



(51) International Patent Classification:

A61B 5/00 (2006.01) A61B 17/29 (2006.01)
A61B 5/0215 (2006.01) A61B 18/00 (2006.01)

(21) International Application Number:

PCT/GB2019/053508

(22) International Filing Date:

11 December 2019 (11.12.2019)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

1820240.8 12 December 2018 (12.12.2018) GB

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

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,

(54) Title: SURGICAL PROBE, PRESSURE SENSOR AND MEDICAL SENSING SYSTEM

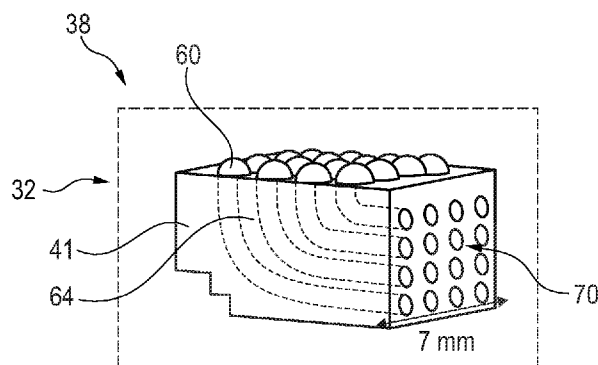


Fig. 6

(57) Abstract: A surgical probe (10) includes a probe head (14) provided with first and second probe arms (22, 24) movable relative to one another. The first probe arm (22) supports a first array (34) of sensor elements, and the second probe arm (24) supports a second array (35) of sensor elements. The first and second arrays of sensor elements are disposed in facing relationship to one another. There is also disclosed an optical sensor element (32) for a surgical probe (10) including a support unit having a plurality of separate channels (64) disposed therewithin. The support unit includes a sensor face; there being provided a light reflection element disposed at an output of each channel and a deformable section and a tactile element extending beyond the sensor face. Pressure on the tactile element deforms and changes the optical properties of the reflection element. A medical sensing system using such a probe includes a processing unit coupled to the first and second sensor arrays and including an input unit for receiving sensor signals from the sensor elements of the first and second arrays, a processor for generating from the received signals a map of sensor signals, the map being indicative of the characteristics of biological material disposed between the first and second sensor arrays, the processing unit including an output unit configured to generate an output representative of the generated map.



MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

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

SURGICAL PROBE, PRESSURE SENSOR AND MEDICAL SENSING SYSTEM

Technical Field

5 The present invention relates to a surgical probe, preferably in the form of a surgical gripper, to a pressure sensor for a surgical probe and to a medical sensing system and method particularly for identifying and characterising body parts.

10 Background Art

 Keyhole surgery or laparoscopy is a common technique used to perform surgery as it is minimally invasive, resulting in patients suffering less pain and trauma, and leading to quicker recovery times compared to open surgery.

15 Laparoscopy is a commonly performed technique to remove organs, for example due to cancer or other problems. During laparoscopic surgery it may be necessary to identify, cut and seal feeding arteries before safely removing the organ. As srteries and veins can look almost identical, one of the only ways to identify an artery over a vein is to feel its pulsation.

20 While laparoscopy has many benefits over open surgery, a disadvantage of this technique is that surgeons cannot benefit from their sense of touch as they must rely on robotic or other elongate tools for the procedure. As it is essential to identify the artery to seal it prior to removing the associated organ, the lack of ability to feel which vessel is the artery leads to prolonged operation time.

25 Moreover, if the artery is accidentally injured the patient may suffer from catastrophic bleeding which may put the patient's life in danger.

 Some laparoscopic tools with sensor elements are known, of which examples include WO-2013/134411, US-2017/0042626, EP-2,815,697 and as disclosed in "Design and Testing of a Pressure Sensing Laparoscopic Grasper by
30 Vakili et al in Proceedings of the 2011 Design of Medical Devices Conference, April 12-14, 2011 in Minneapolis USA.

Summary of the invention

The present invention seeks to provide an improved probe able to detect and characterise body parts such as arteries and veins during a surgical procedure. By means of the developed probe it has been possible also to develop a medical sensing system and method able to detect and characterise reliably a variety of body parts and characteristics useful not only in the course of a medical procedure but also in diagnosis.

According to an aspect of the present invention, there is provided a sensor for a surgical probe including a support unit having a plurality of channels disposed therewithin and a sensor face; there being disposed in each channel a sensor element including a deformable section made of flexible material, a deforming member in contact with the deformable section, the deforming member being of a rigid material, a head extending beyond the sensor face and connected to the deforming member, and a reflective member disposed at an outlet of each channel; whereby pressure applied to the head causes movement of the deformable element, deformation of the deformable section, and a change in shape of the reflective member.

The preferred structure is able to minimise distortions of the sensor caused by lateral forces applied to the sensor heads and as a result provides much more accurate sensing of pressure at the sensor face and the ability to provide a reliable map of biological material and therefore a much more accurate diagnosis.

In a preferred embodiment, the head is made of a rigid material. In other embodiments, the head could be made of a deformable material.

Advantageously, the head and the deforming member are a unitary element. The head and the deforming member may be formed from the same material.

In the preferred embodiment, the head is hemispherical.

In practical embodiments, the deforming member is at least partially disposed in a recess within the deformable section so as to be at least partially embedded therein. It may, though abut the deformable section without being embedded therein.

5 Advantageously, each channel includes a first portion extending substantially perpendicular to the sensor face, and each deforming member is cylindrical or frusto-conical.

10 In the preferred embodiments, the sensor includes a sprung return element coupled to each head and operable to bias the head and the deforming member to a non-pressed position. The sprung return element may comprise a layer of elastomeric material disposed at the sensor face, the or each head having a portion extending over the return element.

15 Each channel may have a uniform or tapering diameter along its length. A tapering (reducing) diameter to the channel can amplify the effect of pressure applied to the sensor heads and result in greater sensitivity.

 Preferably, the sensor heads are arranged in a two-dimensional array at the sensor face.

 In a practical embodiment, the support unit is in the form of a removable cartridge for a surgical probe.

20 According to another aspect of the present invention, there is provided a surgical probe including:

 a probe head provided with first and second probe arms movable relative to one another,

25 the first probe arm supporting a first array of sensor elements as herein disclosed,

 the second probe arm supporting a second array of sensor elements as herein disclosed,

 wherein the first and second arrays of sensor elements are disposed in facing relationship to one another.

30 Advantageously, the sensor elements of the first and second arrays of sensor elements are disposed in interdigitating manner. The sensor elements of

the first and second sensor arrays may be disposed in sets of spaced lines, wherein the sensor lines of the first and second arrays are disposed so as to interdigitate.

