

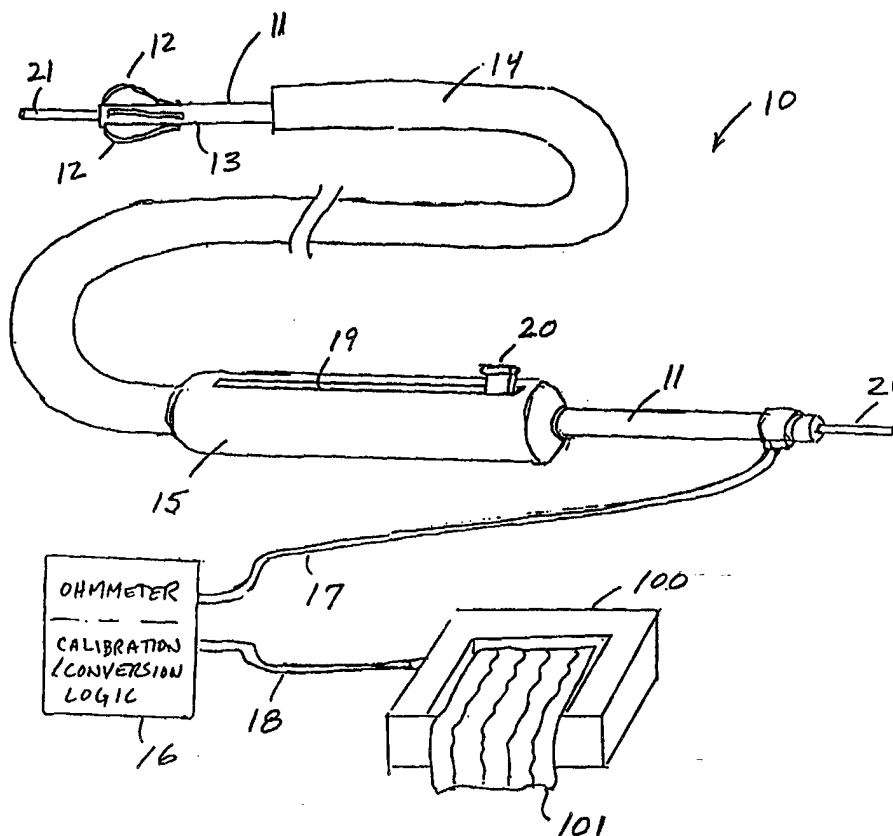


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<b>(21) International Application Number:</b> PCT/US98/05675 <b>(22) International Filing Date:</b> 24 March 1998 (24.03.98) <b>(30) Priority Data:</b> 08/828,317      28 March 1997 (28.03.97)      US <b>(71)(72) Applicant and Inventor:</b> SHAH, Ajit [US/US]; 112 Crescent Avenue, Portola Valley, CA 94028 (US). <b>(74) Agents:</b> PISANO, Nicola, A. et al.; Fish & Neave, 1251 Avenue of the Americas, New York, NY 10020 (US).		<b>(81) Designated States:</b> CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). <b>Published</b> <i>With international search report.          Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

**(54) Title:** APPARATUS FOR VASCULAR MAPPING AND METHODS OF USE**(57) Abstract**

Apparatus and methods are provided for mapping an interior surface of a section of a body lumen comprising a catheter having a plurality of elements circumferentially disposed around its distal end that contact the interior surface of a body lumen and provide output signals corresponding to the local diameter of the lumen. In a preferred embodiment, the contacts are of an electrical-mechanical type, such that an output signal may be generated which is proportional to the degree of deflection of the contact caused by the local diameter of the body lumen. The distal end of the catheter is translated through the body lumen for a predetermined distance, while the output signals are reproduced on either an analog recorder or as a digital three-dimensional display. A drive system for translating the catheter, and methods of use, are also provided.



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APPARATUS FOR VASCULAR MAPPING  
AND METHODS OF USE

Field Of The Invention

5           The present invention relates to apparatus  
and methods for mapping the interior surface topology  
of a body lumen, for example, preparatory to or after  
performing a dilatation procedure, such as percutaneous  
transluminal angioplasty ("PTA"). More particularly,  
10 the apparatus and methods of the present invention  
provide a simple and relatively uncomplicated system by  
which the diameter of a body lumen may be  
characterized.

Background Of The Invention

15           In recent years minimally-invasive apparatus  
and methods for treating narrowing of body vessels,  
especially the coronary arteries, have been developed  
as a substitute for invasive surgical procedures, such  
as bypass grafting. For example, percutaneous  
20 transluminal coronary angioplasty ("PTCA") is commonly  
performed on patients to restore patency to coronary  
arteries that have become narrowed due to vascular

- 2 -

disease and plaque buildup.

Typically, PTCA procedures involve the insertion of a mechanical dilatation device -- usually a balloon catheter -- transluminally to a constricted  
5 location of a coronary artery. The device is then dilated to a selected diameter, and the pressure maintained approximately constant to compress plaque lining the artery, thereby increasing the diameter of the artery and restoring flow therethrough.

10 A drawback common to PTCA, and dilatation procedures that are performed in other body lumens, is the inability to gauge the diameter of the body lumen. Such information is important for assessing the potential efficacy of a proposed course of therapy, for  
15 example, PTCA, PTCA followed by the implantation of a vascular prosthesis, or coronary artery bypass grafting ("CABG"). Often, due to the tortuosity of a vessel, it is difficult to assess the degree of narrowing of the vessel using conventional fluoroscopic and angiographic  
20 techniques. In particular, fluoroscopy provides only a two-dimensional view of the vessel, and may not adequately represent the degree of constriction occurring in three dimensions.

One promising method that has been developed  
25 to assess the topology of diseased vessels is intraluminal ultrasound technology. Typically, a catheter carrying an ultrasound element is disposed within a diseased vessel to provide a cross-sectional view of the vessel wall (and stenosis) at a given  
30 longitudinal location within the vessel. Drawbacks of intraluminal ultrasound systems, however, are that the images are typically fairly noisy, and of such high contrast that they have limited utility. Moreover,

- 3 -

because the ultrasound image is in a plane transverse to the vessel axis, it is difficult to obtain an accurate mapping of the vessel along the entire section of the stenotic region. While attempts to construct  
5 three-dimensional views of the vessel and stenotic region using offline postprocessing have been made, such systems are expensive, require specialized hardware, and are time consuming, leading to limited acceptance in the medical community.

10 In view of the foregoing, it would be desirable to provide apparatus and methods for providing, in real-time, a detailed map of the interior surface topology of a vessel, including a stenotic region.

15 It also would be desirable to provide apparatus and methods for mapping the interior surface topology of a body lumen that employs relatively simple electrical and mechanical components, thereby providing a system that costs less than previously known  
20 ultrasound technology, but which provides significantly better performance.

It further would be desirable to provide apparatus and methods for providing, in near real-time, a three-dimensional view of the interior surface of a  
25 vessel, using low cost, readily available components.

#### Summary Of The Invention

In view of the foregoing, it is an object of this invention to provide apparatus and methods for providing, in real-time, a detailed map of the interior  
30 surface topology of a vessel, including a stenotic region.

It is another object of the present invention

- 4 -

to provide apparatus and methods for mapping the interior surface topology of a body lumen that employs relatively simple electrical and mechanical components, thereby providing a system that costs less than  
5 previously known ultrasound technology, but with significantly better performance.

