300**. To prevent the distal end of core wire **12** from making electrical contact with the sensor housing **24**, a droplet of insulating fluid **328** is placed just distal to the conductive fluid **326**. Suitable surface treatments corresponding to the surfaces that contain the conductive and insulating fluid droplets are contemplated to ensure that each droplet stays in its intended location. For example, the proximal insulating sleeve **302** may incorporate a surface that attracts the conductive fluid **326**, whereas a portion of the sensor housing **24** may be treated to attract and hold the insulating fluid drop **328**. FIG. **15***b* illustrates this embodiment in cross section.

[0131] It is also contemplated that the electronic components in the distal portion **20** of guide wire **10** may not require a separate substrate for mounting. As shown in FIG. **22**A (side view), the IC **28** may serve as substrate for other electrical components. Here, the capacitor **322** and the sensor **26** are mounted directly to the IC **28**. IC **28** is then electrically connected to the core wire **12** and distal core wire **36** by connector leads **324**. FIG. **22**B is a top view of the IC **28** in such an arrangement, with a number of bond pads **310** for electrical bonding to corresponding electrical components. Other arrangements of the IC **28**, sensor **26**, and capacitor **322** (if desired) are also contemplated, with or without a separate substrate **300**.

[0132] It is also contemplated that one or more of the IC **28**, sensor **26** or capacitor **322** could be fabricated integrally. For example, the IC **28** and sensor **26** could be fabricated from the same chip.

[0133] Any of the contemplated embodiments of the distal portion **20** of guide wire **10** may include an insulating layer **362**, as shown in FIG. **22**B, covering some or all of the electrical components including, for example, the IC **28**, sensor **26**, capacitor **322**, substrate **300**, or the electrical connections of these components to the core wire **12** or distal core wire **36**. An example of such an insulating layer is paralene coating.

[0134] FIGS. **16***a* and **16***b* (section view) illustrate an embodiment of an electrical connector **44** which serves to electrically connect the power source **64** to the guide wire **10**. Connector **44** may also be used to steer and manipulate the guide wire **10** in the patient. Connector **44** may be secured at any point along the proximal portion **18** of guide wire **10**. In this region of the guide wire **10**, the core wire **12** may include a lubricious coating **32**, which tends to be an electrical insulator. Connector **44** includes a conductive collet or clamp **48** for gripping the guide wire **10**. Collet **48** may include sharpened or serrated surface features **330** on inside surfaces to penetrate the lubricious coating **32** and make electrical contact with the core wire **12** beneath. Connector **44** includes a body **332** configured for manipulation by a user's fingers.

[0135] Body **332** includes a conductive sleeve **334**, which defines an interior lumen. The collet **48** nests inside the distal portion of the conductive sleeve **334**. A nut **50** squeezes the collet **48** inwardly when tightened against the body **332**. An electrically conductive rotary union **336** may be mounted about an exposed portion of the conductive sleeve **334**. Lead wire **58** connects to the rotary union **336**. In this manner, rotation and manipulation of the body **332** serves to rotate the guide wire **10**, but allows the lead wire **58** to stay in position, not rotating, and thereby not encumbering or becoming entangled with the guide wire **10**.

[0136] Rotary union **336** may take the form of many known electrical connections which permit relative rotation including, for example, a conductive ball bearing cartridge, or a conductive bushing with one or more brushes extending in to make contact with the conductive sleeve **334**. To further facilitate good electrical contact between the rotary union **336** and the conductive sleeve **334**, a conductive lubricant may be used.

[0137] One embodiment of the setup of guide wire **10**, as was shown in FIG. **3**, makes use of a ground pad **42** for return of the current to the power source **64**. An alternative embodiment, illustrated in FIG. **17**, makes use of a guide catheter clip **338**, to return current to the power source **64**. Guide catheter clip **338** is connected to the outside of the guide catheter **62** in an exposed location outside of the patient and near the percutaneous entry point.