Preferably, the first and second probe arms are pivotally coupled together.

5 The surgical probe may include a pressure sensor coupled to the first and second arms and configured to sense pressure applied between the first and second arms.

10 The probe may include an operator handle connected to the probe head and configured to control movement of the first and second arms. The operator handle may include the or a pressure sensor for sensing pressure applied to the first and second arms.

The probe advantageously includes at least one of an accelerometer and a gyroscope.

Advantageously, the probe is in the form of a surgical gripper.

15 According to another aspect of the present invention, there is provided a medical sensing system, comprising:

a surgical probe as herein disclosed;

a processing unit coupled to the first and second sensor arrays;

20 the processing unit including an input unit configured to receive pressure sensor signals from the sensor elements of the first and second arrays, a processor configured to generate from the received signals a map of sensor signals, the map being indicative of the characteristics of biological material disposed between the first and second sensor arrays, the processing unit including an output unit configured to generate an output representative of the generated
25 map.

Advantageously, the map is a pressure image based on pressure sensed by each sensor element of the first and second arrays.

Preferably, the processor is configured to determine at least one of acceleration, velocity and displacement at the first and second probe arms.

30 The processor may be configured to determine at least one of mass, viscosity and stiffness of biological material disposed between the first and second

sensor arrays of the basis of determined acceleration, velocity and/or displacement of the first and second probe arms.

Preferably, the processor is configured to determine:

- (i) a tissue type based, and/or
- 5 (ii) the presence of a vessel within the probe head, and/or
- (iii) the structure of a vessel within the probe head,

on the basis of at least one of measured mass, viscosity and stiffness.

In some embodiments, the processor is configured to determine the presence and/or characteristics of fluid flow within a vessel on the basis of the
10 generated map. The processor may be configured to determine at least one of: direction of fluid flow, degree of fluid flow and/or fluid pressure within a vessel.

According to another aspect of the present invention, there is provided a method of characterising biological material using a surgical probe as disclosed herein, the method including the steps of:

15 applying the first sensor array of the first probe arm to a first side of a volume of biological material;

applying the second sensor array of the second probe arm to a second side of said volume of biological material, said second side facing the first side;

generating from signals from the sensor arrays a map of pressure signals
20 orthogonal to the sensor faces, the map being indicative of the biological material disposed between the first and second sensor arrays, and generating an output representative of the generated map.

The method preferably includes the step of determining at least one of acceleration, velocity and displacement at first and second probe arms.

25 The method may include the step of determining at least one of mass, viscosity and stiffness of biological material disposed between the first and second sensor arrays of the basis of determined acceleration, velocity and/or displacement of the first and second probe arms.

Advantageously, the method includes the step of:

- 30 (i) determining a tissue type, and/or

(ii) the presence of a vessel between the first and second sensor arrays and/or

(iii) the structure of a vessel

on the basis of at least one of the determined mass, viscosity and/or stiffness.

5 The method may include the step of determining the presence and/or characteristics of fluid flow within a vessel on the basis of the determined map.

Advantageously, the method includes the step of determining at least one of: direction of fluid flow, degree of fluid flow and/or fluid pressure within a vessel.

10 Other aspects and advantages of the teachings herein will become apparent from the description that follows.

Brief Description of the Drawings

15 Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a representation of connective tissue and fat in a patient;

Figure 2 is a photograph showing a distal end of a surgical tool located in a patient's body and showing the difficulty of locating an artery by eye;

20 Figure 3 is a perspective view of a preferred embodiment of surgical gripper probe;

Figure 4 is a perspective view of a preferred embodiment of gripper head of the probe of Figure 3;

Figure 5 is a perspective view of the gripper head of Figure 4 in a substantially closed position;

25 Figure 6 is a perspective view of one of the sensor units of the gripper head of Figure 4;

Figures 7 and 8 are perspective views of the gripper head of Figure 4 showing an optical coupling thereto;

30 Figures 9 and 10 are schematic diagrams showing a prior art structure for one of the sensor elements of the surgical probe;

Figures 11 and 12 are views showing various characteristics of the preferred sensor arrays;

Figure 13 is a schematic diagram of an embodiment of probe structure according to the teachings herein;

5 Figures 14 to 16 depict the operational characteristics of the sensor elements of the preferred form of surgical probe;

Figure 17 shows finite element analysis results for the deformable sensor member;

10 Figures 18A and 18B are schematic cross-sectional views of another embodiment of sensor structure having an elastic layer disposed between a rigid deforming element and the deformable element of the sensor;

Figure 19 is a schematic diagram of a test jig used to demonstrate the performance of the sensor structure depicted in Figures 18A and 18B compared to a sensor structure without an elastic layer;

15 Figure 20 is a graph showing the performance of the sensor structures of Figures 18A to 19;

Figure 21 is a side elevational view of a practical implementation of probe assembly;

20 Figure 22 is a schematic diagram depicting the spring-viscosity-mass system provided by the preferred sensor structure;

Figure 23 is a series of graphs depicting given parameters of tissue by means of the probe and sensor assembly taught herein;

Figure 24 is a series of graphs depicting the collected data from an example of tissue by means of the probe and sensor assembly taught herein;

25 Figure 25 is a series of graphs depicting estimated parameters of tissue by means of the probe and sensor assembly taught herein;

Figure 26 is a series of graphs depicting given parameters of an artery by means of the probe and sensor assembly taught herein;

30 Figure 27 is a series of graphs depicting the collected data from an artery by means of the probe and sensor assembly taught herein;

Figure 28 is a series of graphs depicting estimated parameters of an artery by means of the probe and sensor assembly taught herein;

Figure 29 is a schematic diagram depicting the probe head in use;

Figures 30 to 32 depict the optical results obtainable by the optical sensor elements disclosed herein; and

Figures 33 and 34 are pictorial representations of the probe assembly in use in accordance with the teachings herein.

Description of the Preferred Embodiments

10

In certain surgical operations, the detection of arterial pulsation is an essential step of the procedure, either to isolate the artery and cut and seal it, as is the case for example in nephrectomy and adrenalectomy, or to preserve the artery as is the case for example in a varicocelectomy procedure. In other types of operations, knowing the size of the artery and number of branches helps to plan the procedure, as is the case for example with the treatment of an arterio-venous fistula.

In all such cases, detailed knowledge of where the artery is, its size and the direction of blood flow through the artery is imperative to enable the surgeon to carry out the procedure in a safe and effective manner. A great deal of natural variation exists amongst patients and blood vessels are usually wrapped in connective tissue and fat that the surgeon needs to dissect and remove before being to locate the artery. Figures 1 and 2 are images showing the difficulties encountered in such procedures.

