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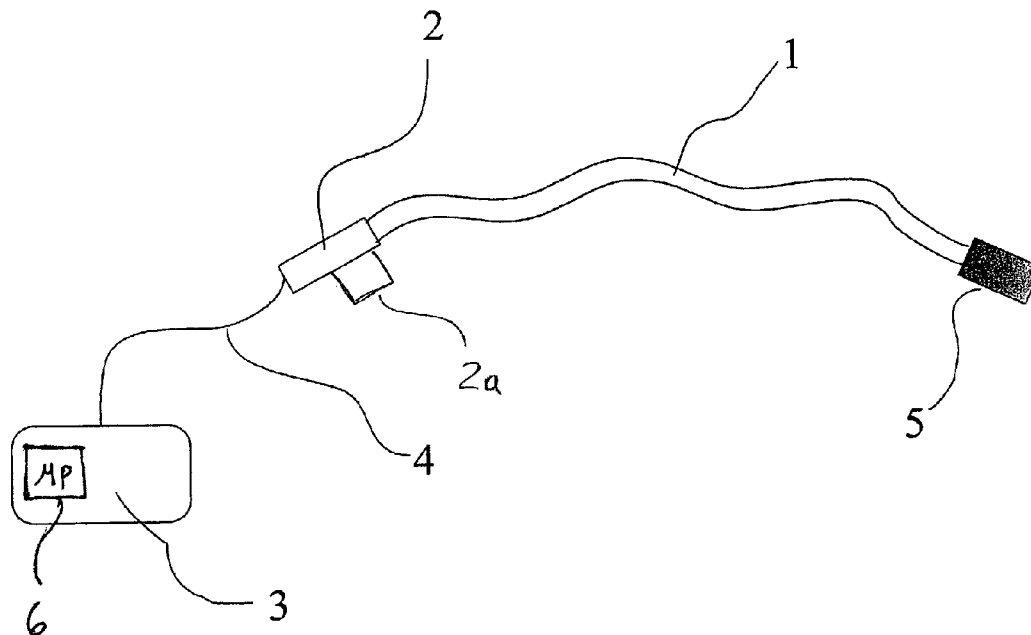
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(54) Title: MEDICAL APPARATUS SYSTEM HAVING OPTICAL FIBER LOAD SENSING CAPABILITY



(57) Abstract: Apparatus is provided for diagnosing or treating an organ or vessel, wherein a deformable body (5) having at least two optical fiber sensors disposed in a distal extremity thereof is coupled to processing logic (6) programmed to compute a multi-dimensional force vector responsive to detected changes in the optical characteristics of the optical fiber sensors arising from deflection of the distal extremity resulting from contact with the tissue of the wall of the organ or vessel. The force vector may be used to facilitate manipulation of the deformable body either directly or automatically using a robotic system (3).

MEDICAL APPARATUS SYSTEM HAVING OPTICAL FIBER LOAD
SENSING CAPABILITY

Field Of The Invention

5 The present invention relates to apparatus for
exploring and treating an organ that permits computation
of a multi-dimensional force vector resulting from
contact between the distal extremity of the apparatus and
the tissue of the wall of the organ.

10 Background Of The Invention

For many years, exploration and treatment of
various organs or vessels has been possible using
catheter-based diagnostic and treatment systems. Such
catheters are introduced through a vessel leading to the
15 cavity of the organ to be explored or treated or
alternatively may be introduced directly through an
incision made in the wall of the organ. In this manner,
the patient avoids the trauma and extended recuperation
times typically associated with open surgical procedures.

20 To provide effective diagnosis or therapy, it
is frequently necessary to first map the zone to be
treated with great precision. Such mapping may be
performed, for example, when it is desired to selectively
ablate current pathways within a heart to treat atrial
25 fibrillation. Often, the mapping procedure is

complicated by difficulties in locating the zone(s) to be treated due to periodic movement of the heart throughout the cardiac cycle.

Previously-known systems for mapping the interior of a vessel or organ are described, for example, in U.S. Patent Nos. 6,546,271 and 6,226,542. The catheters described in those patents employ electromagnetic, magnetic or acoustic sensors to map the position of a distal end of the catheter in space and then construct a three-dimensional visualization of the vessel or organ interior.

One drawback of such previously known mapping systems is that they rely on manual feedback of the catheter and/or impedance measurements to determine when the catheter is properly positioned in the vessel or organ. Those systems do not measure contact forces with the vessel or organ wall or detect contact forces applied by the catheter against the organ or vessel wall that may modify the true wall location. Instead, previously known mapping methods are time-consuming, dependent upon the skill of the clinician, and cannot compensate for artifacts created by excessive contact forces.

It therefore would be desirable to provide apparatus and methods for detecting and monitoring contact forces between a mapping catheter and the wall of the organ or vessel to permit faster and more accurate mapping. It also would be desirable to provide apparatus and methods that permit the process to be automated, thereby improving registration of measured electro-physiologic values and spatial coordinates, for example, by recording such values only where the contact forces fall within a predetermined range.

Once the topography of the vessel or organ is mapped, either the same or a different catheter may be employed to effect treatment. Depending upon the specific treatment to be applied to the vessel or organ,
5 the catheter may comprise any of a number of end effectors, such as RF ablation electrodes, a rotary cutting head, laser ablation system, injection needle or cryogenic fluid delivery system. Exemplary systems are described, for example, in U.S. Patent Nos. 6,120,520,
10 6,102,926, 5,575,787, 5,409,000 and 5,423,807.

Because the effectiveness of such end effectors often depends having the end effector in contact with the tissue of the wall of the organ or vessel, many previously-known treatment systems include expandable
15 baskets or hooks that stabilize the distal extremity of the catheter in contact with the tissue. Such arrangements, however, may be inherently imprecise due to the motion of the organ or vessel. Moreover, the previously-known systems do not provide the ability of
20 sense the load applied to the distal extremity of the catheter by movement of the tissue wall.

For example, in the case of a cardiac ablation system, at one extreme the creation of a gap between the end effector of the treatment system and the tissue wall
25 may render the treatment ineffective, and inadequately ablate the tissue zone. At the other extreme, if the end effector of the catheter contacts the tissue wall with excessive force, it may inadvertently puncture the tissue, resulting in cardiac tamponade.

30 In view of the foregoing, it would be desirable to provide a catheter-based diagnostic or treatment system that permits sensing of the load applied to the distal extremity of the catheter, including periodic

loads arising from movement of the organ or tissue. It further would be desirable to have a load sensing system coupled to control operation of the end effector, so that the end effector is operated, either manually or
5 automatically, only when the contact force is detected to fall within a predetermined range.

U.S. Patent No. 6,695,808 proposes several solutions to measure the force vector arising from contact with the tissue surface, including mechanical,
10 capacitive, inductive and resistive pressure sensing devices. One drawback of such devices, however, is that they are relatively complex and must be sealed to prevent blood or other liquids from disturbing the measurements. In addition, such load sensing devices may result in an
15 increase in the insertion profile of the distal extremity of the catheter. Still further, sensors of the types described in that patent may be subject to electromagnetic interference.

One previously-known solution for dealing with
20 potential electromagnetic interference in the medical environment is to use light-based systems rather than electrical measurement systems, such as described in U.S. Patent No. 6,470,205 to Bosselman. That patent describes a robotic system for performing surgery comprising a
25 series of rigid links coupled by articulated joints. A plurality of Bragg gratings are disposed at the articulated joints so that the bend angle of each joint may be determined optically, for example, by measuring the change in the wavelength of light reflected by the
30 Bragg gratings using an interferometer. Calculation of the bend angles does not require knowledge of the characteristics of the rigid links.

International Publication No. WO 01/33165 to Bucholtz describes an alternative spatial orientation system wherein wavelength changes measured in a triad of optical fiber strain sensors are used to compute the spatial orientation of a catheter or other medical instrument. Although the publication discloses that the strain sensors may be encased within a deformable sheath, as in Bosselman, calculation of the bend angles is not described as requiring characterization of the material properties of the deformable sheath.

Accordingly, it would be desirable to provide diagnostic and treatment apparatus, such as a catheter or guide wire, that permits sensing of loads applied to a distal extremity of the apparatus, but which do not substantially increase the insertion profile of the apparatus.

It further would be desirable to provide diagnostic and treatment apparatus, such as a catheter and guide wire, that permits computation of forces applied to a distal extremity of the apparatus, and which are substantially immune to electromagnetic interference.

Summary Of The Invention

In view of the foregoing, it is object of the present invention to provide diagnostic or treatment apparatus that permits sensing of the load applied to a distal extremity of apparatus, including periodic loads arising from movement of the organ or tissue.

It is another object of this invention to provide apparatus and methods for detecting and monitoring contact forces between an interventional apparatus, such as a mapping catheter or guide wire, and

the wall of the organ or vessel to facilitate the speed and accuracy of such mapping.

It is a further object of the present invention to provide apparatus and methods that enable a mapping or treatment process to be automated, thereby improving registration of measured electro-physiologic values and spatial coordinates, for example, by recording such values only where the contact forces fall within a predetermined range.

It is also an object of this invention to provide apparatus wherein a load sensing system is coupled to control operation of an end effector of a diagnostic or treatment apparatus, so that the end effector is operated, either manually or automatically, only when the contact force is detected to fall within a predetermined range.

It is another object of this invention to provide diagnostic and treatment apparatus, that permit sensing of loads applied to a distal extremity of the apparatus, but which do not substantially increase the insertion profile of the apparatus.

It is a further object of this invention to provide diagnostic and treatment apparatus that permit computation of forces applied to a distal extremity of the apparatus, and which are substantially immune to electromagnetic interference.

It is also an object of this invention to provide apparatus for use in a hollow-body organ, such as the heart, that permits sensing of loads applied to a distal extremity of the apparatus during movement of the organ, so as to optimize operation of an end effector disposed within the distal extremity.

These and other objects of the invention are accomplished by providing medical apparatus, illustratively a catheter, comprising a deformable body having at least two optical fiber sensors disposed in a distal extremity thereof to deform with the deformable body, and processing logic programmed to compute at least a two-dimensional force vector responsive to detected changes in the optical characteristics of the optical fiber sensors. The apparatus of the present invention may be configured as a catheter or guide wire, or may be employed in other medical apparatus where knowledge of tissue contact forces is desired.

More preferably, the apparatus of the present invention comprises three optical fiber sensors disposed within the deformable body so that they are not coplanar. For example, the three optical fiber sensors may be arranged at the apices of an equilateral triangle centered on the geometric axis of the apparatus, although other configurations also may be employed. Use of three such optical fiber sensors advantageously permits the computation of a three-dimensional force vector. The optical fiber sensors preferably are chosen from among a Fiber Bragg Grating (FBG), an Intrinsic Fabry-Perot Interferometer (IFPI), an Extrinsic Fabry-Perot Interferometer (EFPI), a Long Period Grating (LPG), a two, three or four arm Michelson interferometer (MI), a Brillouin scattering strain sensor, or intensity-based fiber optic strain sensor.