It is a further object of the invention to provide apparatus and methods for providing, in near real-time, a three-dimensional view of the interior  
10 surface of a vessel, using low cost, readily available components.

These and other objects of the present invention are accomplished by providing a catheter having a plurality of simple mechanical elements  
15 circumferentially disposed on a distal end of the catheter. The elements contact the interior surface of a body lumen and provide output signals corresponding to the local diameter of the lumen. The distal end of the catheter may be translated through the body lumen  
20 for a predetermined distance, while the output signals are reproduced on either an analog or digital display.

In a preferred embodiment of the present invention, the apparatus comprises a catheter having a plurality of contacts disposed around its  
25 circumference. The contacts are of an electrical-mechanical type, such that an output signal may be generated which is proportional to a degree of deflection of the contact caused by the local diameter of the body lumen. The catheter may be translated  
30 manually or by a drive system and includes an encoder that outputs a signal corresponding to an instantaneous position of the distal end of the catheter.

Outputs generated by the contacts may be

- 5 -

amplified, converted to deflection values using suitable logic (e.g., a look-up table), and provided to an analog recorder, for example, a strip chart having one channel per contact. Alternatively, a digital to  
5 analog converter may be used to sample the output signals of the contacts. The digitized samples may then be transmitted to a digital computer for some simplified post-processing and displayed on a video terminal as a three-dimensional image.

#### 10 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 description of the preferred embodiments, in which:

15 FIG. 1 is a perspective view (not to scale) of an illustrative embodiment of apparatus constructed in accordance with the present invention;

FIG. 2 is a cross-sectional view of a single contact employed in the apparatus of FIG. 1;

20 FIGS. 3A and 3B are, respectively, a partial perspective view and an end view of the distal end of the apparatus of FIG. 1;

FIG. 4 is a cross-sectional view of the handle portion of the apparatus of FIG. 1;

25 FIGS. 5A and 5B are cross-sectional views showing the deflection of the contacts of the apparatus of FIG. 1 as it is advanced through a section of a body lumen;

FIG. 6 is a portion of a strip chart  
30 generated by advancing the apparatus of FIG. 1 through the body lumen depicted in FIGS. 5;

FIG. 7 is a perspective view of a motorized

- 6 -

drive system for use with the handle portion of FIG. 4;

FIG. 8 is a block diagram of the components needed to render a digital three-dimensional view of interior surface of a body lumen employing the  
5 apparatus of FIG. 1;

FIGS. 9A and 9B are, respectively, side and end sectional views of an alternative contact for use in apparatus constructed in accordance with the present invention;

10 FIG. 10 is a partial side sectional view of an alternative embodiment of the present invention wherein deflection is detected based upon inductive techniques; and

FIG. 11 is a partial side sectional view of  
15 an alternative embodiment of the present invention wherein deflection is detected using a strain gauge.

#### Detailed Description Of The Invention

The present invention relates generally to apparatus and methods for mapping the interior  
20 structures of a body lumen, especially a vessel including a congenital constriction or stenosis. In accordance with the present invention, a catheter is provided that includes a plurality of contacts that measure the diameter of a body lumen. The present  
25 invention is particularly useful for mapping and characterizing the topology of a vessel, for example, prior to treatment, to determine an appropriate course of treatment. The apparatus of the present invention also may be advantageously used after a minimally-  
30 invasive procedure, such as PTCA, has been completed, to assess the efficacy of the treatment.

Referring to FIG. 1, illustrative apparatus



- 7 -

10 constructed in accordance with the present invention is described. Apparatus 10 (which is not drawn to scale) includes catheter 11 having plurality of contacts 12 disposed on distal end 13, outer sheath 14, and handle portion 15. Measurement and processing circuitry 16 is connected to contacts 12 via cable 17 and conductive leads disposed in catheter 11. Measurement and processing circuitry 16 illustratively includes ohmmeter circuitry that senses the resistance of contacts 12 corresponding to the degree of radial deflection caused by a constriction within the body lumen, as described in greater detail hereinafter. The output of measurement and processing circuitry 16 is provided via cable 18 to analog chart recorder 100. Handle portion 15 includes slot 19 through which button 20 extends for translating catheter 11 within handle 15. Apparatus 10 is preferably inserted transluminally to the site of a diseased vessel by advancing apparatus 10 along guide wire 21, using, for example, an over-the-wire arrangement. Analog recorder 100 preferably provides strip chart 101 that records the output signal generated by each one of the plurality of contacts 12.

Referring now to FIGS. 2, 3A and 3B, distal end 13 of catheter 11 includes plurality of contacts 12 which are sensed by the ohmmeter circuitry of measurement and processing circuitry 16 to generate a signal proportional to the degree of radial deflection of the contacts caused by the topology of the inner wall of the body lumen. In FIG. 2, a single contact is depicted as bow-type spring 25 having distal end 26 embedded in distal end 13 of catheter 11, and bulbous proximal end 27 that slides along resistive strip 28. Distal end 26 of bow-type spring 25 is connected by

- 8 -

conductive lead 29 to cable 17 and the ohmmeter circuitry. Resistive strip 28 likewise is connected by conductive lead 30 and cable 17. Conductive leads 29 and 30 are illustratively shown in FIG. 2 embedded in catheter 11; alternatively, a lumen (separate from guide wire lumen 31) may be provided for housing the conductive leads.

Alternatively, the position of bow-type spring 25 may be reversed with respect to catheter shaft 11, i.e., affixed to catheter 11 at a proximal position with bulbous distal end arranged to slide in a distal direction when the bow-type spring is deflected inward. It will be understood by one of skill in the art that the following description of the present invention applies equally to such alternative embodiments.

As shown in FIG. 3A (in which only two contacts 12 are illustrated for clarity), bow-type springs 25 preferably have a rectangular cross-section, to prevent sideways tilting of proximal end 27. In accordance with the present invention, resistive strip 28 has a predetermined resistance per unit length. When bulbous proximal end 27 of bow-type spring 25 contacts resistive strip 28, it forms an electrical circuit (which includes the ohmmeter circuitry of measurement and processing circuitry 16). As is conventional, the ohmmeter circuitry includes circuitry for passing a very low current through the contact circuit to determine the overall resistance of the contact circuit. The ohmmeter circuitry preferably employs a very low voltage DC power supply, for example, a 9 volt DC battery, to individually measure the resistance of each of contacts 12.

- 9 -

The electrical resistance presented by resistive strip 28 varies linearly with the distance between proximal end 27 of bow-type spring 25 and the point of connection of wire 30 to resistive strip 28. Thus, as bow-type spring 25 deflects radially from its unloaded position, proximal end 27 slides proximally along resistive strip 28, reducing the resistance of the circuit. The electrical resistance of bow-type spring 25 and resistive strip 28, as sensed by the ohmmeter circuitry, accordingly may be calibrated to the amount of radial deflection of bow-type spring 25.

Measurement and processing circuitry 16 also comprises calibration logic for storing values obtained during calibration, and conversion logic for converting measured values of resistance to radial deflections. In particular, calibration and conversion logic comprise circuitry for correlating a measured value of resistance to radial deflection by comparing the measured value to a stored calibration table containing radial deflections as a function of resistance (for each contact). The circuitry may then interpolate within the table to compute a radial deflection corresponding to the measured resistance. Of course, other types of conversion logic may be used. For example, an empirical equation may be fit to the calibration data of deflection versus resistance, and the resulting empirical equation may be programmed into the calibration and conversion logic, instead of the look-up table described hereinabove.