An unexpected extra artery or slightly variable position of the artery increases the risk of damage to the artery before full dissection and isolation of the intact artery is possible. The ability of the surgeon to perform a safe and quick operation can be greatly enhanced if the surgeon is able to locate the vessels during the operation in a safe and efficient way. However, this ability is usually impaired when the procedure is laparoscopic because of the loss of tactile feedback that a surgeon benefits from when using his/her fingers. As a

consequence, a surgeon has had to rely on previous experience and visual cues to perform a dissection around the area where the artery is expected to be located.

This problem is addressed by the described embodiments, which seek to provide a mechanism to locate arterial blood vessels without interfering with the surgical technique. The gripper described in detail below is able to sense arterial pulsation, the size of the artery and direction of blood flow through the vessel and also if there is more than one artery in that section of tissue. It is important to note that while the detection of arterial pulsation when carrying out laparoscopic surgery is important, there are other possible surgeries where identifying the artery is essential and the taught apparatus and method can be applied to multiple surgical uses.

Another example of the technology is to help identify the testicular artery during varicocele procedure. This is an open surgical procedure, where the surgeon ties and cut most of the veins while sparing the solitary artery feeding the testicle. Any damage to the artery can cause necrosis of the testicle. Currently surgeons occasionally use Doppler ultrasound to identify the artery. However most of the time this is not practical because the handheld Doppler device doesn't give detailed information of the location of the artery. It generates "pings" or noise that grows louder when the artery gets closer to the probe and fainter when the artery is far, causing the surgeon to have to guess where the artery is based on loud noise or faint noise signals.

Another use of a device and method as taught herein is during an operation to form a connection between an artery and a vein, called an arterio-venous fistula. This is performed for patients who have kidney failure and need dialysis. The operation is usually performed on the vessels of the arm and forearm. A skin incision is made over where the vessels are usually located. The surgeon then performs dissection of the tissue to locate the vein and the nearby artery to subsequently join the vein to the side of the artery. Over time, this will cause the vein to dilate and allow easy vascular puncture access such that dialysis can be carried out. The device and method taught herein can help a surgeon to locate and map the arteries in the forearm before proceeding with forming the fistula.

Known tactile sensing methods commonly involve the use of piezoresistive or capacitive materials, strain gauges, conductive elastomer or liquid and fibre-optics, but none of these methods is used in laparoscopic surgery. It is difficult to use existing current tactile sensing technologies to create distributed tactile
5 sensing capability on small and three-dimensional surfaces, and also the fabrication processes are both complex and high cost. Consequently, no surgical grasper with distributed tactile sensing elements is currently available commercially.

The surgical probe disclosed herein, in its preferred implementations,
10 embeds sub-millimetre soft material channels within a given three-dimensional support structure. The soft material channels act in a manner similar to tactile afferent nerve fibres within human tissue by transforming forces applied to the structure surface into micro soft material deformations. Each tactile sensing node can be made larger compared to a single tactile array cartridge design and thus to
15 increase sensitivity of tactile sensing. A multi-core optical fibre is preferably used for measurement of multiple soft material channels. In such a multi-core fibre, one or more fibre cores will be used as light transmitting fibres, and multiple fibre cores will be used as light receiving fibres. The precision, simplicity and flexibility of 3D printing technology may also be used to produce bespoke designs of sensor
20 arrays for specific purposes.

Referring now to Figure 1, this shows a perspective view of the preferred embodiment of surgical gripper 10, which is in the form of a laparoscopic gripper. The assembly includes at the gripper proximal end a handle assembly 12 and a probe head 14 at the gripper distal end. The handle assembly 12 includes a
25 trigger formed of two finger grips 16a and 16b with finger holes and which are pivotally coupled together by a pin 17. The handle assembly 12 also includes an inertial measurement unit 18 that includes in this embodiment two inertial sensing units 19 and 21, described in further detail below.

A shaft 20 extends distally from the handle assembly 12 and connects to
30 the probe head 14. In this embodiment, the probe head 14 includes first and second arms or jaws 22, 24 pivotally coupled together. Within each jaw 22, 24

there is provided an array 30, 32 of sensor elements 34, 35. Within the shaft 20 there is provided a linkage mechanism for coupling the trigger of the handle assembly 12 to the jaws 22, 24 of the probe head 14 as well as an optical cable described in further detail below. In this embodiment, the sensor elements 34, 35
5 are pressure sensitive optical elements and may be formed of light transmissive material, although this is not essential.

There may be provided a stop flange 25 at the proximal end of the shaft 20. In this embodiment, the flange 25 is in the form of an enlarged disc.

The probe head 14 is shown in enlarged view in Figures 4 and 5. The
10 probe head arms or jaws 22, 24 are pivotally connected via pivot pin 44 so as to be able to move or pivot between an open configuration and a closed configuration, shown respectively in Figures 4 and 5. As will be apparent from Figures 4 and 5, the lower arm or jaw 24 is fixed relative to the shaft 20, whereas the upper arm or jaw 26 pivots about pin 44.

15 The sensor arrays 30, 32 are provided on removable supports or cartridges 36, 38 described in further detail below.

In both open and closed configurations, the sensor arrays 30, 32 face one another, so in practice are able to sense within a common area or volume located in the space between the sensor elements 34, 35. The size of this space or
20 volume can change in dependence upon the degree of pivoting of the arms or jaws 26, 28 relative to one another, thereby in use to accommodate body parts or organs of different sizes.

While the embodiment shown uses a pivot to move the sensor arrays 30, 32 relative to one another, the skilled person will appreciate that other coupling
25 arrangements may be used.

In this embodiment, the sensor arrays 30, 32 are in the form of removable cartridges 36, 38, which are releasably mountable within associated recesses in the bodies of the jaws 22, 24 and for which an appropriate coupling mechanism may be provided, the example of Figures 4 and 5 having embossed fitting features
30 40 that fit into respective slots 42 in the jaw bodies, allowing the cartridges 36, 38 to be readily and reliably fitted in the jaws 22, 24 and removed therefrom. Other

suitable interlocking arrangements or a friction fit can be used to hold the cartridges 36, 38 securely within the jaws 22, 24.

5 The cartridges 36, 38 may extend beyond the distal end of the jaw bodies, and in some embodiments be made of a different coloured material, enabling a clinician to verify readily whether the cartridges 36, 38 have been properly loaded into the probe head 14 prior to use of the device.

10 Replaceable cartridges allow the device to be used multiple times, by changing the cartridges from patient to patient, and they also permit, should it be deemed advantageous, the use of cartridges with different sensor designs and configurations. The cartridges 36, 38 can be provided as sterile single-use disposable components.