Further in accordance with the principles of the present invention, the apparatus includes processing logic, such as programmed general purpose microprocessor or application specific integrated circuit, operatively coupled to receive an output signal from the optical

fiber sensors, and to compute a two- or three-dimensional force vector from that output signal, depending upon the number of optical fiber sensors employed. The processing logic may be programmed with a matrix of values
5 associated with physical properties of an individual deformable body, and applies those values to the detected changes in wavelength to compute the external forces applied to the distal extremity. More preferably, a force-strain conversion matrix specific for each
10 deformable body is determined during manufacture, and that force-strain conversion is associated with the deformable body via an appropriate memory device, label or tag.

In accordance with the one aspect of the
15 present invention, two optical fiber sensors may be used provided that the neutral axis of the deformable body of the apparatus is well characterized. More preferably, three optical fiber sensors are disposed within the distal extremity of the deformable body to allow
20 deformations (elongation or contraction) imposed on the deformable body to be measured at three or more non-planar points.

The extremely small dimensions of the optical fiber sensors provides ample space in the distal
25 extremity of the apparatus to house for other diagnostic or treatment devices. When configured as a catheter or guide wire, the deformable body substantially reduces the insertion profile of the apparatus relative to previously-known systems having force-sensing capability.
30 In addition, the optical nature of the sensors ensures that the possible presence of liquids does not disturb the measurements, and ensures a high degree of immunity from electromagnetic interference.

The apparatus of the present invention optionally may include any of a number of previously-known end effectors disposed in the distal extremity for treating a vessel or organ, for example, an electrode to measure an electric potential (e.g., to perform an endocavity electrocardiogram), an electrode configured to ablate tissue by deposition of radiofrequency energy, an irrigation channel, and/or a three-dimensional positioning sensor.

Advantageously, the load sensing system of the present invention may be employed to continuously monitor deflection of a distal end of the deformable body. For example, the signal output by the load sensing system may be used to guide or control the use and operation of an end effector of a catheter either manually or automatically. Illustratively, when employed as part of an electrophysiology mapping catheter, the present invention permits electrical potentials of the tissue to be measured only at contact positions where the contact force applied to the distal extremity of the catheter by the tissue wall falls within a predetermined range. Such an arrangement not only offers to improve spatial registration between the mapped values and tissue location, but also makes possible the use of robotic systems capable of automating the mapping process. As a further example, the output of the load sensing system may be used to control operation of a treatment end effector, for example, to position the end effector in contact with the organ wall and to energize the ablation electrode only when the contact force is detected to fall within a predetermined range.

In addition, the distal part of at least one of the optical fibers, or an additional optical fiber,

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extends beyond the others and is equipped with an additional FBG, LPG, IFPI, EFPI or Brillouin scattering type sensor to permit the temperature of the distal extremity of the deformable body to be monitored.

5 Alternatively, or in addition, a temperature sensor may be disposed in the distal extremity in close proximity to the optical fiber sensors. Temperatures measured by the temperature sensor may be used to compensate for deformations of the deformable body
10 arising from temperature variations, which might otherwise erroneously be interpreted as force-related deformations. The temperature sensor may comprise any of a number of temperature sensors. More specifically, the temperature sensor comprises an additional optic fiber
15 that is not constrained to deform in unison with the deformable body, but instead is free to expand due to temperature variations. In a preferred embodiment, the temperature sensor comprises an additional FBG, LPG, IFPI, EFPI or Brillouin scattering type optical fiber
20 sensor.

 The additional optical fiber also could extend beyond the other optical fibers and include an additional FBG, LPG, IFPI, EFPI or Brillouin scattering type sensor to measure the temperature of the distal extremity of the
25 deformable body. Alternatively, the distal part of the additional fiber extends beyond the other optical fibers in the deformable body and includes a temperature sensor comprising a Michelson interferometer sensor or an intensity sensor.

30

Brief Description Of The Drawings

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed

5 description of the preferred embodiments, in which:

Figure 1 is a schematic view of apparatus according to the invention;

Figure 2 is a schematic plan view of the distal extremity of the deformable body of Figure 1;

10 Figure 3 is a section according to III-III of Figure 2;

Figure 4 is a schematic view of the side of the distal extremity of the deformable body showing the disposition of the Fiber Bragg Grating (FBG) or Long
15 Period Grating (LPG) sensors;

Figure 5 is a schematic view of the side of the distal extremity of the deformable body showing the disposition of the Intrinsic Fabry-Perot Interferometer (IFPI) sensors;

20 Figure 6 is a schematic view of the side of the distal extremity of the deformable body showing the disposition of the Extrinsic Fabry-Perot Interferometer (EFPI) sensors;

Figure 7 is a schematic view of the side of the
25 distal extremity of the deformable body showing the disposition of the Michelson interferometer sensors;

Figure 8 is a schematic view of the side of the distal extremity of the deformable body showing the disposition of the High Resolution Brillouin sensors;

30 Figure 9 is a schematic view of the side of the distal extremity of the deformable body showing the disposition of the reflection intensity sensors;

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Figure 10 is a schematic view of the side of the distal extremity of the deformable body showing the disposition of the microbending intensity sensors;

Figure 11 is a perspective view of three
5 optical fibers in contact with each other;

Figure 12 is a perspective view of three optical fibers in contact with each other and forming an integral part;

Figure 13 is a schematic plan view of the
10 distal extremity of the deformable body with the optical fibers of Figure 6 forming an integral part of the distal extremity;

Figure 14 is an exploded perspective view of the distal extremity of an exemplary catheter constructed
15 in accordance with the present invention;

Figure 15 is a schematic plan view of the distal extremity of the deformable body including a fourth optical fiber; and

Figure 16 is a schematic view of apparatus of
20 the present invention wherein the output of the load sensing system is utilized to control automated operation of the apparatus.

Detailed Description Of The Invention

The present invention is directed to medical
25 apparatus and methods for use with diagnostic and treatment systems wherein it is desired to measure contact forces between a distal extremity of the apparatus and a tissue wall of an organ or vessel. The load sensing capability of the present invention may be
30 used intermittently to measure the contact forces at discrete points, or alternatively, used to continuously

monitor contact forces to assist in manipulation and operation of the apparatus.

Medical apparatus incorporating the present invention illustratively may be configured as catheters or guide wires to be manually manipulated by a clinician, with the clinician using a visual or audio cue output by the load sensing system to determine, for example, optimum position for measuring an electrophysiologic value or performing treatment. Alternatively, the medical apparatus may be robotically controlled, with the load sensing system of the present invention providing a feedback and control system.

Advantageously, medical apparatus equipped with the load sensing system of the present invention are expected to permit faster, more accurate diagnosis or treatment of a vessel or organ, with improved registration between measured values and spatial locations. For example, a catheter with the inventive load sensing system would permit mapping of cardiac electrical potentials by providing reproducible contact forces between the distal extremity of the catheter and the tissue wall, thereby making the results of the mapping process less dependent on the skill of the individual clinician and facilitating automated procedures.

Referring now to Figures 1 and 2, exemplary apparatus constructed in accordance with the principles of the present invention comprises deformable body 1 having proximal end 2 coupled to console 3 via cable 4. As described in detail below, deformable body 1 includes distal extremity 5 that illustratively carries any one or more of a number of end effectors known in the art for diagnosing or treating a vessel or organ. While the

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present invention is described in the context of a catheter system for cardiac mapping and ablation, it will be understood that medical apparatus constructed in accordance with the present invention advantageously may
5 be used for other purposes, such as delivering drugs or bioactive agents to a vessel or organ wall or performing transmyocardial revascularization or cryo-ablation, such as described in the above-referenced patents.

Proximal end 2 preferably includes storage
10 device 2a, such as a memory chip, RFID tag or bar code label, which stores data that may be used in computing a multi-dimensional force vector, as described herein after. Alternatively, storage device 2a need not be affixed to proximal end 2, but instead could be a
15 separate item, e.g., packaging, individually associated with each deformable body. Proximal end 2 may be manipulated manually or automatically to cause a desired amount of articulation or flexion of distal extremity 5 using mechanisms which are per se known in the art, such
20 as pull wires or suitably configured electroactive polymers. Deformable body 1 also may be advanced, retracted and turned manually or automatically.

Deformable body 1 comprises at least two optical fiber sensors disposed in distal extremity 5 that
25 extend proximally and are coupled to console 3 via proximal end 2 and cable 3. More preferably, deformable body includes three optical fiber sensors disposed therein. In addition, control signals to and from the end effector(s) in distal extremity 5 are transmitted via
30 suitable components of cable 4 to console 3, to a tactile component of proximal end 2. As will be apparent, the nature of cable 4 depends on the nature of the end

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effectors disposed in distal extremity 5 of deformable body 1.

Console 3 comprises electronic and optical components to drive the optical fiber sensors and to
5 interpret the output signals therefrom. Console 3 further includes processing logic 6, such as a programmed general purpose microprocessor or application-specific integrated circuit, which receives an output signal corresponding to wavelength changes manifested in the
10 optical fiber sensors due to forces applied to the distal extremity of the deformable body. Processing logic 6 computes a multi-dimensional force vector based upon that output signal and a matrix of physical characteristics of the individual deformable body, as described in detail
15 below. Console 3 preferably also includes means to manifest an output from the load sensing system, such as a visual display or an auditory device. Alternatively, console 3 may output a signal for display on a separate monitor.

20 Referring now to Figures 2 and 3, deformable body 1 preferably has at least two optical fiber sensors 7 disposed within it, so that deformation of deformable body 1 is transferred to the sensors 7. Two optical fiber sensors may be employed so long as the location of
25 the neutral axis of the deformable body is known or determined during manufacture. More preferably, deformable body 1 includes at least three optical fiber sensors, and comprises a molded, machined or extruded material, such as typically are used in the making guide
30 wires or catheters. To ensure that the optical fibers form an integral part of deformable body 1, the optical fibers may be affixed within the deformable body using adhesive or other means as, for example, overmolding or

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co-extrusion. In Figure 3, optical fibers 7 are glued into deformable body 1 using adhesive 8.

Where three optical fiber sensors are employed, optical fibers 7 are disposed in deformable body 1 so
5 that the optical fiber sensors are not co-planar, ie., are not situated in a single plane. Illustratively, the optical fibers are disposed at the apices of an equilateral triangle centered on the longitudinal axis of the catheter. Other configurations are possible, so long
10 as optical fibers experience different degrees of bending and elongation during deformation of deformable body 1. Optical fiber sensors 7 may be chosen from among a Fiber Bragg Grating (FBG), a Long Period Grating (LPG), an Intrinsic Fabry-Perot Interferometer (IFPI), an Extrinsic
15 Fabry-Perot Interferometer (EFPI), a two, three or four arm Michelson interferometer (MI), a Brillouin scattering strain sensor, or intensity-based fiber optic strain sensor.