[0138] Guide catheters are typically constructed using a metallic conductive braid **340** that extends within the walls. This facilitates their torqueability and kink resistance. Guide catheter clip **338** may include a penetration feature to make direct electrical contact with this braid **340**.

[0139] FIG. **18** is a simplified schematic showing the entire circuit (primary circuit **114**) of the present embodiment, with a connection **44** to the proximal portion of the guide wire **10**, and a direct connection **338** to the guide catheter braid **340** (shown in FIG. **20***a*), near its proximal end.

[0140] The power source **64** which delivers power to the IC **28** may be an alternating drive signal. Alternating signals in excess of 1 kHz may be safer than DC signals of similar amplitude. A preferred signal is 100 kHz. If the drive signal is alternating, the current flow is influenced by capacitive characteristics of the circuit. Therefore much of the current is lost through capacitive leakage from the elongate guide wire **10**. Much of this loss current **342** may therefore be contained and not passed through patient tissue if it is collected by the guide catheter braid **340** and brought back to the power source **64** by means of the guide catheter clip **338**.

[0141] The remaining current (IC current **342**) powers the IC **28** and is then passed back to the guide catheter braid **340**, mostly to the exterior surface. In this fashion, the RMS current that passes through the patient is greatly reduced.

[0142] A further alternative embodiment, as shown in FIG. **19**, makes use of both a guide catheter clip **338** and a patient ground pad **42**. In this embodiment, most of the capacitive loss current **342** is still captured by the guide catheter braid **340**, but most of the IC current **344** will travel to the patient ground pad **42**. Since the IC current **344** is now in a separate branch of the circuit, it can be monitored. This may provide for additional safety related capabilities, such as shutting the circuit down or modifying the power input in the case of various fault conditions that may impact the current or voltage detected via the patient ground pad **42**. Also, normal variations in the patient circuit may be monitored in this branch.

[0143] One simplified embodiment of guide catheter clip **338** is shown in FIG. **20**A. Clip **338** may be formed of two clamshell pieces **346**, **348** that snap together around guide catheter **62**. A first clamshell **346** may incorporate a sharpened penetrator **350**, configured to penetrate the outer layer of the guide catheter **62** and make direct electrical contact with the braid **340**. A clip lead wire **352**, connected to the penetrator **350** may be connected to the power source **64**. The guide catheter clip **338** is preferably secured around the guide catheter **62** near its proximal end, and just distal to the strain relief **341** if present.

[0144] Another embodiment is illustrated in axial section in FIG. **20**B, may include V-shaped troughs **354** on the surfaces that contact the guide catheter **62**. One or both clamshells **346**, **348** may include a sharp penetrator **350** such as a razor blade, preferably oriented at an angle such that as it penetrates the outer surface of the guide catheter **62**, it performs a slicing action (here both clamshells incorporate sharp penetrator **350**). The slicing action allows the penetrator **350** to cut easily through the relatively soft outer layer of guide catheter **62** until the penetrator just makes contact with the braid **340**. A second clamshell **348** may include a spring-loaded bed **356**. In this fashion, the guide catheter clip **338** may work with a range of guide catheter sizes. One or more clamshell locks **358** serve to keep the clip **338** in place around the guide catheter **62**. Locks **358** may be reversible to facilitate removal of clip **338**. Additionally, clip lead wire **352** may be removable. FIG. **20**C is an axial section view of the same embodiment of FIG. **20**B.

[0145] Another embodiment for modulating and encoding (e.g. digitizing) the input waveform is now described. Power source **64** delivers an alternating balanced square wave constant amplitude current **100***i*, for example at 100 kHz.