It will be appreciated that the use of replaceable sensor cartridges is a preferred feature and not essential and that in other embodiments the sensor arrays 30, 32 may be integral with the probe arms or jaws.

15 In this embodiment, the cartridges 36, 38 extend along approximately two thirds of the length of the jaws 22, 24 leaving approximately a third of the length jaws 22, 24 for internal sensor channels, shown in Figure 9 and described below.

20 As shown in Figures 4 and 5, fit within the jaws 22, 24 such that the top surface 41, 43, of each cartridge 36, 38 lies flush with the internal jaw surfaces 26, 28 and the sensor elements 34, 35 extend beyond the jaw surfaces 26, 28. The sensor elements 34 of the top sensor array 30 interdigitate, that is fit in spaces between the sensor elements 35 of the bottom sensor array 32, and vice versa.

25 In this embodiment, the sensor arrays 30, 32 are formed as an array of 3 x 4 sensor elements 34. The skilled person will appreciate that this is an example only and that any other number of sensor elements 34, 35 may be provide din other embodiments. However, the number and arrangement shown herein has proven to be optimal for the indicated procedures.

30 A multi-core optical fibre 50 and a jaw driving linkage 52 extend proximally from the probe head 14, to the handle assembly 12. The optical fibre 50 and linkage 52 are disposed in the sheath 20 shown in Figure 3 but omitted in Figures 4 and 5 for the sake of clarity.

Referring now to Figure 6, this shows an embodiment of cartridge 36, 38. The cartridge 36, 38 is depicted semi-transparent so as to show the sensor elements 34, 35 housed within the cartridge 36, 38 but it will be appreciated that in practice the cartridge is preferably made of opaque material. Each sensor element 34, 35 includes a hemispherical element 60 protruding above a top surface 41 of the cartridge 36, 38. The hemispherical element 60 is advantageously rigid.

Each sensor element 34, 35 also includes an optical member 64 extending from the hemispherical element 60 to a rear, output, surface 70 of the cartridge.

The optical elements 64 may be formed of soft material disposed in channels through the cartridge 36, 38. The cartridges 36, 38 provide a rigid support for the optical elements 64, and described in detail below.

Figures 7 and 8 show cartridge 38 assembled into the lower jaw 24 and illustrate the components forming the optical system of the probe. Referring to Figure 7 the cartridge 38 is shown in line drawing form so as to show the optical elements 64 within the cartridge 38. A multi-core optical fibre 50 (shown also in Figure 8) extends proximally from the jaw 24 and is coupled thereto by a suitable fitting 82 having a plurality of guide channels aligned with the pressure sensitive optical sensor elements 64.

One or more cores in the multi-core optical fibre 50 are light transmitting fibres 88 that transmit light to the sensor elements 34, 35, while other cores in the multi-core optical fibre 50 are light receiving fibres 90 arranged to receive light from the sensor elements 34, 35. A single multi-core optical fibre may be used to transmit and receive light from both the top and bottom optical elements 34, 35 or two multi-core optical fibres may be provided one for the top sensor elements 34 and one for the bottom sensor elements 35.

The optical fibres 50 are spaced from a face of the sensor elements 34, 35, specifically from the face of the cartridge 36, 38. As described below, this allows for the surface of the deformable optical element 64 facing the optical fibres 50 to flex as pressure is applied to the probe head, which flexure causes changes in the amount of light that is reflected off the surfaces and back into the optical fibres 50.

This change is representative of the existence and amount of pressure applied to the hemispherical elements 60.

Figures 9 and 10 are schematic diagrams of a prior art example of sensor element 64. In this example, the hemispherical element 60 is of deformable material, as is the optical element 64 located within a channel of the support or cartridge 70. The end of the optical element 64, at the location identified as D_{out} , the element is provided with a reflective surface, for instance by being coated with metallic particles or powder. The optical fibres are spaced from the surface D_{out} so as to allow deflection of the surface D_{out} as depicted in Figures 9 and 10. In use, light is transmitted from one of the light transmitting cores 88 of the optical fibre 50 through the optical element 64 and at least a proportion is reflected back by the surface 72 (D_{out}) of the to a light receiving fibre 90, which surface 72 is deflected by any pressure applied to the hemispherical element 60. As will be apparent from Figure 6, each optical element 64 includes a dedicated output 72.

As force, illustrated by the arrow 94, is applied to the hemispherical element 60, it deforms by compression of its top surface 96, which in turn causes deflection of the output surface 72, thereby changing the optical characteristics, and in practice the intensity of light reflected back through the associated optical fibre. The change in reflected light can be detected and quantified, so as to give an indication of the existence and amount of deflection of the element 60 and in practice of the force applied to the surface of the sensor element 34, 35. A given amount of force F applied to the hemispherical element 60, causes a change represented by $\Delta\alpha_i$ in the reflected light, which is transmitted through the optical member 64 to the output 72. This optical change is proportional to the amount of force applied to the sensor element 34, 35, which can therefore be calculated.

The sensor elements 34, 35 are designed such that the diameter D_{in} of the hemispherical element 60 is larger than the diameter D_{out} of the output 72. This increases the sensitivity of the optical readings measured at the output 72.

The channels in the cartridge or support 70 may have reflective surfaces to increase the light reflected back and improve the optical reading. The reflective surfaces may be formed by a chrome silver powder surface with mirror-like effect

or a mirror effect paint. The skilled person will appreciate that other means for providing a reflective surface are also suitable.

Figure 10 shows in greater detail the example of sensor element 34, 35 with a compressive force F applied to the deformable tactile element 60, as would occur when the sensor is pressed against, for example, an organ or other biological material. As described above, the force F causes the tactile element 60 to deform by an amount of volume $\Delta\alpha_i$. This deformation compresses the soft material optical element 64 by an amount Δd_i and results in a volume change $\Delta\alpha_o$ at the output channel 72. On the application of force F , the surface at the output channel 72, hereinafter referred to as a transducing surface 108, changes from a concave shape to a convex shape as shown in Figure 32.

The changes from a concave shape to a convex shape can be characterised by considering the displacement of the transducing surface 108 in particular, the displacement of the centre node of the transducing surface 108. The centre node displacement is quantified as Δd_o . By quantifying Δd_o an indication of the amount of force F applied to the tactile element 60 can be achieved. In practice, the optical fibre, including the transmitting or emitting fibres, are positioned at a distance d to the transducing surface 108.

The force F is applied over an area, hereinafter referred to as the contact area 104, which, in practice, is defined by the diameter D_{in} of the hemispherical tactile element 60.