Referring now to Figure 4, deformable body 1 is
20 depicted housing three optical fibers 7 having FBG or LPG strain sensors 9 disposed in distal extremity 5. An FBG sensor is an interferometer in which a stable Bragg grating is permanently impressed (e.g., photo-etched) into the core of the fiber. The region of periodic
25 variation in the index of refraction of the fiber core acts as a very narrowband reflection filter that reflects light having a predetermined Bragg wavelength. Light therefore is reflected from the FBG in a narrow spike with a center wavelength that is linearly dependent on
30 the Bragg wavelength and the mean index of refraction of the core. Consequently, deformations that alter the grating characteristics result in a shift in the reflected Bragg wavelength.

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A LPG is similar in construction to an FBG, and comprises a single mode fiber having periodic index modulation of the refractive index of the fiber core with a much longer period than a FBG. Use and operation of a deformable body employing LPGs rather than FBGs is similar to that described below.

During use of the apparatus, the distal extremity of deformable body 1 is compressed and bent due to loads imposed by contacting the tissue of the organ. The portions of optical fibers 7 that are situated in the distal extremity also are deformed but in a varying degrees according to their respective positions in the distal extremity.

The initial calibration of the FBG sensors, i.e., the average wavelength reflected from the Bragg grating in the absence of any applied forces (referred to as the "Bragg wavelength") is determined from grating characteristics impressed during manufacture of the optical fiber. Any deviations from the Bragg wavelength are proportionately related to an exact parameter, such as strain. In the embodiment of Figure 4, the Bragg grating allows the deformation (elongation or contraction) of each of optical fibers 7 to be quantified by measuring the change in wavelength of the light reflected by the Bragg grating.

The foregoing information, together with known physical properties of the deformable body, enable processing logic 6 of console 3 to calculate the components of a multidimensional force vector with appropriate algorithms. The force vector then may be displayed or otherwise manifested, for example, as a graphic on a display screen or by varying the pitch

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emitted from an auditory device housed in or associated with console 3.

Still referring to Figure 4, one of the optical fibers 7 preferably extends beyond the others and includes second FBG (or LPG) 10 for measuring the temperature of the front end of the deformable body. Temperature changes at the front end of the deformable body may arise, e.g., due to operation of an ablation electrode, and will cause a change in the associated Bragg wavelength. By knowing the physical properties of the fiber and measuring the wavelength of the light reflected by the grating, processing logic 6 may compute the temperature at the level of the distal extremity, for example, to monitor tissue ablation progress.

Referring again to Figure 1, console 3 comprises a laser, preferably a tunable laser diode, arranged to inject a beam of light into the optical fibers through cable 4, and a photodetector that detects variations in the characteristics of the reflected light beam due to deformations imposed on the strain sensors and deformable body. Preferably, the console 3 includes a Fiber Bragg Grating Demodulator.

In such a system, each of the optical fiber sensors has a Bragg grating with a different wavelength, and which therefore responds in a specified range of frequency. A tunable laser is coupled to all of the optical fiber sensors and scans a certain frequency several times per second. A photodiode records the wavelength change for each Bragg grating when the frequency of the laser centers on the grating frequency. In this manner, each of the optical fiber sensors may be interrogated as the tunable laser scans through the grating frequencies of the sensors.

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Further in accordance with the principles of the present invention, processing logic 6 is programmed to compute a two- or three-dimensional force vector from the output of the Fiber Bragg Grating Demodulator. The theory underlying these computations is now described.

For apparatus having three fiber optic Bragg strain sensors embedded within a deformable body comprising polyetheretherketone ("PEEK"), the total strain may be computed using:

$$\begin{bmatrix} \varepsilon_{1,t} \\ \varepsilon_{2,t} \\ \varepsilon_{3,t} \\ \Delta T_t \end{bmatrix} = \begin{bmatrix} C_\varepsilon & 0 & 0 & C_{\varepsilon T} \\ 0 & C_\varepsilon & 0 & C_{\varepsilon T} \\ 0 & 0 & C_\varepsilon & C_{\varepsilon T} \\ 0 & 0 & 0 & C_T \end{bmatrix} \cdot \left(\begin{bmatrix} \lambda_{1,t} \\ \lambda_{2,t} \\ \lambda_{3,t} \\ \lambda_{4,t} \end{bmatrix} - \begin{bmatrix} \lambda_{1,r} \\ \lambda_{2,r} \\ \lambda_{3,r} \\ \lambda_{4,r} \end{bmatrix} \right) \quad (1.1)$$

$$\mathbf{a} = \mathbf{C} \cdot (\mathbf{\lambda}_t - \mathbf{\lambda}_r) \quad (1.1a)$$

Where: r – time when reference (zero) measurement is set

t – time relative to reference time

$\lambda_{i,r}$, i=1,4 – reference wavelengths of Bragg-gratings

$\lambda_{i,t}$, i=1,4 – wavelengths of Bragg-gratings at time t

$\varepsilon_{i,t}$, i=1,3 – total strain values at time t

ΔT_t – Temperature change at time t

C_ε – coefficient of linearity between the wavelength and strain

$C_{\varepsilon T}$ – coefficient of temperature compensation of the Bragg-grating

C_T – coefficient of linearity between the wavelength and temperature

$\mathbf{\lambda}_r$ – Matrix (vector) of Bragg-gratings reference wavelengths

$\mathbf{\lambda}_t$ – Matrix (vector) of Bragg-gratings wavelengths at time t

\mathbf{a} – Matrix (vector) of total strain and temperature changes

\mathbf{C} – Strain transducer and compensation matrix

10

The total strain includes a component due to thermal expansion of the deformable body arising from the difference between the measured temperature of the deformable body and a predetermined reference temperature. The elastic strain, which is a function of the applied force, therefore may be calculated using:

15

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$$\begin{bmatrix} \varepsilon_{el1,t} \\ \varepsilon_{el2,t} \\ \varepsilon_{el3,t} \end{bmatrix} = \begin{bmatrix} 1 & 0 & 0 & -\alpha_{Tc} \\ 0 & 1 & 0 & -\alpha_{Tc} \\ 0 & 0 & 1 & -\alpha_{Tc} \end{bmatrix} \cdot \begin{bmatrix} \varepsilon_{1,t} \\ \varepsilon_{2,t} \\ \varepsilon_{3,t} \\ \Delta T_t \end{bmatrix} \quad (1.2)$$

$$\mathbf{\varepsilon}_{el,t} = \mathbf{\alpha}_T \cdot \mathbf{\varepsilon} \quad (1.2a)$$

Where: $\varepsilon_{el,i}$, $i=1,3$ – elastic strain values at time t
 α_T – Thermal expansion coefficient of catheter material (PEEK)

$\mathbf{\varepsilon}_{el,t}$ – Matrix (vector) of elastic strain at time t

$\mathbf{\alpha}_T$ – Temperature reduction matrix

$$(1.1a) \wedge (1.2a) \Rightarrow \mathbf{\varepsilon}_{el,t} = \mathbf{\alpha}_T \cdot \mathbf{C} \cdot (\mathbf{\lambda}_t - \mathbf{\lambda}_r) \quad (1.3)$$

The elastic strains are related to the internal forces experienced by the optical fiber sensors as a function of both the physical dimensions of, and the material properties of, the deformable body:

$$\begin{bmatrix} \varepsilon_{el1,t} \\ \varepsilon_{el2,t} \\ \varepsilon_{el3,t} \end{bmatrix} = \begin{bmatrix} 1 & y_1 & -x_1 \\ 1 & y_2 & -x_2 \\ 1 & y_3 & -x_3 \end{bmatrix} \cdot \begin{bmatrix} \frac{1}{E_{ten} \cdot A} & 0 & 0 \\ 0 & \frac{1}{E_{flex} \cdot I_x} & 0 \\ 0 & 0 & \frac{1}{E_{flex} \cdot I_y} \end{bmatrix} \cdot \begin{bmatrix} N_{z,t} \\ M_{x,t} \\ M_{y,t} \end{bmatrix} \quad (2.1)$$

$$\mathbf{\varepsilon}_{el,t} = \mathbf{G} \cdot \mathbf{\delta} \cdot \mathbf{I}_{F,t} \quad (2.1a)$$

Where: x_i and y_i , $i=1,3$ – coordinates of Bragg-gratings with respect to center of gravity of the catheter cross-section

E_{ten} – Equivalent tension / compression Young modulus of catheter

E_{flex} – Equivalent flexural Young modulus of catheter

I_x – Moment of inertia with respect to x axis

I_y – Moment of inertia with respect to y axis

N_{zt} – Normal force in direction of z axis at time t

M_{xt} – Bending moment with respect to x axis at time t

M_{yt} – Bending moment with respect to y axis at time t

\mathbf{G} – Geometry matrix

$\mathbf{\delta}$ – Matrix of flexibility

$\mathbf{I}_{F,t}$ – Matrix (vector) of internal forces at time t

Equation (2.1) may be rearranged to solve for the internal forces as a function of the elastic strain. The elastic strain from equation (1.3) may then be substituted into the rearranged matrix system to compute

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the internal forces as a function of the elastic strain, as shown in Equation (2.3) below:

$$(2.1) \Rightarrow \begin{bmatrix} N_{z,t} \\ M_{x,t} \\ M_{y,t} \end{bmatrix} = \begin{bmatrix} E_{\text{ten}} \cdot A & 0 & 0 \\ 0 & E_{\text{flex}} \cdot I_x & 0 \\ 0 & 0 & E_{\text{flex}} \cdot I_y \end{bmatrix} \cdot \begin{bmatrix} 1 & y_1 & -x_1 \\ 1 & y_2 & -x_2 \\ 1 & y_3 & -x_3 \end{bmatrix}^{-1} \cdot \begin{bmatrix} \epsilon_{\text{el}1,t} \\ \epsilon_{\text{el}2,t} \\ \epsilon_{\text{el}3,t} \end{bmatrix} \quad (2.2)$$

$$(2.1a) \Rightarrow I_{F,t} = S \cdot G^{-1} \cdot \epsilon_{\text{el},t} \quad (2.2a)$$

Where: $S = \delta^{-1}$ - Stiffness matrix

$$(1.3) \wedge (2.1a) \Rightarrow I_{F,t} = S \cdot G^{-1} \cdot \alpha_T \cdot C \cdot (\lambda_t - \lambda_r) \quad (2.3)$$

It remains only to relate the internal forces experienced by the optical fiber sensors to the external contact forces actually exerted on the distal extremity of the deformable body by the tissue wall. These forces are computed based on the positions of the optical fiber sensors from the exterior wall of the deformable body, assuming the deformable body is substantially incompressible:

$$\begin{bmatrix} F_{x,t} \\ F_{y,t} \\ F_{z,t} \end{bmatrix} = \begin{bmatrix} 0 & 0 & -\frac{1}{d} \\ 0 & \frac{1}{d} & 0 \\ -1 & 0 & 0 \end{bmatrix} \cdot \begin{bmatrix} N_{z,t} \\ M_{x,t} \\ M_{y,t} \end{bmatrix} \quad (3.1)$$

$$F_t = d \cdot I_{F,t} \quad (3.1a)$$

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Where: F_{xt} – Touching external transversal force at time t , in direction of x axis (with opposite sense)
 F_{yt} – Touching external transversal force at time t , in direction of y axis (with opposite sense)
 F_{zt} – Touching external normal force at time t , in direction of z axis (with opposite sense, compression is positive)
 d – distance between the touching point of lateral forces and the cross-section with sensors (along z axis)