As shown in FIG. 3B, in a preferred embodiment, apparatus 10 includes four contacts 12, as described hereinabove, spaced equi-distant apart around the circumference of catheter 11. To electrically

- 10 -

isolate contacts 12 from fluids flowing in the body lumen, as well as to prevent conductive fluids from providing erroneous resistance measurements, each of contacts 12 is enclosed within a loose-fitting light-weight plastic covering 32. The plastic covering, which may be formed, for example, from thin polyethylene, forms a series of lobes over each of contacts 12. While plastic covering 32 provides a fluid impervious barrier and electrical isolation between contacts 12 and body fluids, the plastic covering is sufficiently thin that it does not interfere with radial deflection of contacts 12.

Referring now to FIG. 4, handle portion 15 of apparatus 10 is described in greater detail. Handle portion 15 comprises an enlarged portion 35 that forms a hand grip to which the proximal end of outer sheath 14 is affixed. Handle portion 15 includes longitudinal slot 19. Arm 36 is affixed to catheter 11 and includes a portion extending through slot 19 and terminating in button 20. Arm 36 carries encoder 37 and traction wheel 38 on its lower end. Traction wheel 38 engages the inner surface of enlarged portion 35, so that it rotates as arm 36 is translated in slot 19. Encoder 37 employs a modified form of a rotary encoder typically used in computer pointing devices (i.e., a mouse), so that traction wheel causes encoder 37 to generate pulses corresponding to longitudinal displacement of arm 36. Encoder 37 is coupled to display device 100 via suitable lead wires (not shown).

Catheter 11 is slidably disposed in outer sheath 14 so that when button 20 is moved in the distal direction, distal end 13 of catheter 11 is translated an equal distance. Accordingly, catheter 11 extends

- 11 -

through hole 39 in the proximal end of handle portion 15 at least a distance equal to the length of slot 19 (with cable 17 connected to catheter 11 proximally of that length). Consequently, the distal end of catheter 5 11 may be translated in the distal direction (beyond the end of outer sheath 14) by a distance equal to the length of slot 19. As arm 36 is translated in slot 19, encoder 37 outputs a signal corresponding to the instantaneous position of arm 36 within handle portion 10 15. This signal also corresponds to the displacement of distal end 13 of apparatus 10 within a vessel being mapped, and may be output by display device 100 to provide an indication of diametral change of the vessel as a function of distance, as described hereinbelow.

15 In a preferred embodiment of the invention, catheter 11 and outer sheath 14 comprise material typically used in catheter construction, for example, poly vinyl chloride or high density polyethylene. Catheter 11 and outer sheath 14 are preferably about 20 1.0 m and 1.1 m long, respectively, while outer sheath preferably has an outer diameter suitable for advancement within target body lumen. Contacts 12 preferably comprise a resilient metal alloy, such as stainless steel, while resistive strips 28 may comprise 25 a suitable high resistance foil. Conductive leads 29 and 30 may comprise copper or a copper alloy wires, while measurement and processing circuitry 16 preferably includes four channels for measuring the resistance across each of contacts 12 individually. 30 Alternatively, measurement and processing circuitry 16 may include multiplexing logic for measuring the resistances of contacts 12 serially. The measured resistances of contacts 12 are then converted to

- 12 -

appropriate values of radial deflection, for example, using a suitable analog or digital look-up table, and the resulting deflection values are provided to analog recorder 100.

5               With respect to FIGS. 5A, 5B and 6, operation of the apparatus of the present invention is now described. In FIG. 5A, distal end 13 of apparatus 10 is shown disposed on guide wire 21 that spans a diseased section 201 of body lumen 200. When  
10 positioned as shown in FIG. 5A, contacts 12 have deflections A' and A'', corresponding to the healthy portion of the body lumen, and button 20 on handle portion 15 is in the proximal-most position. The clinician then slowly slides button 20 in the distal  
15 direction with one hand while holding handle portion immobile with the other hand, thereby causing distal end 13 to traverse diseased section 201 of body lumen 200. Alternatively, apparatus 10 may be employed by first moving arm 36, and distal end 13, to the distal-  
20 most position, and then retracting arm and distal end 13 in a proximal direction to measure the vessel topology as a function of distance.

As seen in FIG. 5B, as catheter 11 is translated in vessel 200, contacts 12 are deflected  
25 inward by amounts B' and B'' by the constriction in section 201. Accordingly, measurement and processing circuitry 16 senses the reduction in resistance in the individual contacts, and computes a corresponding value of radial deflection.

30               The output of apparatus 10 is then transmitted to analog recorder 100, which provides a visual indication of the topology of section 201 as illustrated in FIG. 6. In FIG. 6, traces of the

- 13 -

deflections from the 0 degree contact position and the 180 degree position are plotted side by side (with the 180 degree signal inverted), thereby providing a visual representation of the narrowing within the vessel (the traces from the other pair of contacts may be likewise reproduced with one signal inverted). Output of encoder 37 of handle portion 15 may also be displayed on display device 100, so that the narrowing of the vessel as a function of distance along the length of the vessel may be observed. The clinician may then retract button 20 and repeat movement of catheter 11 to determine, in real-time, the local diameter of the diseased section of body lumen at a given location within the vessel.

Referring now to FIG. 7, drive system 40 is described for use with the apparatus of FIG. 1 for automatically generating a three-dimensional map of the internal structure of a body lumen. Drive system 40 includes support members 41 and 42 for accepting handle portion 15 of apparatus 10, motor 43, spiral gear 44 coupled to the output shaft of motor 43 via pinion gear 45, button cradle 46, and motor controller 47. Handle portion 15 of apparatus 10 is fastened into support blocks 41 and 42 so that button 20 is engaged in button cradle 46. When motor 43 is activated by motor controller 47, it rotates, causing spiral gear 44 to rotate at a user selected speed. Rotation of spiral gear 44 in turn translates button cradle 46, which causes button 20 on handle 15 to be moved at a uniform speed. Drive system 40 may be advantageously used to translate distal end 13 of catheter 11 in accordance with the method described above.

Referring now to FIG. 8, system 50 is

- 14 -

described in which apparatus 10 and drive system 40 may be used to generate a three-dimensional image of the topology of the body lumen. System 50 includes drive system 40 of FIG. 7, including motor controller 47 and motor 43, digital sampler 51, general purpose computer 52 and video monitor 53. Digital sampler samples the measured resistances from contacts 12, and provides that information to computer 52.

Computer 52, which may be, for example, an IBM-compatible personal computer, is programmed to correlate the position data output by encoder 37 with the digitized samples of the measured resistance, and to compute the radial deflections from the measured resistances (based on the calibration data or an empirically derived formula). Computer 52 then computes a three dimensional image of the interior of the body lumen using well known programming techniques for rendering three-dimensional views from arrays of data. Video monitor 53 therefore provides a near real-time three-dimensional map of the topology of the diseased section of the body lumen, shown as illustrative display 54 on video monitor 53.

As will be apparent from the foregoing description, the present invention provides apparatus and methods for obtaining real-time visual displays, i.e., either as two-dimensional analog graphs as a function of distance, or three-dimensional digital images, of the interior surface topology of a body lumen, using simple electrical and mechanical components, and readily available processing hardware.