As mentioned above, the diameter D_{in} is larger than the diameter D_{out} of the output channel 72 where the measurements are taken, which increases the sensitivity of the optical signals at the output channel 72. In some examples, this increase in sensitivity is in the order of A_{in} to $3A_{out}$.

In some examples, the optical element 64 is formed of a homogenous soft elastomer channel. However, using a homogenous soft elastomer channel as the optical element 64 can in some cases result in high hysteresis causing the optical readings to deteriorate. Moreover, the inventors have discovered that a soft sensor element of the nature shown is prone to mismeasurement caused by lateral forces imparted to the element, leading to a measure of applied pressure

that is not truly representative of orthogonal pressure and as a consequence an imprecise mapping of the biological tissue held within the gripper assembly.

Figures 11 and 12 show the interdigitating arrangement of the optical sensor elements 34, 35 with respect to each other. Figure 11 shows the cartridges 36, 38 aligned side by side and Figure 12 shows how the cartridges would be disposed one of top of the other. More specifically, the sensor elements 34, 35 of each array are disposed in a series of spaced rows 54, 56 and are located on their respective supports such that the sensors 34 or one row 54 face a space between rows 55 of the sensor elements 35 of the other array of sensors.

As a result, the sensor elements 34, 35 sense different sections in the longitudinal direction of the cartridges 36, 38 (or sensor arrays), thereby effectively increasing the resolution of the probe head.

While the described embodiments show interdigitation across the longitudinal direction of the probe head, it will be apparent to the skilled person that the interdigitation could be in any other suitable pattern, for example in the longitudinal direction of the probe head, by intermeshing both transversally and longitudinally and so on. It is preferred, though to have an interdigitating pattern as shown in the preferred embodiments, which leads to optimisation of the width of the probe head.

The dimensions of the cartridges 36, 38 shown in Figure 11 are exemplary only.

As a consequence of the shortcomings of the prior art sensor structure, preferred embodiments of the optical channel 64 include a generally rigid deforming element 92 embedded in the soft material portion 100 of the optical element 64, .

Figure 13 shows an embodiment of pressure sensitive optical sensor cartridge in accordance with the teachings herein and a cross-sectional view through line A-A thereof. The hemispherical, or other tactile, elements 60 are not shown for the sake of clarity. The elements 60 include a rigid deforming member 92 which is disposed in a respective channel 64 of the cartridge. Each deforming member, in this embodiment, has a frusto-conical proximal end 92 embedded in

the soft material of the optical members 64. The head may also be rigid, for example made of the same material as the deforming member 92, and such that when deforming pressure is applied to the head this will press upon the rigid element, which in turn will compress the deformable section or portion of the sensor element. The probe includes at the front surface of each element 64 a reflective surface 72 equivalent to that shown in Figures 9 and 10 and described above, similarly formed of a reflective, such as metallic, particulate material such as powder.

Advantageously, the rigid deforming members 92 have a length that extends into the soft optical members 64 by a distance related to the length of the optical member, as will be apparent from the cross-sectional view of Figure 13, and specifically so that each probe element will generate deflection of the surface 72 at the end of the cartridge, in equivalent manner as shown in Figures 9 and 10.

As force is applied to the heads (not visible in Figure 13) this pushes the deforming elements 92 into the optical elements 64, causing them to compress and deform, particularly at their soft material portion 100. This deformation results in a change in the shape of the reflective surfaces 72 and as a result a change in the light reflected back from the reflective surfaces 72. The inventors have found that the deforming elements 92 provide greater compression and deformation of the optical elements 64 and that the change in reflected light as force is applied to sensors is amplified, resulting in a more sensitive pressure based optical system. Moreover, the use of rigid deforming elements or at least the inserted portions 92 that locate within the channels 64, limits and advantageously eliminates the effect of lateral pressure applied to the elements, such that deformation of the surfaces 72 occurs solely or substantially solely as a consequence of direct opposing pressure. The inventors have found that the use of frusto-conical elements 92, rather than cylindrical as in other embodiments described below, does not materially alter the lateral sensitivity (insensitivity) of the sensor elements.

The reflected light is received by the receiving fibres 90 of the optical fibre 50 which transmit the reflected light to a processing unit described in further detail below.

With reference to Figures 14 and 15, the inventors have performed Finite Element Analysis (FEA) studies of the optical element 64 including a rigid deforming element 92 embedded in the soft material portion 100 of the optical element 64. They have found that the rigid deforming element 92 concentrates the strain applied to the soft portion 100 of the optical element 64 when force or pressure is applied to the tactile element 60 and minimises or eliminates sensitivity to lateral pressure applied to the sensor elements.

The inventors have also found that sensitivity of the optical readings can be controlled by adjusting the length of the deforming element 92 embedded in the optical element 64 and by adjusting the radius at which the optical elements 64 curve within the cartridge.

More specifically, Figure 14 depicts an analysis performed on designs of tactile sensing channel, modified by increasing the firm elastomer length and increasing radius of the centre curve. The diameter of the sensing channel is 1mm ($\phi_{in} = \phi_{out} = 1mm$). The radius (r) is increased from 1mm to 4mm, while vertical and horizontal lengths are fixed by 5 mm. Increasing the radius (r) reduces the straight vertical length indicated by the blue arrows in the Figure 1, so that embeddable length of the firm elastomer becomes shorter. Radius of hemisphere for the contact area is 0.5mm that allows 0.5 mm displacement of the firm elastomer in the tactile sensing channel. Thus, embeddable length of the firm elastomer is calculated by subtracting 0.5mm from the straight vertical length. Therefore, decided the sensor design configurations to observe relationship between sensor sensitivity and embedding the firm elastomer are as shown in Figure 16.

The tested designs of Figure 16 were analysed using Abaqus (ABAQUS Inc.) software. The soft material selected for the soft portion 100 was Ecoflex 50 (shore hardness: 00-50, Smooth-On Inc.) and the rigid material selected for the deforming element 92 was PMC-790 (shore hardness: 90A, Smooth-On Inc.). Ecoflex 50 is a hyperelastic material and is an almost incompressible material. The 1st order Mooney-Rivlin law ($C10 = 2.67$ kPa, $C01 = 0.67$ kPa and $D1 = 6 \times 10^{-6}$ kPa) was implemented during the simulation. The stiffness of PMC-790 is

greater than of Ecoflex 50, and the amount of deformation caused by a force F on this material is relatively very small. Therefore, a linear elastic model ($E=3\text{GPa}$, Poisson ratio = 0.4) was used for PMC-790 in the simulation. To gain accuracy of the simulation, a number of elements of about 10k was chosen. The boundary condition set for the FEA was that the outer surface of the silicone optical element 64 is adhered to the inner surface of the channel formed in the rigid cartridge body supporting the optical element 64. This takes into account the soft material viscoelasticity of the optical element 64. In other words, the outer surface of the soft optical element 64 does not move.