F_t – Matrix of touching external forces at time t

d – Matrix of conversion

$$(2.3) \wedge (3.1a) \Rightarrow F_t = d \cdot S \cdot G^{-1} \cdot \alpha_T \cdot C \cdot (\lambda_t - \lambda_r) \quad (3.2)$$

$$F_t = K_\lambda \cdot (\lambda_t - \lambda_r) = K_\lambda \cdot \lambda_t - F_r \quad (3.3)$$

Where: K_λ – Force transducer matrix, $K_\lambda = d \cdot S \cdot G^{-1} \cdot \alpha_T \cdot C$ (3.4)

F_r – Reference force matrix (vector), $F_r = K_\lambda \cdot \lambda_r$ (3.5)

Solution of equations (3.1) to (3.5) provides the normal and transverse forces applied to the external surface of the deformable body, i.e., $F_{\text{norm},t} = F_{z,t}$ and

- 5 $F_{\text{trans},t} = \text{square root } (F_{x,t}^2 + F_{y,t}^2)$. The angle γ_t of application of the transverse force may be computed from Table I:

Table I

$F_{x,t}$	$F_{y,t}$	γ_t
≥ 0	≥ 0	$\arcsin(F_{y,t} / F_{\text{trans},t})$
< 0	≥ 0	$\Pi - \arcsin(F_{y,t} / F_{\text{trans},t})$
< 0	< 0	$\Pi - \arcsin(F_{y,t} / F_{\text{trans},t})$
≥ 0	< 0	$2 \cdot \Pi + \arcsin(F_{y,t} / F_{\text{trans},t})$

- 10 Many of the values employed in equations (1.1) to (3.5) are related to the material properties of the deformable body or optical fiber sensors, such as the Bragg wavelengths, thermal expansion coefficients and elastic moduli of the deformable body. Other values,
- 15 such as the distances between the optical fiber sensors and the external surface of the deformable body may be

subject to variations as a consequence of the manufacturing process employed.

To ensure the accuracy of the computed force vector, specific information for each deformable body may be stored in storage device 2a. Generally, the information may take the form of a data file that is input to console 3 prior to use of the deformable body. For example, storage device 2a may comprise a memory chip associated with cable 4 in which such information is stored, or a bar code or a RFID tag located on proximal end 2 of the deformable body or the packaging for the deformable body. Alternatively, data specific to an individual deformable body may be uploaded to console 3 from an item of removable storage (e.g., CD) or via secure download from the manufacturer's website.

The information specific to each deformable body may be obtained during a calibration step, conducted during manufacture of the deformable body, by subjecting the deformable body to a series of known forces. In this case, the foregoing equations may be collapsed so the normal and transverse forces may be computed directly from a force-to-wavelength conversion matrix:

$$\mathbf{F}(t) = \mathbf{K}(\boldsymbol{\lambda}(t) - \boldsymbol{\lambda}_0) \quad (4.0)$$

where:

$\mathbf{F}(t)$ is the vector of forces $[F_{x,t}, F_{y,t}, F_{z,t}]$,
 $\boldsymbol{\lambda}(t)$ is the vector of wavelengths $[\lambda_{1,t}, \lambda_{2,t}, \lambda_{3,t}]$
 measured for the individual sensors,
 $\boldsymbol{\lambda}_0$ is the vector of wavelengths $[\lambda_1^0, \lambda_2^0, \lambda_3^0]$
 measured for the individual sensors with zero applied force, and

\mathbf{K} is a matrix computed when the deformable body is subjected to the series of known forces.

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During the calibration step of manufacture, the deformable body is subjected to the following forces in series: (1) a purely axial force of known magnitude F' ; (2) a lateral force of known magnitude F'' ; and (3) a lateral force of known magnitude F''' applied 90 degrees to the orientation of force F'' . When all of the forces F' , F'' , F''' and wavelengths are known, the force-to-strain conversion matrix K may be computed as:

$$K = F(\lambda(t) - \lambda_0)^{-1} \quad (5.0)$$

10 or:

$$\begin{bmatrix} F_x & F'_x & F''_x \\ F_y & F'_y & F''_y \\ F_z & F'_z & F''_z \end{bmatrix} \begin{bmatrix} (\lambda_1 - \lambda_1^0) & (\lambda'_1 - \lambda_1^0) & (\lambda''_1 - \lambda_1^0) \\ (\lambda_2 - \lambda_2^0) & (\lambda'_2 - \lambda_2^0) & (\lambda''_2 - \lambda_2^0) \\ (\lambda_3 - \lambda_3^0) & (\lambda'_3 - \lambda_3^0) & (\lambda''_3 - \lambda_3^0) \end{bmatrix}^{-1} = \begin{bmatrix} a_{11} & a_{13} & a_{13} \\ a_{21} & a_{22} & a_{23} \\ a_{31} & a_{32} & a_{33} \end{bmatrix} \quad (5.1)$$

Force-to-strain conversion matrix K then may be stored in storage device 2a associated with the corresponding deformable body, as described herein above. The values of the force-to-conversion matrix then may be input to console 3 when the deformable body is coupled to the console using a bar code reader, input pad or direct electrical connection through cable 4. Once matrix K is provided for a given deformable body, the normal force, transverse force and angle of application of the transverse force may be computed as described above and using Table I.

The values for the normal force, transverse force and angle of application of the transverse force, computed as described above, may be output as numerical values to a display monitor that forms part of console 3 or which is associated with console 3. In addition, a graphic including a variable size or colored arrow may be displayed pointing at a position on the circumference of

a circle to visualize the magnitude and direction of the transverse force applied to the distal extremity of the deformable body. By monitoring this display, the operator may continuously obtain feedback concerning the contact forces applied to the distal extremity of the deformable body.

Referring now to Figure 5, an alternative embodiment is described in which optical fiber strain sensors 7 comprise Intrinsic Fabry-Perot Interferometers (IFPI). One of the optical fibers is extended and comprises a second IFPI sensor 13 for measuring the temperature of the front end of the distal extremity.

An IFPI comprises a single mode optical fiber having segment having reflectors 12 disposed at either end to define optical cavity 11. The reflectors may comprise semi-reflective mirror surfaces formed in the fiber, or alternatively may comprise two FBGs. Light emitted from a laser diode disposed in console 3 impinges upon the proximal reflector and is partially reflected back at specific wavelengths 14. Light passing through the proximal reflector and impinging upon the distal reflector is also reflected back. The two reflected beams result in constructive and destructive interferences that are detected by a photodetector disposed in console 3.

A variation in strain or temperature changes the optical length of optical cavity 11 and sensor 13, and influences the reflection characteristics from which relative deflections of the optical fibers may be computed. This information in turn permits computation of the force vector imposed upon distal extremity 5 due to contact with the tissue of the wall of the organ or vessel.

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Figure 6 illustrates a further alternative embodiment of the deformable body of the present invention, in which deformable body 1 contains three Extrinsic Fabry-Perot interferometer (EFPI) sensors. One of the optical fibers extends beyond the others and comprises a second EFPI sensor 17 to measure the temperature of the front end of the distal extremity. An EFPI sensor comprises optical cavity 11 formed by hollow capillary tube 15 and cut ends 16 of the optical fiber. The hollow capillary tube contains air. Operation of the EFPI is similar to that described above for the IFPI, except that the cut ends of the fiber act as the reflectors to reflect specific wavelengths 18. Light reflected from cut ends 16 result in two beams that constructively and destructively interfere. A variation in strain or temperature changes the length of the optical cavity and influences the reflection characteristics.

Figure 7 illustrates a further alternative embodiment of the deformable body of the present invention wherein deformable body 1 contains three optical fibers 7 that form a Michelson interferometer. Each optical fiber 7 includes reflector 19 at its distal extremity; the fibers are coupled at their proximal ends by optical coupler 20. A wave is injected into fiber 21 from a laser diode disposed in console 3 and is separated by coupler 20 into each of the optical fibers ("arms") of the interferometer. The coupler 20 combines the back reflected light from each arm. Using a coherent or low coherence interferometer, variations in the relative phases of the reflected light from the different fibers are measured to compute the strain experienced by deformable body 1. Based upon the computed strain, the

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contact force between the distal extremity of the deformable body and the tissue of the organ or vessel wall may be determined.

Referring now to Figure 8, an embodiment wherein the optical fibers comprise high resolution Brillouin sensors is described. Brillouin sensors use the principle of scattering 22 that is an intrinsic phenomenon of optical fiber. This phenomenon results from the interaction between the light and the phonons (pressure wave) present in the fiber. Wave 23 is backscattered with a shift in optical frequency relative to the injected wave. One of the optical fibers 7 extends beyond the others and comprises a second Brillouin scattering sensor 24 to measure the temperature at the front end of the distal extremity. A variation in strain or temperature changes the shift in optical frequency. Using impulsion, phase modulation or other techniques, it is possible to select different locations 26 along the fiber and to measure the state of strain at these locations.

Referring to Figures 9 and 10, further embodiments of the present invention are described that employ intensity-type optical fiber sensors. More specifically, Figure 9 illustrates use of reflection intensity sensors while Figure 10 illustrates use of microbending intensity sensors.

In Figure 9, reflection intensity sensors comprise connection zones 25 within optical fibers 7. Under the effect of a strain caused by deformation of the distal extremity, or a temperature variation, connection zones 25 modulate the amplitude of the optical wave 26 that is transmitted and/or reflected. The variation in intensity of the reflected light is measured by

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apparatus, which is per se known. An additional optical fiber also may be provided to perform temperature measurement.

5 In Figure 10, microbending intensity sensors comprise connection zones 27 disposed along the length of optical fibers 7. Connection zones 27 may be obtained by introducing microbendings in the fibers. Under the effect of a strain caused by deformation of the distal extremity, or a temperature variation, connection zones 10 27 modulate the amplitude of the optical wave 28 that is transmitted and/or reflected. The variation in intensity of the reflected light is measured by apparatus, which is per se known.

According to a preferred embodiment, the three 15 optical fibers may be assembled with each other to form an integral part, as depicted in Figure 11, or embedded with an adhesive or other suitable deformable material to form cylindrical element 29, as depicted in Figure 12. This arrangement provides a very small solid assembly 20 that may in turn be affixed within a lumen of a catheter of otherwise conventional construction, as depicted in Figure 13, while also protecting the optical fibers from breakage. In accordance with the principles of the present invention, bundling the fibers as shown in 25 Figures 11-13 ensures that all three of the optical fibers are not co-planar.

Referring now to Figures 4 and 14, the distal extremity of an exemplary ablation catheter utilizing the load sensing capability of the present invention is 30 described. Deformable body 1 includes electrodes 30, 31 and 32 and is coupled to front end 33 having irrigation ports 34. Electrodes 30, 31, 32, 33 are provided according to the function of the specific application for

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the catheter, for example, endocavity electrocardiogram, radiofrequency ablation, etc. Front end 33 also may be an electrode. Sensor 35 also may be provided that provides three-dimensional positioning of the distal
5 extremity of the catheter, with sensor 35 being based upon electromagnetic, magnetic, electric, ultrasound principles.