[0146] IC **28** interrogates the sensor **26** at a particular sample rate, for example 200 samples per second. A circuit in the IC **28** converts each individual pressure data point to a series of digital bits. Each bit serves as input to a variable voltage offset circuit that interacts with the input current waveform **100***i* to affect the actual voltage drop **100***v* across the entire primary circuit **114**, for a specified period of time, creating amplitude modulation. For example, if a data bit is "0", the voltage modulation may be reduced for 10 cycles (**100***v*RED), whereas if a data bit is "1", the voltage modulation is increased for 10 cycles (**100***v*INC). The bits of data may be organized to represent the full value of a given pressure sample.

[0147] Additional information may be conveyed in this digital methodology such as sensor temperature or calibration coefficients. One example of a method for conveying digital data that eliminates accumulating DC bias uses "Manchester coding". The coded data could then be used with the above resistance modulated circuit.

[0148] FIGS. **21**A-**21**D serve to further illustrate the resistance modulation and digital encoding with a guide catheter current return path by way of non-limiting example. FIG. **21**A graphically shows the primary circuit **114** voltage waveform **100***v* over several cycles, and the processed pressure waveform **360** as detected by the sensor **26** over a correspondingly short period of time. The zero value line is noted corresponding to the voltage and pressure waveforms. Note that the processed pressure waveform **360** is substantially constant, as the time period shown represents a time interval that may be shorter than the time required for a full pressure sampling. Also, the pressure sampling precedes the processed waveform **360** by a period of time.

[0149] FIG. **21**B extends the timeframe of the waveforms. Here, the voltage waveform **100***v* can be seen to change in amplitude, with a number of less modulated cycles **100***v*RED showing reduced amplitude followed by a number of higher modulated cycles **100***v*INC showing increased amplitude. The pattern of increased and reduced amplitude modulated cycles essentially forms an information bitstream that represents the value of pressure from the pressure sample. Here again, the pressure waveform **360** is substantially constant, as this is still a relatively short period of time where the processed pressure is still from the prior sampling period. The data bits encoded in the voltage waveform **100***v* are part of the sampling that will result in the next pressure value to be charted.

[0150] FIG. **21**C again extends the time of the waveforms. Now, the individual bits of modulated data can be easily discerned as notches on the voltage waveform **100***v*. And the processed pressure waveform **360** shows a slope, representing the fact that multiple samplings are represented, and the processed pressure waveform shows changing values from the multiple samplings. The pressure waveform may interpolate or smoothen the sampled pressure data points, as shown here. This results in a smooth waveform rather than a stairstepped waveform.

[0151] FIG. **21**D represents yet a longer timeframe, such as the time of a full heartbeat. The full pressure pulse of the heart is able to be represented by the amplitude modulation digital encoding scheme as described here. Such a scheme is highly resistant to errors introduced by ambient sources of electrical noise such as fluorescent lights, x-ray imaging equipment, radio telemetry devices, or other electronic devices that may be in proximity to the guide wire **10** during use.

[0152] Referring back to the exemplary primary circuit **114** voltage waveform **100***v* as described in FIG. **21**A and seen in FIG. **23**, the resultant voltage of balanced square wave constant current input **100***i* is shown in FIG. **23**. The resulting voltage waveform **100***v* reflects capacitance and other effects in the full primary circuit **114**. The first slope **100***a* of the voltage waveform **100***v*, in this example, is due primarily to the capacitance of the guide wire **10** formed with the interior of the guide catheter (and creating the loss current **342**). Once the voltage reaches a certain level, in this case after a transition of about 9 volts (peak to peak), the IC **28** circuit is energized, allowing current to flow through the IC **28**, to charge the capacitor **322**. The second slope **100***b* represents additional capacitive effects from the exposed distal portion **20** of the guide wire **10**. This latter current is essentially operating current **344** for the IC **28**. This IC current **344** is leaked to the patient. This current **344** may be over and above what is needed to power the IC **28**, due to the additional capacitive effect seen in slope **100***b*.