The embodiment described hereinabove illustratively includes four contacts 12 spaced equidistant around the circumference of the catheter,



- 15 -

although as few as two and more than four contacts may be used as required for a particular application. Advantageously, when three or more contacts 12 are used to characterize the body lumen, it is irrelevant  
5 whether the guide wire is disposed concentrically within the body lumen. For example, if the guide wire is off-center in a three contact system, then two of the contacts will measure higher deflections, while the third contact will measure correspondingly smaller  
10 deflections. In the aggregate, however, the local diameter of the body lumen should nevertheless be accurately determined.

Referring now to FIGS. 9A and 9B, an alternative embodiment of apparatus 60 of the present  
15 invention is described. Apparatus 60 resembles the device of FIG. 1 except that the bow-type sensors of apparatus 10 of FIG. 1 have been replaced with a resistive plunger arrangement. In particular, catheter 61 includes bores 62 that extend along chords of the  
20 cross-section of the catheter on either side of central guidewire lumen 63. Plungers 64 are biased by springs 65 to project from the surface of catheter 66, while springs 65 are retained in bore 62 by endcaps 59. Plungers 64 also may include roller-type contacts (not  
25 shown) on their distal ends 71 for contacting the interior of the body lumen.

Electrical lead 67a connects to conductive collar 68, which is in sliding electrical contact with plunger 64. Collar 67 both energizes plunger 64 and  
30 retains the plunger within bore 62. Electrical lead 67b is coupled to film resistor 69 disposed on an interior surface of bore 62. Film resistor has a uniform resistance per unit length, and is in

- 16 -

electrical contact with flanged edge 70 of plunger 64.

Plunger 64 forms part of a circuit including electrical lead 67a, collar 68, plunger 64, flange 71, film resistor 69 and electrical lead 67b. When plunger  
5 64 is displaced inwardly due to a constriction within the body lumen contacting tip 71 of plunger 64, the depth of depression of the plunger creates a corresponding change in the overall resistance of the circuit. This change in resistance is detected by  
10 circuitry similar to that described hereinabove with respect to FIGS. 1-3.

With respect to FIG. 10, another alternative embodiment of the apparatus of the present invention is described. Only the distal end of apparatus 80 is  
15 shown in detail, with the remainder of the apparatus being similar in appearance to the device of FIG. 1. Apparatus 80 includes bow-type spring 81 which is mounted in a distal end 82 of catheter 83. Catheter 83 includes inductive coil 84 embedded in its distal end  
20 region which is electrically coupled via electrical leads 85 and 86 to form part of an oscillator circuit(not shown). A magnetic material or ferrous alloy 87 is disposed on an interior face of bow spring 81 to face inductive coil 84.

25 Inductive coil 84 is arranged so that changes in inductance caused by movement of the magnetic material or ferrous alloy 87 in proximity to inductive coil 84 causes a frequency change in the circuit, which is then detected. Such circuitry is conventional in  
30 the design of metal detector circuits used for treasure hunting, as described, for example, in Encyclopedia of Electronic Circuits, Vols. 1-6 (edited by Rudolf Graf and William Sheets), McGraw-Hill (1996) and its

- 17 -

extension to the present invention will be apparent to one of skill in the art of analog circuit design. The detected change in inductance caused by inward deflection of bow-spring 81 may be correlated to the  
5 deflection of the bow spring, from which the actual inward deflection of the bow spring, and hence the local diameter of the body lumen, may be computed.

In FIG. 11 yet another alternative embodiment of apparatus constructed in accordance with the present  
10 invention is described. In FIG. 10, apparatus 90 includes catheter 91 including bow-type spring 92 affixed to its distal end 93, and strain gauge 94 affixed to bow spring 92. Strain gauge 94, which may be of the thin film type, has a resistance which varies  
15 as a function of strain induced in the gauge, and is coupled via leads 95 and 96 to measurement circuitry which is per se known. Electrical leads 95 and 96 may be embedded within catheter 91 or alternatively routed along an external surface.

20 As will be apparent from inspection of the embodiment of FIG. 11, deflection of bow spring 92 will impose a strain on strain gauge 94. The output of strain gauge 94 may be calibrated to correspond to deflection of the bow-spring using either analog or  
25 digital tables or formulas, as described hereinabove. Accordingly, the outputs of apparatus 90 may be used to map the topology of an interior surface of a body lumen. In addition, while the embodiment of FIGS. 1-3 are expected to require a loose-fitting light-weight  
30 plastic covering (see FIGS. 3), the embodiments of FIG. 9-11 obviate the need for such encapsulation, thereby enhancing ease of manufacture.

While the preferred embodiment has been

- 18 -

described with respect to resistance and inductive based systems, it will be apparent to one of skill in the art of medical equipment design that other physical or electrical parameters can be advantageously used to practice the present invention. For example, deflection of springs 25 could alter the capacitance of the contact. Further, for example, springs 25 of FIG. 1 may include an optical fiber while resistive strip 28 may be replaced by a linear array of photodetectors, so that as the spring experiences greater deflections, the optical fiber illuminates photodetectors which are located progressively more proximal on catheter 11.

While preferred illustrative embodiments of the invention are described above, it will be obvious to one skilled in the art that various changes and modifications may be made therein without departing from the invention and the appended claims are intended to cover all such changes and modifications which fall within the true spirit and scope of the invention.

- 19 -

What Is Claimed Is:

1. Apparatus for mapping an interior surface of a body lumen, the apparatus adapted for connection to a display device, the apparatus comprising:

a catheter having a proximal end and a distal end;

a first contact disposed on the distal end, the first contact having a feature that varies as a function of a deflection imposed on the first contact by the interior surface of the body lumen;

circuitry for measuring the feature;

circuitry for correlating the measured feature to the deflection and for providing an output to the display device corresponding to the deflection.

2. The apparatus as defined in claim 1 wherein the feature varies as a function of radial deflection of the first contact.

3. The apparatus as defined in claim 1 wherein the first contact comprises a resilient member having a bow shape, a first end and a second end, the first end affixed to the catheter, the second end free to slide a distance in a direction away from the first end as a function of the deflection of the bow shape.

4. The apparatus as defined in claim 3 wherein the second end makes a sliding connection with a strip, the feature varying as a function of the distance attained by the second end.

- 20 -

5. The apparatus as defined in claim 4 wherein the feature is electrical resistance, and the strip has a predetermined resistance per unit length.

6. The apparatus as defined in claim 3 further comprising a strain gauge mounted on the resilient member, the strain gauge generating a signal corresponding to a degree of deflection of the resilient member.

7. The apparatus as defined in claim 3 further comprising a coil disposed within the catheter and wherein the resilient member comprises a ferrous material, so that movement of the ferrous material relative to the coil generates a detectable change in the inductance of the coil.

8. The apparatus as defined in claim 1 wherein the first contact comprises a plunger and means for detecting inward movement of the plunger.

9. The apparatus as defined in claim 5 wherein the circuitry for measuring the feature comprises ohmmeter circuitry for measuring the resistance of the first contact.

10. The apparatus as defined in claim 1 wherein the circuitry for correlating compares a value of the measured feature to a stored calibration table containing deflections as a function of value of the feature, and interpolates within the table to compute a deflection corresponding to the measured feature.

- 21 -

11. The apparatus as defined in claim 1, wherein the distal end of the catheter has a circumference, the apparatus further comprising second, third and fourth contacts, the first, second, third and fourth contacts disposed around the circumference of the distal end.