Deformable body 1 includes at least three fiber optic sensors 9 configured as described hereinabove. One
10 of the optical fibers extends beyond the others and includes, for example, second Bragg grating 10 that serves as a temperature sensor. Bragg grating 10 is received within front end 33 and may be used to compute temperature changes in front end 33 resulting from
15 operation of the electrode. Irrigation ports 34 communicate with one or more channels situated inside the catheter and may be used to deliver a cooling solution, e.g., saline, to the distal extremity of the catheter during operation of the front end electrode to lower the
20 temperature of the front end and control the ablation of tissue.

Although front end 33 is illustratively described as configured for performing radiofrequency ablation, other tissue ablation or treatment end
25 effectors could be used, such as laser, ultrasound, radiation, microwave and others. Furthermore, other therapeutic means such as the injector of medication, stem or other types of cells may also be situated in the head of the catheter.

30 With respect to Figure 15, a further alternative embodiment is described wherein a fourth optical fiber is used to measure the temperature of the deformable body in the vicinity of the other optical

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fiber strain sensors. Because the material of deformable body 1 may be sensitive to temperature variations, a change of temperature of the deformable body may result in expansion or contraction of the deformable body and the embedded optical fibers. This effect may result in computation of a false force vector. Accordingly, fourth optical fiber 7 is slidably disposed in deformable body 1 so that it is not affected by temperature induced expansion or contraction of the deformable body, and thus provides a reference measurement. If the temperature of the sensor body is known, however, such as by using a fourth optical fiber, thermal expansion or compression of the deformable body may be compensated in the computation of the force vector.

Referring now to Figure 16, and alternative embodiment of apparatus utilizing the load sensing system of the present invention is described. Apparatus 40 includes deformable body 41 having distal extremity 42 and proximal end 43 coupled to console 45 via cable 44. Construction and operation of components 41-45 is similar to that described above for the embodiment of Figure 1.

In accordance with one aspect of the present invention, apparatus 40 of Figure 16 further includes robotic control system comprising controller 46, input and display device 47 and actuator 48. Actuator 48 is coupled to deformable body 41 to manipulate the deformable body responsive to commands generated by programmed microprocessor 46. Controller 46 is programmed via instructions input via input and display device 47, and the operation of the actuator 48 may be monitored via a display portion that device 47. Controller 46 is coupled to console 45 to receive the output of the load sensing system of the present

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invention, and to use that information to control manipulation of deformable body 41 and actuator 48. Console 45 also may receive an input from controller 46 that is used to determine when the end effector of
5 deformable body 41 is operated.

For example, deformable body 41 may comprise an electrophysiology catheter designed to map electrical potentials within a patient's heart. In this case, distal extremity 42 may include a series of mapping and
10 ablation electrodes as described herein above with respect to Figure 14. As described above, previously known methods of mapping electrical potentials within a patient's heart is a time consuming activity, because the clinician determines engagement of with the tissue wall
15 by tactile feedback through the catheter shaft or using impedance measurements.

In accordance with the principles of the present invention, actuator 48 comprises a multi-axis tool capable of advancing and rotating the catheter
20 within the patient's heart. Controller 46 may be programmed to manipulate the catheter until the contact force encountered by distal extremity 42 falls within a predetermined range, as determined via monitoring by console 45. Once the contact force is determined to fall
25 within the predetermined range, the electrical potential may be measured and recorded. Controller 46 then may reposition the catheter as required to map other desired portions of the patient's heart.

Advantageously, because the contact forces
30 applied by the distal extremity can be controlled within desired ranges, the risk of deforming the tissue wall is reduced. Accordingly, if a three dimensional locator system also is provided in the catheter, such as

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described above, accurate registration of the measured values and the spatial locations of the measurement points may be obtained. The load sensing system of the present invention similarly may be integrated into a treatment system, for example, including the ablation electrode described above with respect to Figure 14, in which the ablation electrode may be energized to ablate tissue only when the contact force between the distal extremity and the tissue wall exceeds a predetermined minimum value or falls within a predetermined range.

In addition, where distal extremity 42 of deformable body 41 is articulable, controller 46 also may provide a signal to console 45 that adjusts the degree of articulation of the distal extremity. In this manner, the load sensing system of the present invention may be configured not only to serve as part of a feedback loop to an external controller, but may itself accept an external control signal that controls operation of an end effector of catheter 41.

In summary, use of optical fiber strain sensors permits computation of a multi-dimensional force vector that arises during contact of the distal extremity of the deformable body with the tissue of the wall of the organ or vessel. When such information is combined with a 3D positioning sensor, precise mapping may be obtained to permit diagnosis or treatment of tissue at an optimal applied force. The small size of the optical fiber strain sensors and high resolution of measurements obtained by these devices allows highly precise measurements to be obtained even in environments that are humid and subject to electromagnetic interference.

While preferred illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention.

- 5 The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

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What is Claimed is:

1. Apparatus for diagnosis or treatment of a vessel or organ, the apparatus comprising:
a deformable body having a distal extremity;
at least two optical fiber sensors affixed within the distal extremity; and
processing logic operatively coupled to receive an output of the optical fiber sensors, the processing logic programmed to compute a multi-dimensional force vector corresponding to a contact force between the distal extremity and a tissue wall of the organ or vessel.
2. The apparatus of claim 1, wherein the two optical fiber sensors are affixed to one another.
3. The apparatus of claim 1 further comprising a third optical fiber sensor, the third optical fiber sensor disposed within the deformable body so that the three optical fiber sensors are not coplanar.
4. The apparatus of claim 3 wherein the processing logic is programmed to compute a three-dimensional force vector responsive to the output of the optical fiber sensors.
5. The apparatus of claim 1 wherein the optical fiber sensors are selected from the group consisting of: Fiber Bragg Grating optical fiber strain sensors, Long Period Grating optical fiber strain sensors, Intrinsic Fabry-Perot Interferometer optical fiber strain sensors, Extrinsic Fabry-Perot

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Interferometer optical fiber strain sensors, Michelson interferometer optical fiber strain sensors, Brillouin scattering optical fiber strain sensors and intensity interferometer optical fiber strain sensors.

6. The apparatus of claim 1, wherein a distal part of an optical fiber of one of the optical fiber sensors extends distally beyond the other optical fiber sensor and further comprises an additional optical fiber sensor.

7. The apparatus of claim 1, wherein the optical fiber sensors are selected from the group consisting of Michelson or intensity interferometer optical fiber strain sensors and an additional optical fiber extends beyond the optical fiber sensors and includes an additional optical fiber sensor to measure temperature.

8. The apparatus of claim 1, further comprising another optical fiber sensor slidably disposed within a lumen of the deformable body to measure a temperature of the deformable body.

9. The apparatus of claim 1, wherein the distal extremity further comprises at least one electrode to measure an electric potential of the tissue of the organ or vessel.

10. The apparatus of claim 9 further comprising a processor programmed to measure the electrical potential when the contact force falls within a determined range.

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11. The apparatus of claim 1, wherein the distal extremity further comprises at least one electrode for ablating tissue by depositing radiofrequency energy.

12. The apparatus of claim 10 further comprising a processor programmed to permit actuation of the electrode to ablate tissue only when the contact force falls within a determined range.

13. The apparatus of claim 1, wherein the distal extremity further comprises an irrigation channel.

14. The apparatus of claim 1, wherein the distal extremity further comprises a three-dimensional positioning sensor.

15. The apparatus of claim 1 further comprising a Fiber Bragg Grating Demodulator coupled to the optical fiber sensors to generate the output.

16. The apparatus of claim 15 further comprising means for articulating the distal extremity, wherein articulation of the distal extremity is determined responsive to the output.

17. The apparatus of claim 15 further comprising a robotic control system that manipulates the deformable body responsive to the output.

18. The apparatus of claim 1 wherein the deformable body has a corresponding force-strain conversion matrix.

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19. The apparatus of claim 18 wherein the force-strain conversion matrix is stored in a memory chip, bar code or RFID tag provided with the deformable body.

20. The apparatus of claim 18 wherein the force-strain conversion matrix is provided to the processing logic prior to use of the deformable body.

21. Apparatus for diagnosis or treatment of a vessel or organ, the apparatus comprising:

an elongated body having proximal and distal ends and a distal extremity, the distal extremity comprising a deformable material;

three optical fibers extending through the elongated body and affixed within the distal extremity so that the optical fibers are not co-planar;

at least one optical strain sensor disposed within the distal extremity and coupled to each one of the three optical fibers; and

a storage device associated with the elongated body, the storage device containing a force-strain conversion matrix of that enables computation of a three-dimensional force vector corresponding to a contact force between the distal extremity and a tissue wall of the organ or vessel.

22. The apparatus of claim 21 further comprising a console having a laser diode, a photodetector and processing logic, wherein the processing logic is programmed to receive an output from the optical strain sensor and to compute a three-

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dimensional force vector using the force-strain conversion matrix.

23. The apparatus of claim 21, wherein the three optical fibers are affixed to one another to form a sub-assembly.

24. The apparatus of claim 21 wherein the optical fiber strain sensor is selected from the group consisting of: a Fiber Bragg Grating optical fiber strain sensor, a Long Period Grating optical fiber strain sensor, an Intrinsic Fabry-Perot Interferometer optical fiber strain sensor, an Extrinsic Fabry-Perot Interferometer optical fiber strain sensor, a Michelson interferometer optical fiber strain sensor, a Brillouin scattering optical fiber strain sensor and an intensity interferometer optical fiber strain sensor.

25. The apparatus of claim 21, wherein a distal part of one of the optical fibers extends distally beyond the other optical fibers and further comprises an additional optical fiber sensor for use in determining temperature.

26. The apparatus of claim 21, wherein the three optical fibers comprise arms of a Michelson or intensity interferometer optical fiber strain sensor and an additional optical fiber extends through the elongate body and distally beyond the other optical fibers and includes an additional optical fiber sensor to measure temperature.

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27. The apparatus of claim 21, further comprising a fourth optical fiber strain sensor slidably disposed within a lumen of the elongated body to measure a temperature of the distal extremity.

28. The apparatus of claim 22, wherein the distal extremity further comprises an end effector to perform a diagnosis or treatment of the organ or vessel.

29. The apparatus of claim 28, wherein the end effector comprises at least one electrode for measuring an electric potential of the tissue of the organ or vessel.

30. The apparatus of claim 29, wherein the console is programmed to measure the electrical potential when the contact force falls within a determined range.

31. The apparatus of claim 28, wherein the end effector comprises at least one electrode for ablating tissue by depositing radiofrequency energy.

32. The apparatus of claim 31 wherein the console is programmed to permit actuation of the electrode to ablate tissue only when the contact force falls within a determined range.