[0153] To further minimize current that flows through the patient (beyond the use of the guide catheter braid **340**), various alternative drive signals are also contemplated, beyond the balanced current square wave **100***i* previously described. One alternative is a stepped square wave current **116***i*, as shown in FIG. **24**. A first portion of stepped square wave **116***a* has a higher amplitude, for purposes of quickly ramping up the capacitive charging between the guide wire **10** and guide catheter **62**. But thereafter the current decreases significantly to a second portion of stepped square wave **116***b*. This portion of the waveform is substantially less than that in FIG. **23**. The result of the stepped square wave current is a lower voltage waveform **116***v* (shown here as a dashed line). An RMS calculated current within the patient is thus substantially lowered with this type of stepped square wave current drive.

[0154] Other ways to minimize current delivered to the patient are also contemplated. For example, the IC **28** may be configured to operate on a low voltage, for example 1 to 2 volts, or even lower, in contrast with the 4.5 volt (9 volt peak to peak) example described above. The IC **28** may be configured to operate at any nominal voltage, the lower the operating voltage, the lower the required current to power it because less time is spent changing charge polarity of the guide wire **10** within the guide catheter **62**.

[0155] Many of the embodiments of guide wire **10** contemplated include a core wire **12** which is of a single material, for example stainless steel, or more specifically cold worked type 304 stainless steel. However alternate materials are also contemplated, such as other stainless steels, nickel titanium alloy, cobalt chromium alloys, or other materials that exhibit high strength and high resilience. Some of the core wire **12** may be fabricated of one material, while some may be fabricated from another material. For example, the proximal portion **18** may be stainless steel, while the intermediate portion **22** may be fabricated from nickel titanium alloy, using suitable joining techniques. Also some or all of the core wire could be fabricated from a composite material, such as carbon fiber/epoxyor drawn-filled tube.

[0156] The distal core wire **36** may be in the form of a ribbon, or may be generally circular in cross section for a portion of its length, and generally rectangular for a portion of its length, or may be generally circular for its entire length. Distal core wire **36** may also have one or more tapering diameter sections. While it may be preferable to form the distal core wire **36** of 304 stainless steel, other materials are contemplated as well, such as nickel titanium alloy, cobalt chromium alloys, other 300 or 400 series stainless steel, other spring steels, or other suitable materials.

[0157] The distal core wire **36** may have multiple components, for example a circular wire extending alongside a ribbon, each one extending for a portion or fully through the distal portion from the sensor housing **24** to the distal tip **40**. Other structures are contemplated as well, for example a braid, a twisted ribbon, a hollow cable, or a solid cable, or combinations of these or other components described previously.

[0158] Other embodiments of the present disclosure will be apparent to those skilled in the art from consideration of the specification and practice of the features disclosed herein. Also, features and embodiments of the present disclosure may be used separately or in any suitable combination. Further, while the specification describes certain details of the present disclosure to illustrate various embodiments and features, it is intended that the specification be considered as exemplary only, with a true scope and spirit of the disclosure being indicated by the following claims.

1. An elongate intravascular guide wire, comprising:

an electrically conductive core wire connected to a sensor housing;

an insulating layer covering at least part of the core wire;

a pressure sensor and an integrated circuit located within the sensor housing;

at least one return electrode connected to the integrated circuit, wherein the integrated circuit, pressure sensor, and return electrode are electrically connected to form part of a primary electrical circuit; and

an electrical connector disposed on a proximal portion of the core wire, configured to penetrate the insulating layer, and electrically connected to the core wire, said core wire being configured to deliver electrical power to the integrated circuit from the connector, and said integrated circuit being configured to transmit electrical information.

2. The guide wire of claim **1**, wherein the integrated circuit is configured to convert transduced pressure information from the pressure sensor to digital information, and convey the digital information to the primary electrical circuit.

3. (canceled)

4. (canceled)

5. The guide wire of claim **1**, further comprising a distal coil extending from the sensor housing, wherein the distal coil forms at least part of the return electrode.