12. The apparatus as defined in claim 11 wherein the first, second, third and fourth contacts are spaced equidistant apart around the circumference.

13. The apparatus as defined in claim 1 further comprising means for translating the distal end of the catheter to traverse a length of the body lumen and means for generating a signal corresponding to an instantaneous position of the distal end of the catheter.

14. The apparatus as defined in claim 1 wherein the display device comprises an analog recorder.

15. The apparatus as defined in claim 13 wherein the means for translating further comprises means for translating the distal end through the length of the body lumen at a user selected speed.

16. The apparatus as defined in claim 13, wherein the display device comprises a video monitor, the apparatus further comprising a computer programmed to receive an output from the means for generating a signal corresponding to an instantaneous position of the distal end of the catheter, the computer programmed

- 22 -

to provide an output to the display device representing a three-dimensional image of the interior surface topology of the body lumen.

17. Apparatus for mapping an interior surface of a section of a body lumen to generate a three-dimensional representation of the interior surface, the apparatus adapted for connection to a display device, the apparatus comprising:

a catheter having a proximal end and a distal end;

a plurality of contacts disposed circumferentially around the distal end, the plurality of contacts having a feature that varies as a function of deflection imposed on each one of the plurality of contacts by the interior surface;

means for translating the distal end to traverse the section;

means for generating a signal corresponding to an instantaneous position of the distal end of the catheter;

circuitry for measuring the feature along the length of the section; and

circuitry for correlating the measured feature to the deflection along the section and for providing a three-dimensional representation of the interior surface of the section to the display device.

18. The apparatus as defined in claim 17 wherein each one of the plurality of contacts comprises a resilient member having a bow shape, a first end and a second end, the first end affixed to the catheter, the second end free to slide a distance in a direction



- 23 -

away from the first end as a function of the deflection of the bow shape.

19. The apparatus as defined in claim 18 wherein the second end of each one of the plurality of contacts makes a sliding connection with a respective strip, the feature varying as a function of the distance attained by the second end.

20. The apparatus as defined in claim 17 wherein the feature is electrical resistance.

21. The apparatus as defined in claim 17 wherein the circuitry for correlating compares a value of the measured feature to a stored calibration table containing deflections as a function of value of the feature, and interpolates within the table to compute a deflection corresponding to the measured feature.

22. A method of mapping an interior surface of a section of a body lumen, the method comprising steps of:

providing a catheter having a distal end and a plurality of contacts circumferentially disposed on the distal end, each one of the plurality of contacts having a feature that varies as a function of a displacement imposed on the contact by the interior surface;

inserting the catheter transluminally into the section of the body lumen so that the plurality of contacts are displaced by the interior surface;

measuring the feature for each one of the plurality of contacts;

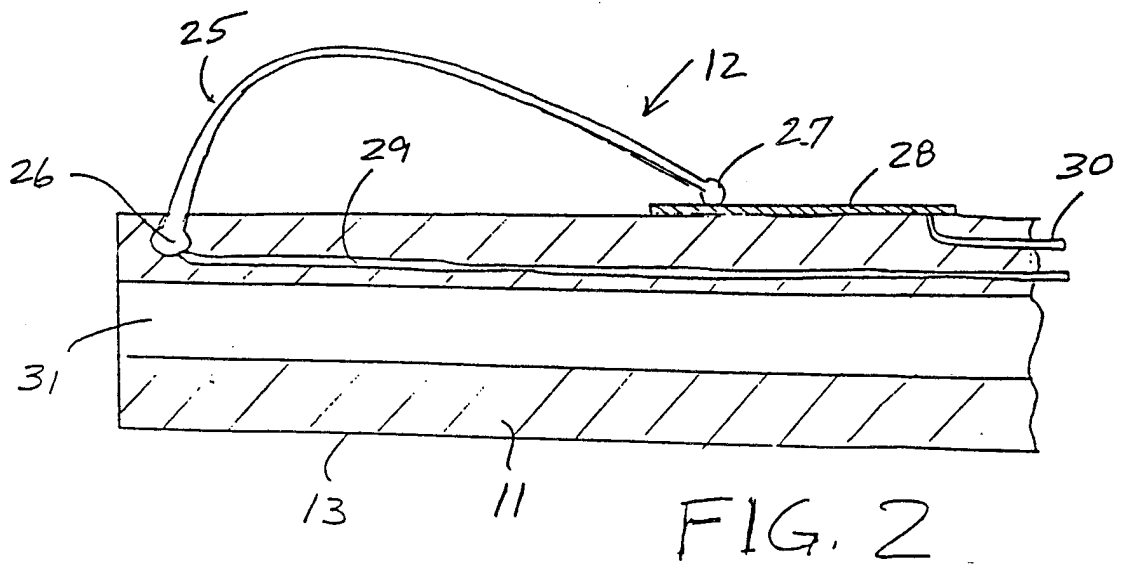
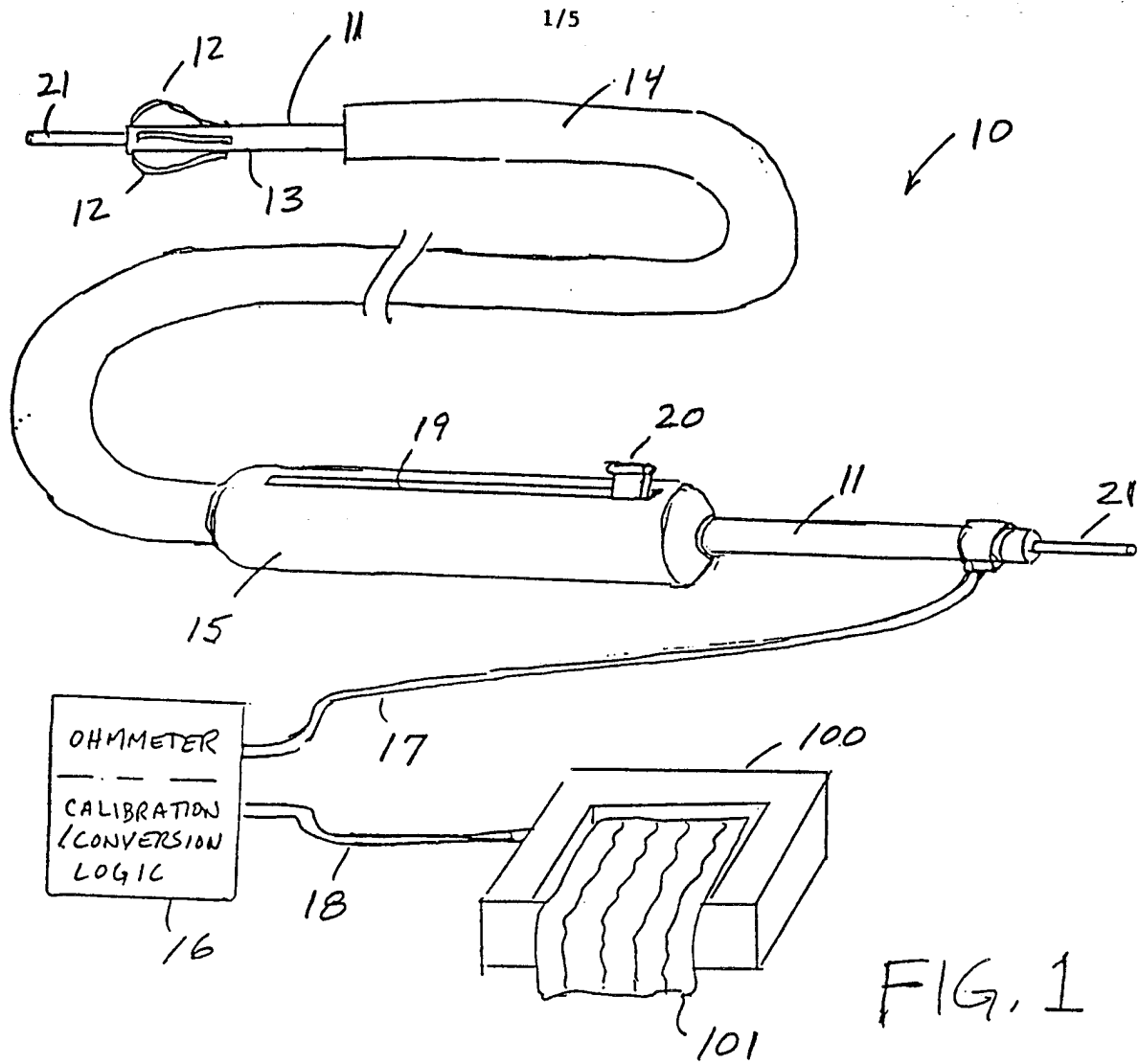
- 24 -