33. The apparatus of claim 31, wherein the distal extremity further comprises an irrigation channel.

34. The apparatus of claim 21, wherein the distal extremity further comprises a three-dimensional positioning sensor.

35. The apparatus of claim 22 further comprising means for articulating the distal extremity, the means for articulating responsive to an output of the processing logic.

36. The apparatus of claim 22 further comprising a robotic control system that manipulates the elongated body responsive to the output.

37. The apparatus of claim 21 wherein the storage device comprises a memory chip, bar code or RFID tag associated with the deformable body.

38. The apparatus of claim 22 wherein the force-strain conversion matrix is input to the processing logic prior to use of the deformable body.

Fig. 1

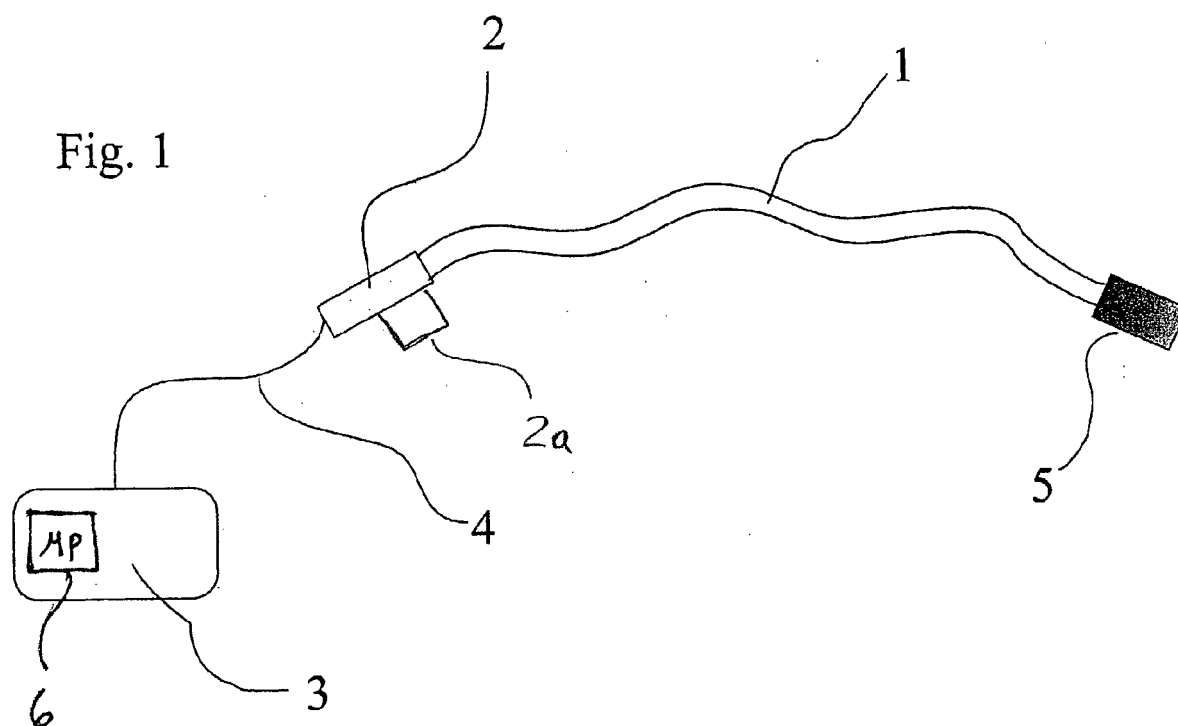
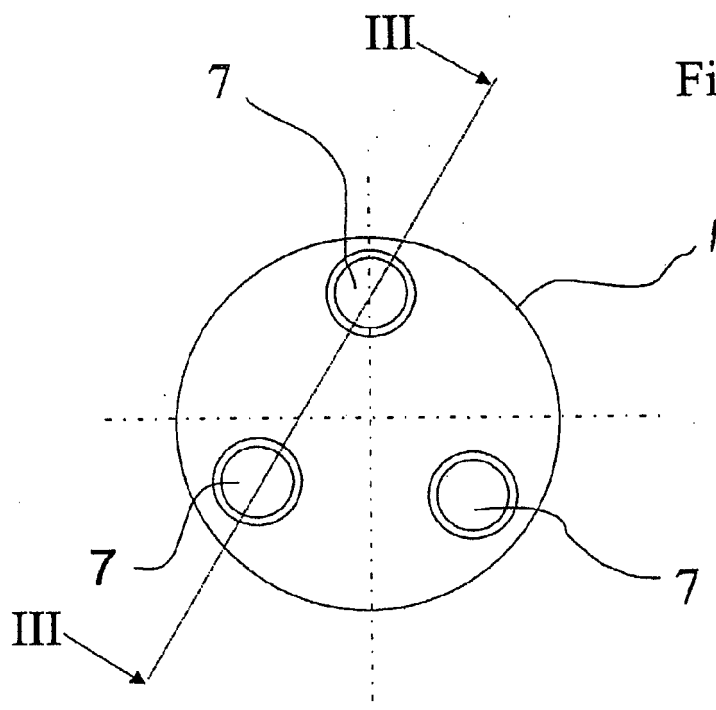