The results of the FEA analysis are shown in Figure 16 (a and b). Different inputs of the FEA study were used for cases 1 to 4 (see the table of Figure 16) compared to cases 5 to 14. The input for cases 1 to 4 was a rigid plate in contact with the hemispherical tactile element 60 and moved by 0.32mm to generate the compressive force as shown in Figure 16 (a). The input for cases 5 to 14 was displacement of the deforming element 92 by 0.32mm as shown in Figure 16 (b). Applying force as per the above described inputs in the FEA analysis causes compression and deformation of the optical element 64. This results in a change in the amount of reflected light intensity received at the output channel. As described above, this also results in the transducing surface 108 changing from a flat or concave shape to a convex shape. The change in amount of reflected light intensity received at the output channel 72 is related to the amount of displacement of the transducing surface 108 (or surface 72 as shown in Figure 13).

The amount of displacement of the transducing surface 108 is indicated by the centre node displacement Δd of the transducing surface. Δd is measured as shown Figure 15. The amount of force F applied at the tactile element 60 can therefore be measured based on the amount of displacement Δd measured at the centre node of the transducing surface 108.

The sensitivity of the optical readings obtained can be calculated using the following equation:

$$S = \frac{\Delta d}{\Delta F}$$

where: S is the sensitivity (mm/N); $\Delta d(mm)$ is the displacement change of the transducing surface 108; and $\Delta F(N)$ is a contact force range from 0 to maximum contact force, value of the $\Delta F(N)$ is the same as the maximum contact force
 5 shown in the table of Figure 16 and Figure 17. Larger displacement Δd with smaller ΔF results in better sensitivity. A higher sensitivity value means that the sensor design has better sensitivity.

Figure 17 shows the results of the FEA analysis. Specifically, Figure 17 (a) shows the FEA results for cases 5 to 14 in the table of Figure 16 fitted into a three-
 10 dimensional surface using surface interpolation technique to observe the sensitivity change in the entire range of the radius (r) and the length of the deforming element 92 (l_{stiff}). Figure 17(b) shows the change in sensitivity based on a change in radius (r). Figure 17(c) shows the sensitivity change based on a change in deforming element length and Figure 17(d) shows the contact force
 15 range based on a displacement of 0mm to 0.32mm of the soft portion 100 by increasing the length of the deforming element 92.

Cases 1 to 4 of the table of Figure 16 do not contain the deforming element 92, but the radius (r) is increased from 1 to 4mm. Increasing the radius improves the sensitivity, but the contact force range (0N to 0.14N) and displacement
 20 (0.02mm) does not change and are insufficient to change the light intensity and to measure force information. In addition, increasing the radius (r) of the soft portion 100 does not change the contact force range ΔF and sensitivity (as shown in Figure 17).

The strain distribution of the FEA result in Figure 15 shows that embedding
 25 the deforming element 92 concentrates strain to the soft portion 100, resulting in increased transduction of the contact force at the output channel 72.

In the cases 5, 9, 12 and 14 in Figures 16 and 17(b), the deforming element 92 is 0.5mm in length and is embedded into the soft portion 100. The contact force range ΔF is 0N to 1.9N, but the sensor loses sensitivity by about 300%

compare to cases 1 to 4. Nevertheless, the contact force range ΔF and the displacement Δd in cases 5, 9, 12 and 14 are sufficient to detect tactile information at the tactile element 60, that is a clinically significant force applied to the tactile element 60. In cases 5, 9, 12 and 14, the contact force range ΔF is increased about 12 times and the displacement Δd is increased about 5 times. Also, as shown in Figure 17(b), increasing the radius by about 1mm improves sensitivity by about 10%. However, Figure 17(c) shows that the sensitivity from cases 5 to 8 increases by about 200% when increasing the length of the deforming element 92 by 3mm. Highest of the each radius is observed in cases 8, 11, 13 and 14, as shown by the red section in Figure 17(a). The cases 8, 11, 13 and 14 also imply that increasing the radius r reduces sensitivity about 160%, due to the shorter length of the stiff elastomer section 100 and the higher ΔF . Therefore, a change in length of the deforming element 92 has a greater effect on sensitivity than a change in the radius r . This is shown in Figure 17(d).

Increasing the length of the deforming element 92 from 0.5mm to 3.5mm decreases the maximum contact force from 1.9N to 1.4N. In other words, a longer deforming element 92 results in increased sensitivity.

In conclusion, the FEA analysis shows that an optical element 64 formed entirely of a homogenous soft elastomer channel results in a low contact force range (0.14N) and output displacement (0.023mm).

Preferred embodiments which include the deforming element 92 result in improved contact force range and output displacement. Sensitivity and contact force range is adjustable by changing the length the deforming element 92, in particular increasing the length the deforming element 92 by 3mm improves sensitivity by 200% and reduces contact force range by 26%. This allows optimised sensitivity and measurable contact force range in the millimetre-scale.

Referring now to Figures 18A and 18B, these shows another embodiment of optical sensor element 160 in which the tactile part spherical head is formed of rigid material as is the deforming element or shaft 162 that extends into and is embedded in the deformable optical member 164. The shaft 162 is shown as being generally cylindrical but it is to be understood that this may take any other

suitable shape including, for example, a conical or frusto-conical shape as with the embodiment of Figure 10. The tactile head and the deforming element may be formed as a unitary component.

5 The inventors found a solution to reduce hysteresis by generating negative pressure using an elastic layer 168 of high stiffness (much less deformable than the material 164) between the rigid deforming element 160/162 and the soft deformable member 164, as shown in Figures 18A and 18B. The rigid deforming element 160/162 is preferably bonded to the elastic layer 168. Applying force, as per the arrow in Figure 18A generates an elastic energy by compressing the
10 elastic layer 168. Removing force releases the elastic energy and induces the elastic layer to act like an elastic spring 170, acting against any hysteresis that might otherwise occur in the tactile sensing channel.

The efficacy of this solution has been established by hysteresis measurement of the tactile sensing channel, as depicted in Figure 19. Two single
15 channel sensors 180, 182, and a 6-axis force/torque sensor 184 (Calibration SI-25-0.25, resolution: $1/160\text{N}$ for F_x, F_y, F_z , $1/32\text{ Nmm}$ for M_x, M_y, M_z , range: $F_x, F_y = \pm 25\text{N}$, $F_z = \pm 35\text{N}$, $M_x, M_y, M_z = \pm 250\text{Nmm}$) were assembled to a motorized linear guide 7 (0.0006mm accuracy, Newmark System Inc).