correlating the measured feature for each of the plurality of contacts to a displacement for each one of the plurality of contacts; and

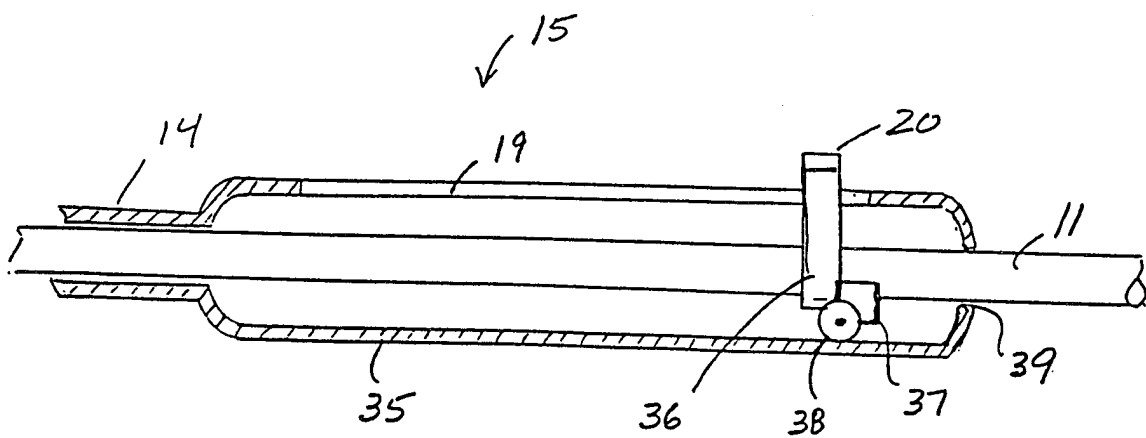
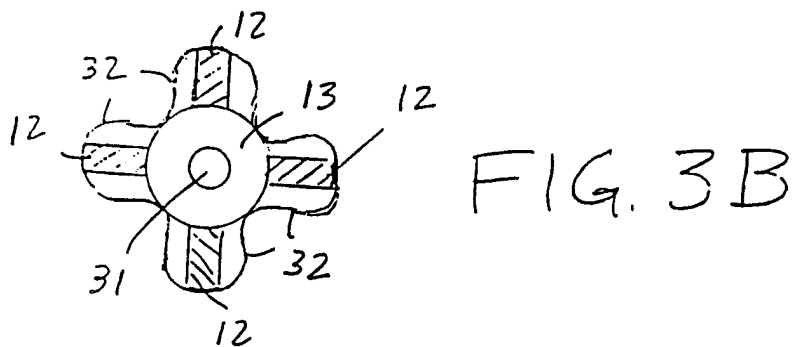
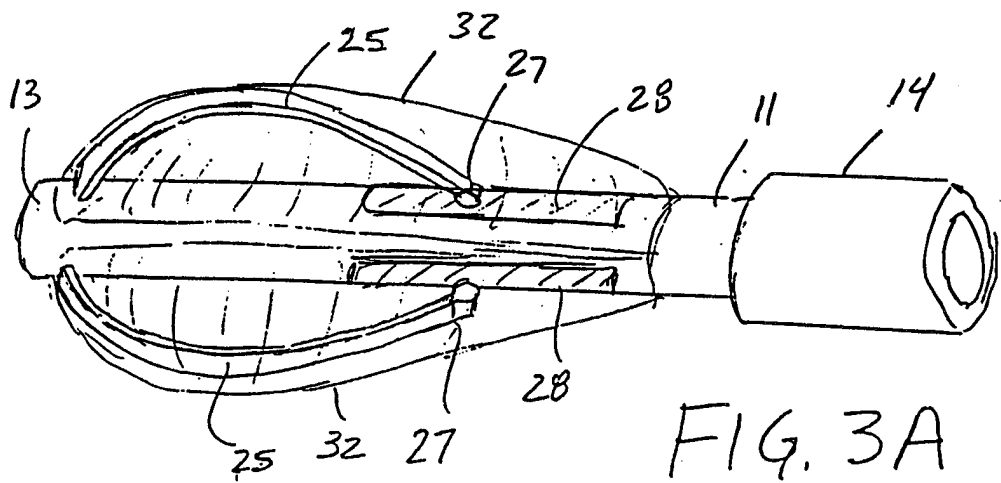
displaying the displacement for each one of the plurality of contacts.

23. The method as defined in claim 22 wherein the step of correlating the measured feature comprises a step of comparing the measured feature to a stored calibration table containing displacements as a function of value of the feature, and interpolating within the table to compute a displacement corresponding to the measured feature.

24. The method as defined in claim 18 wherein the step of displaying the displacement comprises generating and displaying a three-dimensional image of the interior surface of the section.