Fig. 2



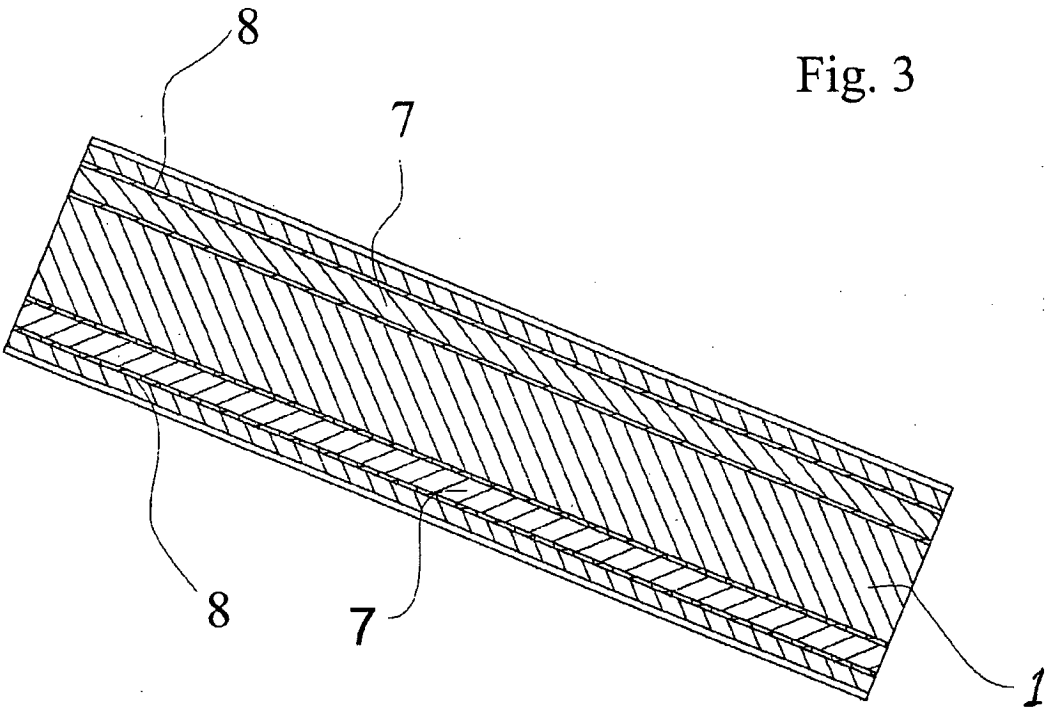


Fig. 4

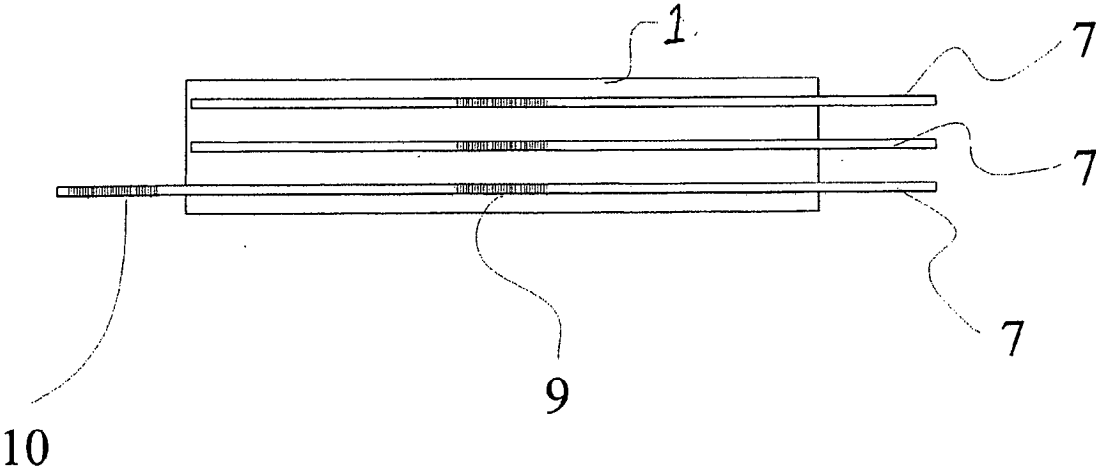


Fig. 5

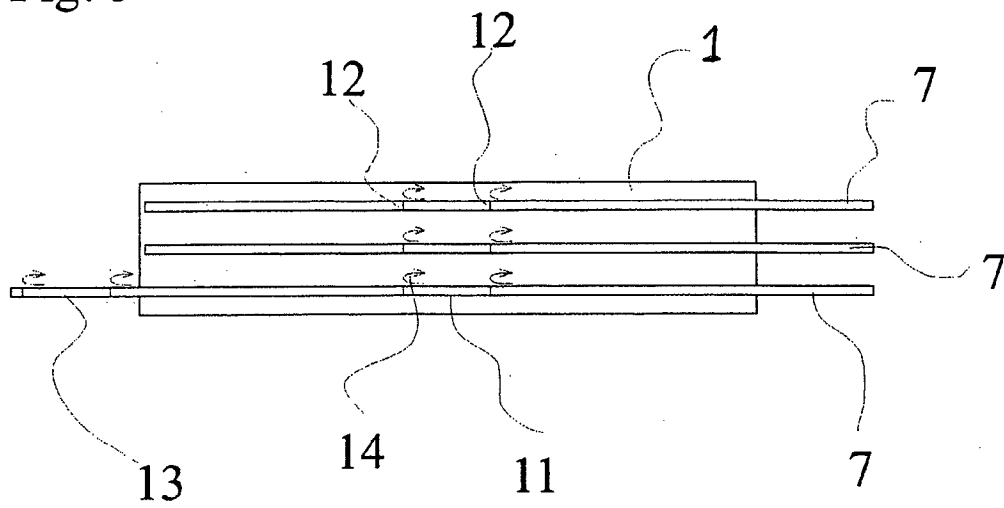


Fig. 6

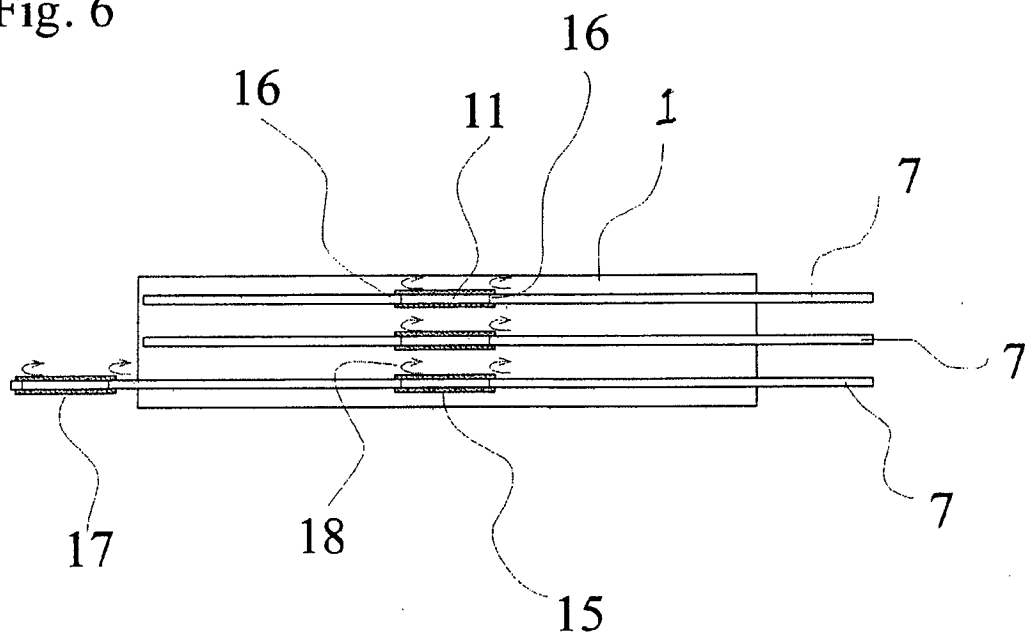


Fig. 7

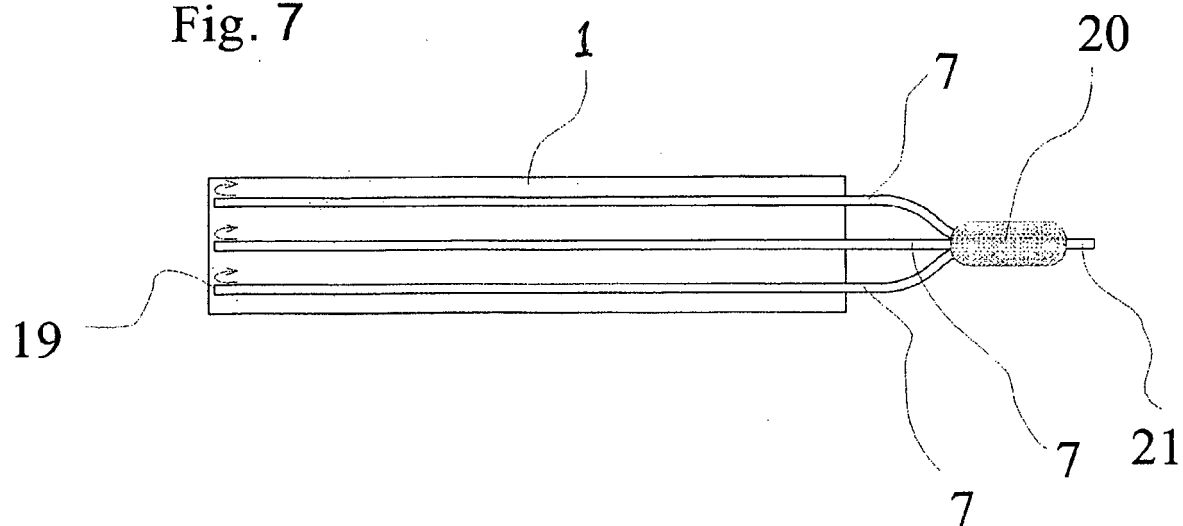


Fig. 8

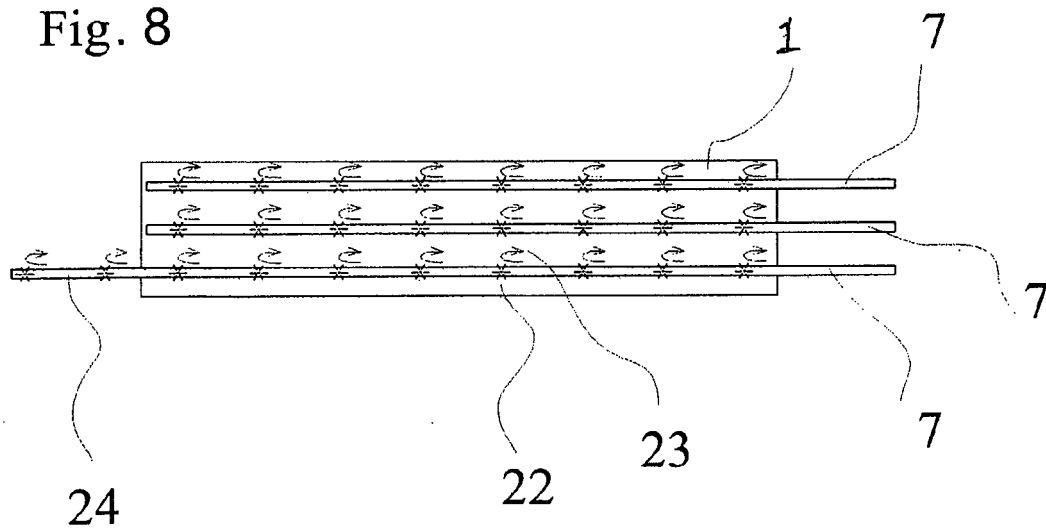


Fig. 9

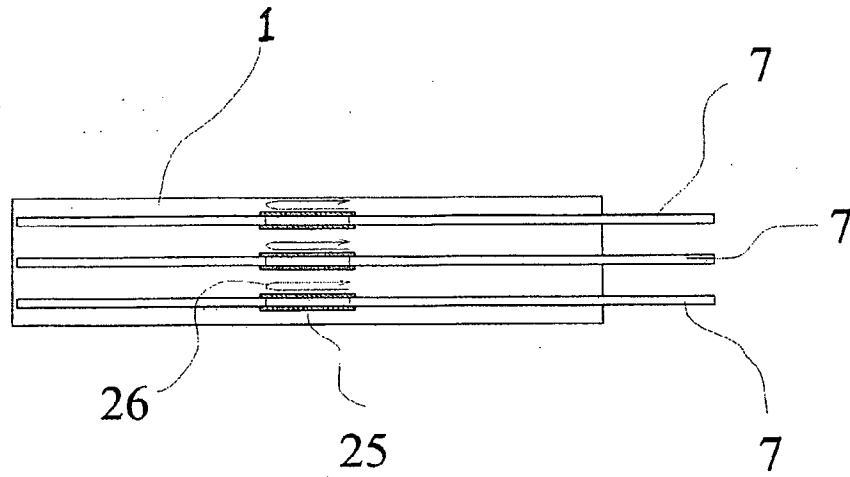


Fig. 10

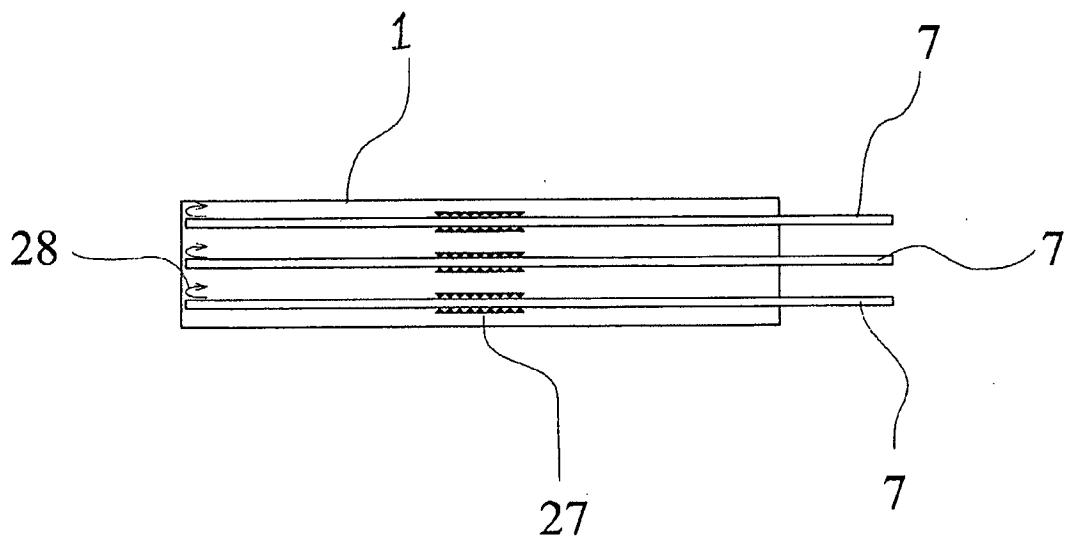


Fig. 11

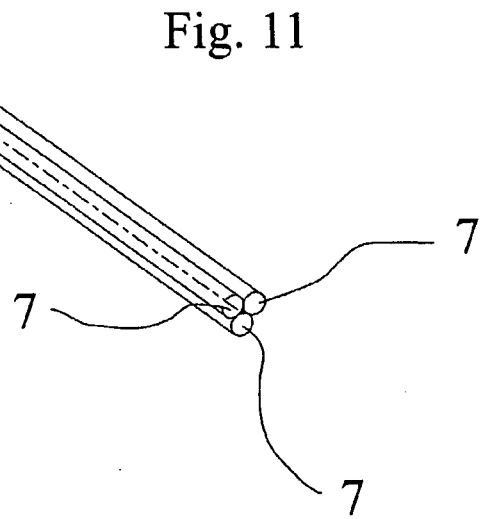


Fig. 12

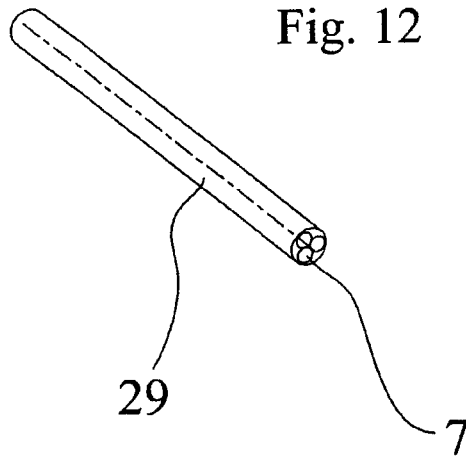


Fig. 13

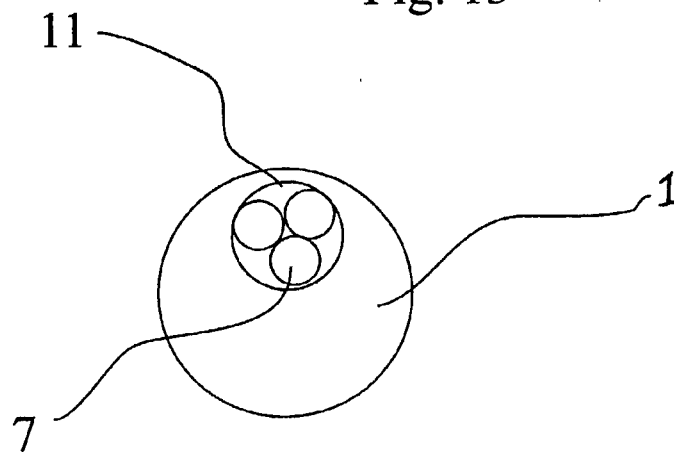


Fig. 14

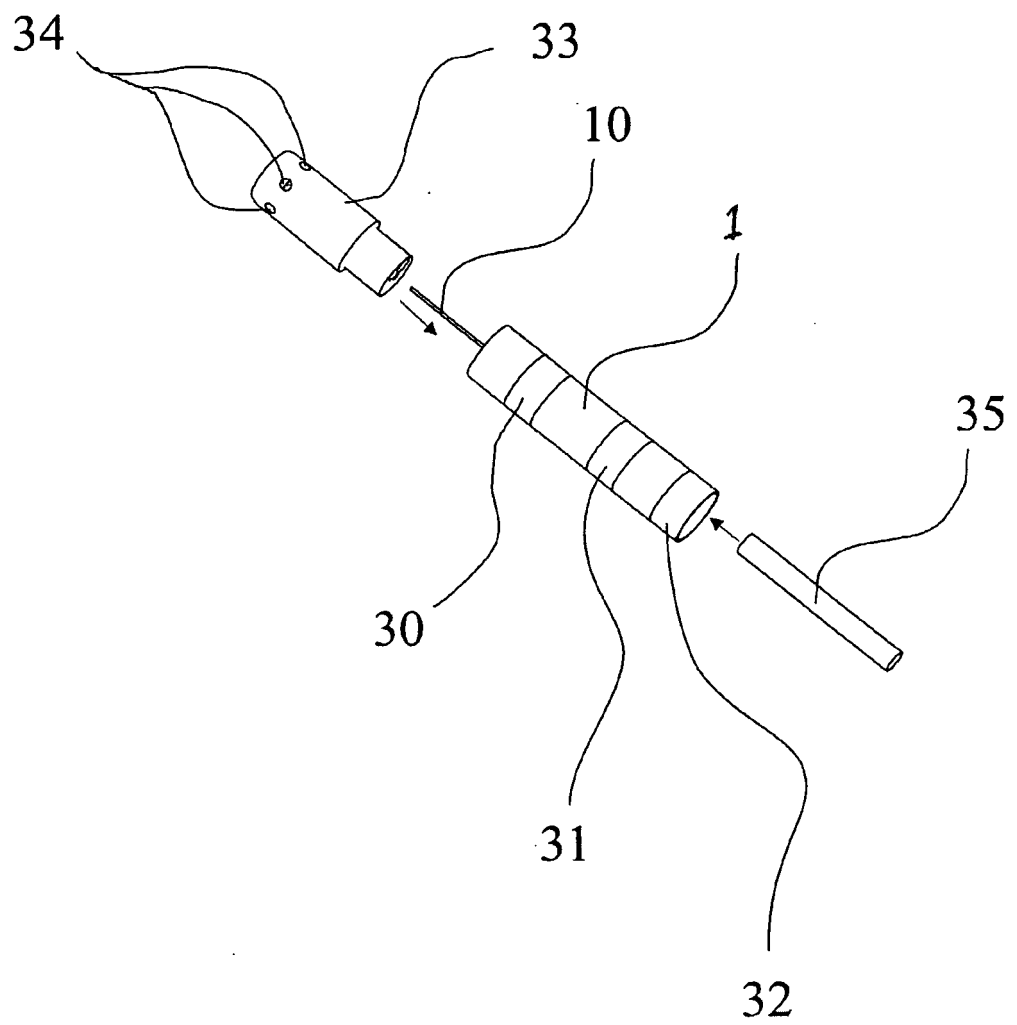


Fig. 15

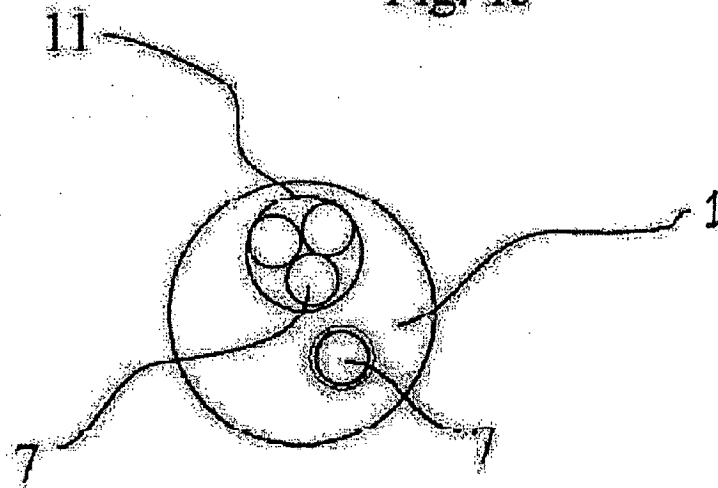
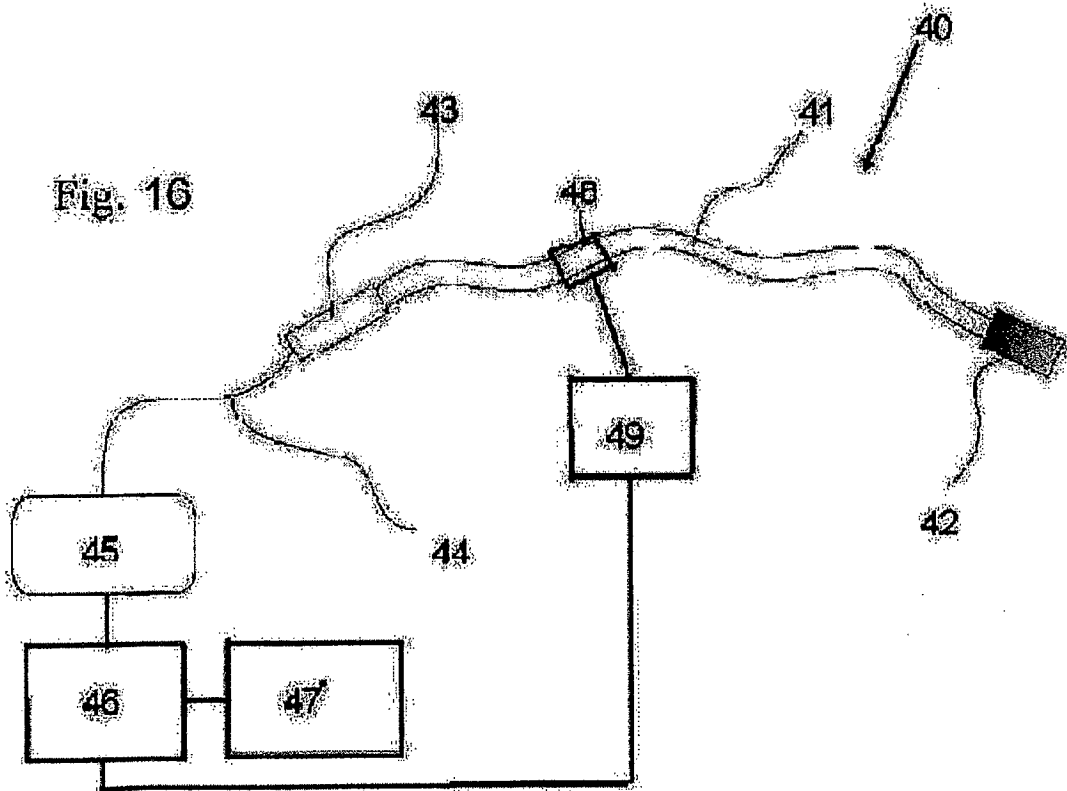


Fig. 16



INTERNATIONAL SEARCH REPORT

national application No
PCT/IB2006/000428

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 G01L1/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B G01D G01L

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

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

EPO-Internal, INSPEC, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	WO 01/33165 A (ADVANCED SENSOR TECHNOLOGY, LLC; BUCHOLTZ, FRANK) 10 May 2001 (2001-05-10) page 5, line 6 - page 8, line 7 -----	21, 23-27, 34, 37 1, 22
Y	US 6 266 551 B1 (OSADCHY DANIEL ET AL) 24 July 2001 (2001-07-24) column 1, line 66 - column 3, line 4 -----	21, 23-27, 34, 37
Y	US 2002/041723 A1 (RONNEKLEIV ERLAND ET AL) 11 April 2002 (2002-04-11) paragraph [0055] - paragraph [0059] -----	24-27
A	US 2004/165810 A1 (FUJITA HIROSHI) 26 August 2004 (2004-08-26) paragraph [0028] - paragraph [0033] ----- -/--	1, 21