The single channel sensor 180 contains only the rigid deforming element
20 and the other single channel sensor 182 contains the rigid deforming element and the top elastic layer as shown Figure 19. The two single channel sensors are designed following the simulation result, diameter of channel is 1mm and length of the rigid deforming member is 3.5mm. The linear guide 186 precisely presses 0.5mm the tactile sensing channel. The tactile sensing channel was filled with
25 Ecoflex Gel (Smooth-on Inc). The stiffness of Ecoflex Gel is softer than of Ecoflex 50, and the amount of deformation caused by a force F on this material is relatively very large. Thickness of the elastic layer in this embodiment was 1mm and was molded using Ecoflex 50.

The effect of hysteresis is shown in Figure 20. Hysteresis of the single
30 sensor without the elastic layer was 75%, but hysteresis of the single sensor with the elastic layer was 9.9%. Thus, negative pressure from the elastic layer 168

was found to reduce hysteresis by over 65%. A hard elastic layer would reduce hysteresis further. The measurable force range was also increased from 0.2N to 0.45N, which is another noticeable benefit shown in Figure 20. The force range can be adjusted by selecting elastic material of the elastic layer.

5 It has been found, therefore, that by providing an elastic layer 168 between the soft channel and the rigid deforming element can reduce hysteresis and facilitate an adjustable measurable force range.

Referring now to Figure 21, this shows an embodiment of surgical gripper apparatus 10, which includes at its distal end, preferably within the probe head 14.
10 At the proximal end, the assembly includes the handle 12, which is provided with the inertial measurement unit 18. In this embodiment, the inertial measurement unit 18 comprises two inertial navigation units (IMUs) 19 and 21, each including an accelerometer and a gyroscope. The IMUs measure the relative acceleration between the two handles portions 16a and 16b from which the relative speed and
15 displacement of the handles can be derived. Based on the transmission relationship determined by the mechanical components, the measurements of acceleration, speed and displacement are used to calculate the kinematics parameters of the jaws 22, 24. At the same time, the sensor elements 34, 35 measure the real time contact force applied to the sensor elements 34, 35. The
20 measured force and kinematic parameters of the sensor elements 34, 35 are fused using multi-sensor fusion based on the Recursive Least Square (RLS)-based method so as to characterise parameters of a body part against which the sensor elements 34, 35 are applied.

A spring-viscosity-mass system is used for modelling, from the readings
25 obtained by the sensor elements 34, 35, the characteristics of biological material, such as a body part, within the detection zone of the sensor elements 34, 35.

Estimating the environmental parameters for such a system plays an important role in the field of process control, signal modelling, communication and electronic technology. In general, parameter estimation algorithm can be derived
30 in the frequency domain from measurement data under persistent excitation condition. Prior identification methods may be classified into three major groups.

The first group is the Matrix Method which is directly based on frequency response functions (FRFs) of a matrix i.e. sensor arrays. The Least squares method has been used to reduce the impact of noise on data processing. The convergence of the least squares parameter estimation algorithm for multivariable systems has
5 been previously used.

When applying the Matrix Method, the Instrumental Variable Method should be emphasised, as it is less sensitive to noise compared to directly using the least squares method. However, when using such a method, the error term is actually unobservable. It is difficult to find a variable that is strictly irrelevant to the error
10 term and highly dependent on random explanatory variable that is replaced.

Therefore, the selection of instrument variable has a certain degree of arbitrariness. The second group depends on modal parameters which are deduced from FRFs, so is also called the Modal Method. In some cases, finite element models need to be used, and the eigenvalue problem related to the
15 viscous damping system needs to be considered. This burdens the calculations required and affects the real-time performance. The last group is the Enhanced Method which aims to compensate for the lack of the first two methods.

The above methods have provided a useful theoretical basis for effective application of parameters identification. However, these methods lack the use of
20 multiple heterogeneous sensors which have the potential to make identifications in the time domain. Prior studies have used the contact force and displacement of a contact point to measure and characterise an unknown object in order to optimise robot-environment interactions. However, these studies were conducted in non-time-varying systems and therefore do not replicate most real situations.

Prior art under-actuated grippers with tactile sensors have been used to identify
25 the parameters of an unknown environment. However, such grippers are mainly used in industry and are not suitable to be miniaturised. Furthermore, grippers that do not have a parallel gripping pattern cannot provide kinematic parameters (displacement, velocity and acceleration) of the contact point through the
30 transmission properties of the mechanism.

Using minimally invasive surgeries provides the advantage of minimised incisions. However, such surgeries have the disadvantages of limited vision and lack of sense of touch. Embodiments of the gripper 10 of the present application aim to obtain multi-information (such as contact force, contact point's kinematic parameters) directly from the gripper 10 in order to classify various body parts, including for example various tissues and/or organs as well as locate various body parts, including for example locating arteries and/or identifying the number of arteries within a clinical area of interest.

Figure 22 is a diagram of the sensor elements 34, 35 applied to a body part and modelled as a spring-viscosity-mass system. The contact force of each sensing element 34, 35 can be described by the following ordinary differential equation:

$$f_i = -M_{Ei}\ddot{x}_i - C_{Ei}\dot{x}_i - G_{Ei}x_i \quad (\text{Eq. 1})$$

where $i \in Z^+$ represents the number of sensing elements, M_{Ei} , C_{Ei} and G_{Ei} are parameter of mass, viscosity and stiffness, respectively. $\ddot{x}_i$, $\dot{x}_i$ and x_i are acceleration, velocity and displacement of each contact point, which change along the normal direction.

To identify the unknown parameters of the body part to which the sensor elements 34, 35 are applied, an estimation method is developed based on the Recursive Least Squares (RLS) algorithm. For the detailed implementation, Equation 1 is discretise and defined as:

$$f_i(k) = -M_{Ei}\ddot{x}_i(k) - C_{Ei}\dot{x}_i(k) - G_{Ei}x_i(k) \quad (\text{Eq. 2})$$

where $k \in Z^+$ stands for step k and Z^+ is a positive integer.