2/5



3/5

FIG. 5A

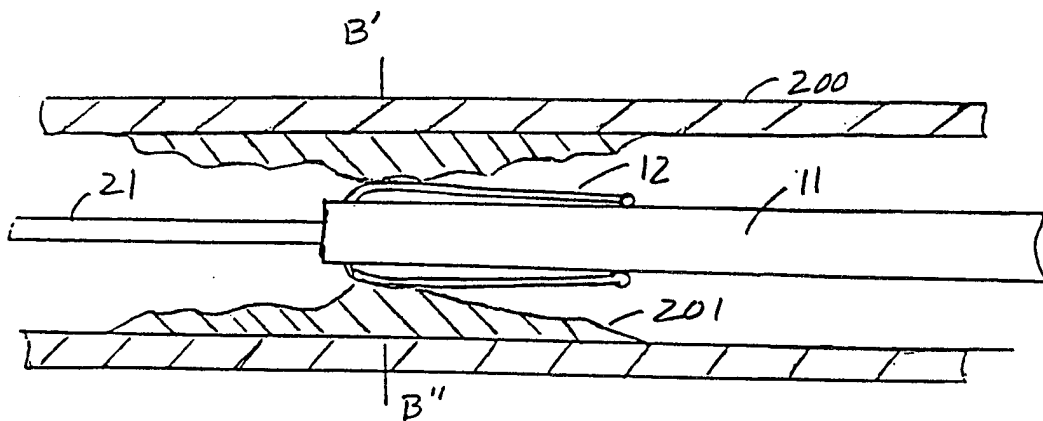
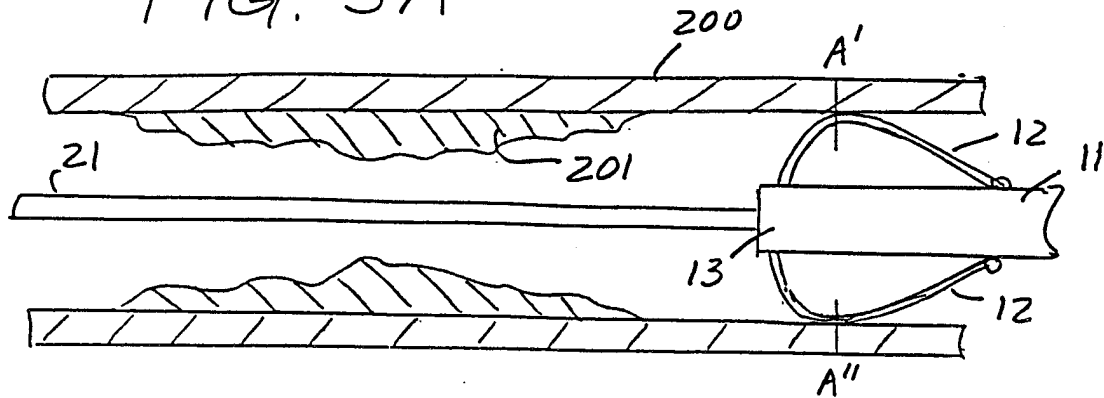