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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& document member of the same patent family

Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2006/000428

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>RAO Y J: "Recent progress in applications of in-fibre Bragg grating sensors" OPTICS AND LASERS IN ENGINEERING ELSEVIER UK, vol. 31, no. 4, April 1999 (1999-04), pages 297-324, XP002337593 ISSN: 0143-8166 * 4. Applications to medicine p. 310-312 * * 4.1 Temperature p. 312-316 *</p>	5-8, 24-27
A	<p>INAUDI D: "Application of optical fiber sensor in civil structural monitoring" PROCEEDINGS OF THE SPIE - THE INTERNATIONAL SOCIETY FOR OPTICAL ENGINEERING SPIE-INT. SOC. OPT. ENG USA, vol. 4328, 2001, pages 1-10, XP002336684 ISSN: 0277-786X * Fiber optic sensor types p. 1-7, tableau 1 *</p>	5-8, 24-27

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2006/000428

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0133165	A	10-05-2001	AU 1236601 A	14-05-2001
			CA 2325036 A1	29-04-2001
			DE 10085151 T0	10-10-2002
			GB 2371361 A	24-07-2002
			JP 2003515104 T	22-04-2003

US 6266551	B1	24-07-2001	NONE	

US 2002041723	A1	11-04-2002	AU 8429601 A	22-03-2002
			WO 0219898 A2	14-03-2002
			GB 2371360 A	24-07-2002

US 2004165810	A1	26-08-2004	JP 2004251779 A	09-09-2004

专利名称(译)	具有光纤负载感测能力的医疗设备系统		
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摘要(译)

提供了用于诊断或治疗器官或血管的装置，其中具有设置在其远端的至少两个光纤传感器的可变形体（5）耦合到编程为计算多维力矢量响应的处理逻辑（6）。检测到由于与器官或血管壁的组织接触而导致的远端末端的偏转引起的光纤传感器的光学特性的变化。力矢量可用于利用机器人系统（3）直接或自动地操纵可变形体。