6-**11**. (canceled)

12. A system for measuring intravascular blood pressure within a mammal, comprising:

an elongate guide wire including:

a core wire,

a pressure sensor at a distal portion of the core wire, the pressure sensor being configured to sense blood pressure, and

an integrated circuit at the distal portion of the core wire, the integrated circuit being electrically connected to the core wire;

a steering device in electrical communication with the core wire;

a controlled current power source connected to the steering device;

a guiding catheter surrounding at least a portion of the guide wire; and

wherein the integrated circuit operates with the pressure sensor to convert the sensed pressure to an information encoded signal sent along the guide wire.

13. The system of claim **12**, wherein the controlled current power source is configured to deliver a substantially square alternating current waveform.

14-38. (canceled)

39. A connector configured to steer a guide wire, comprising:

an elongate body defining a lumen, the lumen being configured to receive the guide wire;

a clamp configured to mechanically grip the guide wire; and

an electrical connection coupled to the clamp, the electrical connection being configured to deliver power from a power source through the clamp and to the guide wire.

40. The connector of claim **39**, wherein the electrical connection includes a lead wire, and a rotary electrical connection coupling the lead wire to the clamp, wherein the rotary electrical connection is configured to allow relative rotation between the lead wire and the clamp.

41-49. (canceled)

50. The guide wire of claim **1**, wherein the electrical connector includes a clamp configured to penetrate the insulating layer, and a nut configured to exert a compressive force on the clamp.

51. The guide wire of claim **1**, wherein the pressure sensor and the integrated circuit are configured to receive power in the form of an alternating current, at least one of the pressure sensor and the integrated circuit is configured to modulate the alternating current based on a sensed pressure, and modulating includes increasing a voltage of the alternating current.

52. The guide wire of claim **51**, wherein a number of modulated cycles of the alternating current corresponds to a digital bit of information.

53. The guide wire of claim **52**, further including a logic circuit external to the patient, the logic circuit being configured for deciphering one or more digital bits of information to produce a pressure waveform.

54. The guide wire of claim **1**, wherein the electrical connector includes at least one tang with a tip configured to penetrate the insulating layer.

55. The guide wire of claim **1**, wherein the electrical connector includes a clamp, a lead wire, and a rotary electrical connection coupling the lead wire to the clamp, wherein the clamp is configured to penetrate the insulating layer, and wherein the rotary electrical connection is configured to allow relative rotation between the lead wire and the clamp.

56. The system of claim **12**, wherein the controlled current power source is configured to provide a stepped square wave current waveform.

57. They system of claim **12**, wherein the core wire is at least partially covered with an insulating layer, and the steering device is configured to penetrate the insulating layer to make electrical contact with the core wire.

58. The system of claim **57**, wherein the steering device includes a clamp configured to penetrate the insulating layer.

59. The system of claim **58**, wherein the steering device includes a nut configured to exert a compressive force on the clamp.

60. The system of claim **58**, wherein the clamp includes at least one tang with a tip configured to penetrate the insulating layer.

61. The system of claim **58**, wherein the steering device includes a lead wire, and a rotary electrical connection coupling the lead wire to the clamp, wherein the rotary electrical connection is configured to allow relative rotation between the lead wire and the clamp.

62. The system of claim **12**, wherein the guide wire includes a distal coil forming at least part of a return electrode, and the integrated circuit is configured to convert the sensed pressure to digital information, and convey the digital information to the return electrode.

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专利名称(译)	带有压力传感器的可操纵导丝和使用方法		
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摘要(译)

具有用于测量血压的压力传感器的高性能导丝可以利用连接到导丝的单个电引线。由导线上的单个电连接供电的集成电路可以与压力传感器连接，并且可以将压力信息转换为编码信号。编码信号可以在电路中检测，并且可以用于显示由压力传感器检测到的压力波形。例如，当用于经皮冠状动脉介入时，这种导丝可以提供高质量的血压测量（例如，用于分数流量储备），同时还具有用于导航曲折解剖结构的优良的可操纵性和操纵特性。