FIG. 5B

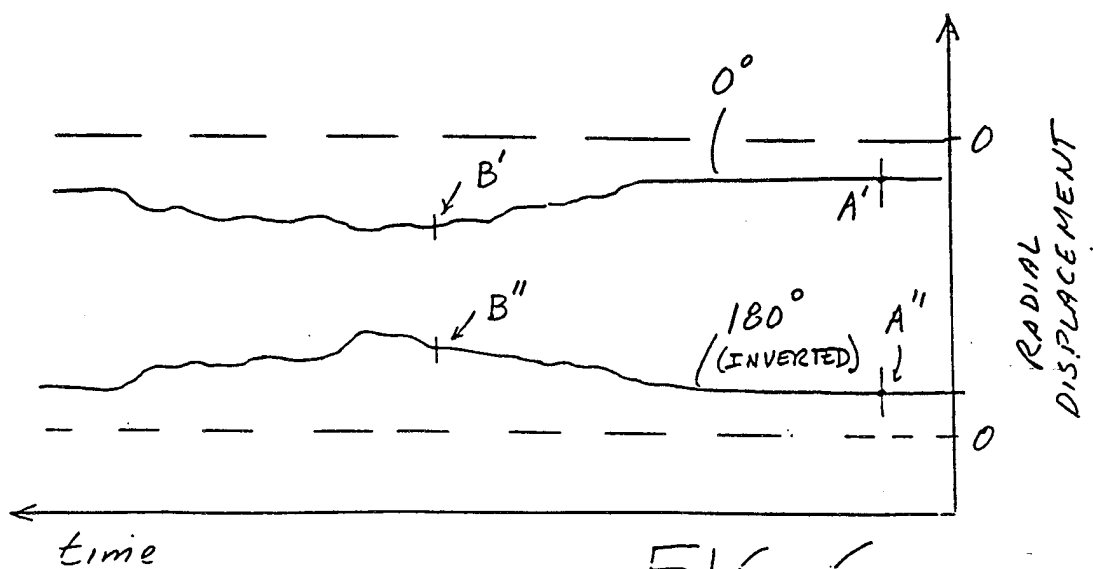
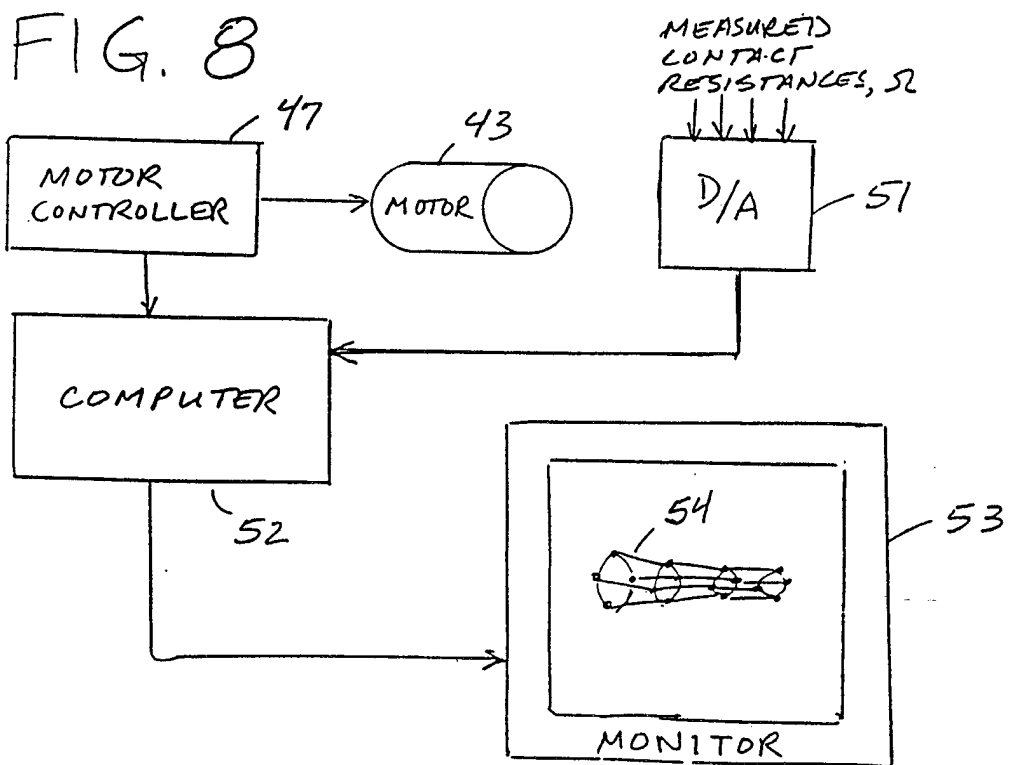
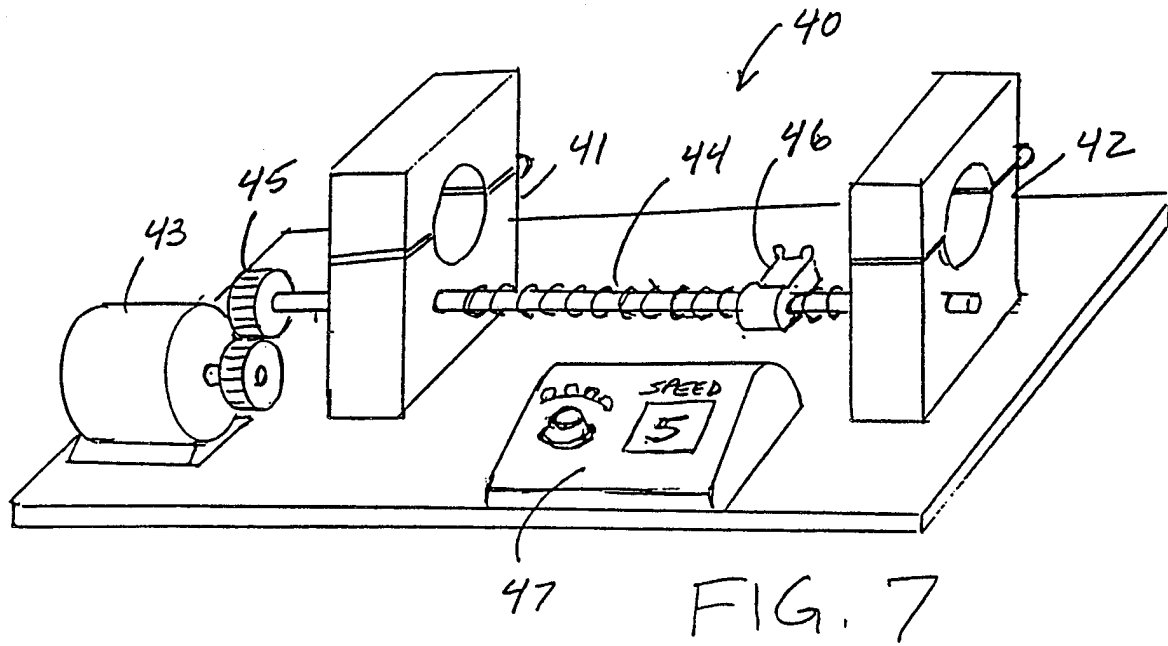
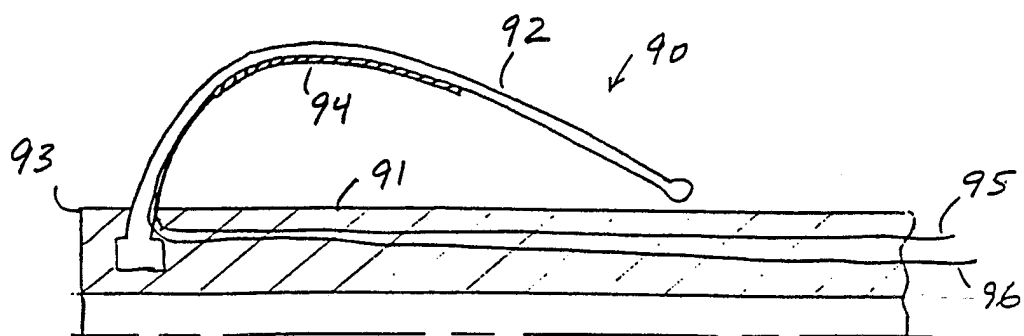
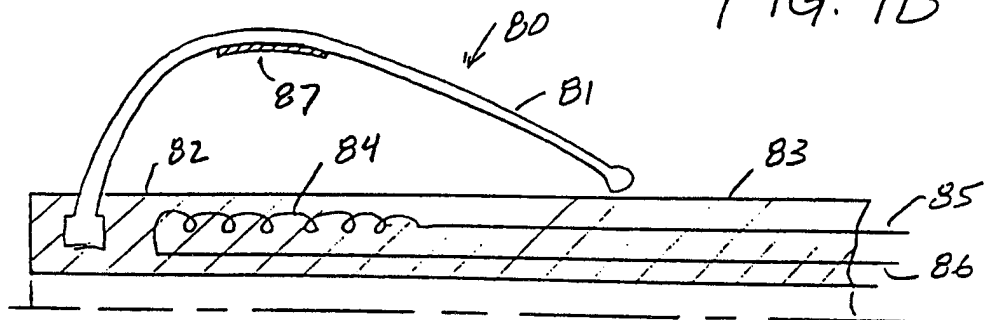
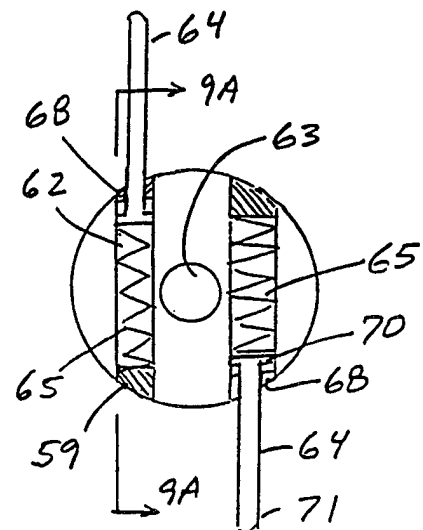
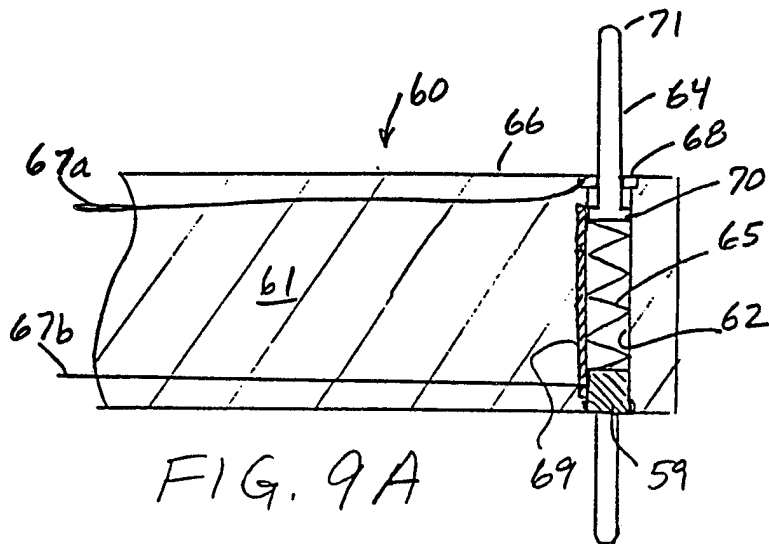


FIG. 6

4/5





## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/05675

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : G01B 07/12

US CL : 33/178, 542, 544, 544.3; 600/114, 117

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)

U.S. : 33/178, 542, 544, 544.3; 600/114, 117

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

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

APS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,235,020 A (DAVIS et al.) 25 November 1980 (25/11/80), Figs. 1, 4-7 with accompanying text, claim 1 comment, Fig. 3 and col. 2 lines 47-53.	1, 2, 14, 22 ----- 8, 10-13, 15
Y	US 4,493,153 A (ESKEN) 15 January 1985 (15/01/85), Fig. 5, col. 3, lines 47-57, line 66 to col. 7, line 13 and col. 4, lines 2-13.	8, 10
Y, P	US 5,665,052 A (BULLARD) 09 September 1997 (09/09/97), Fig. 7 and accompanying text, col. 4 line 66 to col. 5, line 7 and claim 13 comment.	13, 15
Y	US 5,575,754 A (KONOMURA) 19 November 1996 (19/11/96), element (19) and claim 13 comment.	13, 15

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

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*A* document defining the general state of the art which is not considered to be of particular relevance	*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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*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
*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	

Date of the actual completion of the international search

07 AUGUST 1998

Date of mailing of the international search report

10 SEP 1998

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/05675

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,586,968 A (GRUNDL et al.) 24 December 1996 (24/12/96), col. 5, lines 36-43.	15