Equation 1 can be rewritten in matrix form as

$$f_i(k) = -\mathbf{r}_i^T(k)\mathbf{w}_i \quad (\text{Eq. 3})$$

where

$$\mathbf{r}_i^T(k) = [\ddot{x}_i(k) \dot{x}_i(k) x_i(k)]$$

$$\mathbf{w}_i = [M_{Ei} C_{Ei} G_{Ei}]^T$$

The RLS estimation of $\mathbf{w}_i$ is defined as:

5

$$\hat{\mathbf{w}}_i(k) = \hat{\mathbf{w}}_i(k-1) + \mathbf{K}_i(k)[f_i(k) - \mathbf{r}_i^T(k)\hat{\mathbf{w}}_i(k-1)] \quad (\text{Eq. 4})$$

where

10

$$\mathbf{K}_i(k) = \frac{\mathbf{P}_i(k-1)\mathbf{r}_i(k)}{\lambda + \mathbf{r}_i^T(k)\mathbf{P}_i(k-1)\mathbf{r}_i(k)},$$

$$\mathbf{P}_i(k) = \frac{1}{\lambda} [\mathbf{I}_3 - \mathbf{K}_i(k)\mathbf{r}_i^T(k)]\mathbf{P}_i(k-1)$$

The variable $\mathbf{P}_i(N)$ is the covariance matrix which has a 3×3 size, and $\mathbf{P}_i(0) = p_0\mathbf{I}_3$, where p_0 is a large positive number. The estimation error is defined as

15 $\delta = \hat{\mathbf{w}}_i(k+1) - \hat{\mathbf{w}}_i(k)$, which will converge under persistently excited. λ is the forgetting factor, which can affect the convergence rate of $\hat{\mathbf{w}}_i$. Generally, $0 < \lambda \leq 1$. Thus, the parameters of the body part can be obtained using the RLS algorithm during palpation.

Based on the above theoretical analysis, numerical simulation was
 20 performed by MATLAB to verify the effectiveness of the algorithm in recognizing the parameters of a body part. In order to ensure that the estimation parameters converge to the true value, excitation signal must satisfy the continuous condition, which is defined as a power function and is used to simulate the palpation operation by a medical gripper. The advantage of this method is that it does not
 25 require palpation in a constant way, which facilitates the promotion of this technique.

The functions can be described as:

$$x(t) = -(0.5t - 1)^3 + 1 \quad (\text{Eq. 5})$$

$$v(t) = -3(0.5t - 1)^2 \quad (\text{Eq. 6})$$

$$a(t) = -6(0.5t - 1) \quad (\text{Eq. 7})$$

The inventors have simulated analysing a body part and used the above equations to derive characteristics of the body part. The table below provides parameters for the above equations.

	Mass M_E (kg)	Viscosity C_E (Ns/mm)	Stiffness G_E (N/mm)
Tissue	1	10	20
Artery	$1 + \sin(15\pi t)$	$10 + \sin(15\pi t)$	$20 + \sin(15\pi t)$

Figure 23 shows the parameters used for the analysed body part, which in this case is a body tissue. Figure 24 shows the information collected from analysis of the body part.

These channels have similar properties, so it is possible to analyse one sensing element without affecting its performance. The algorithm used collects all information and recognises the parameters at the same time.

Figure 25 shows the resulting parameter estimation for the body tissue analysed.

Figure 26 shows the parameters used for an artery being analysed during the simulation, while Figure 27 shows the information collected from the artery, and Figure 28 shows the resulting parameter estimation for the artery being analysed.

Once palpation is simulated, the results were obtained. Therefore, the operation time can effectively be reduced without affecting the estimation accuracy. In the simulation, regardless of the influence of noise, kinematic

parameters and contact force are collected in real time. During the identification process, 1000 steps of the above information within 2s were discretely acquired as input.

In accordance with real life, during continuous palpation of tissue, the environmental parameters are constant (see Figure 23). The specific values are shown in the table above and the information collected is shown in Figure 24. Combined with the identification results from Figure 25, it will be seen that each parameter quickly converges to the given true value. These results can be used to determine the type of tissue the sensor elements are applied to. In some embodiments, at least one of acceleration, velocity and displacement associated with the body part being analysed are determined. However, in preferred embodiments, the combination of the three parameters acceleration, velocity and displacement are determined as this provides a more detailed information on the characteristics of the body part and provides a more accurate classification of the body part being analysed.

Due to the periodic excitation or pumping of a heart, this imparts particular characteristics to arteries, notably the pulse demonstrated by arteries. This characteristic of pulse is represented by the parameters used for the artery as shown in Figure 26 and by the expressions shown in the above table. The pulse is detected when analysing contact force, as shown in Figure 27. The results in Figure 27 combined with the results in Figure 28 show that each parameter tends to converge. However, by the end of the identification phase, a slight fluctuation in value of each parameter can still be observed (see Figure 28). This is used to identify the presence of arteries within a portion of tissue being analysed and can be used to reduce the risk of misclassification of arterial locations during minimally invasive surgery.

With reference now to Figure 29, in use, a surgeon inserts the surgical gripper 10 into an incision made in a patient and brings the gripper probe 14 to a clinical body part of interest. The surgeon grips the handle portions 16a and 16b and moves the gripper arms or jaws 22, 24 from an open configuration towards one another until they close onto a body part 200 of interest, in this example a

blood vessel. This will cause the sensor elements 34, 35 to come into contact with opposing sides of the body part 200. Further closure of the jaws 22, 24 will cause the deformable parts of the sensor elements 34, 35 to deform against the body part 200, and as a result a change in light passing through the sensor elements.

5 Figure 30 shows an example of tissue characterisation system, including surgical gripper 10 and a connected optical fibre 50. Light is transmitted from the optical fibre 50 to the sensor elements 34, 35 a convex lens 201 which helps in distributing the light transmitted from the optical fibre 50 to the sensor elements 34, 35.

10 Depending on the amount of pressure applied to the sensor elements 34, 35 against the body part 200, that is of the deformation of the deformable parts thereof, a different intensity or amount of light reflected back from the sensor elements 34, 35 to the optical fibre 50. The reflected light passes from the optical fibre 50 to a processing unit which converts the optical readings into an optical
15 image 202. The processing unit analyses the optical image 202 and converts it to a pressure map 204 and/or a tactile image 206 which can then be used to infer characteristics of the body part 200.

 Preferably an optimal amount of pressure applied to the sensor elements 34, 35 in order to achieve a reliable optimal image 202 from the sensor elements
20 34, 35, that is enough to detect a change yet not so much as to cause undesired compression of the body part and distortion of the image. As described above, there is preferably provided a pressure sensor located at the jaws 22, 24 to sense the amount of pressure applied to the jaws. The processing unit may either warn the user of the pressure applied and/or control the amount of pressure applied.
25 There is a variety of suitable pressure and strain sensors for such a purpose and these are known to the skilled person.

 Figure 31 shows the results that can be provided by the tissue characterisation system, in particular details of the optical image 202 formed as the sensor elements are applied to the body part 200 of interest.

30 The system is shown in mathematically annotated form in Figures 33 and 34 in the course of the characterisation of a body part held between the sensor

arrays 35, 36. The accelerometer and the gyroscope of the system measure the relative acceleration between the two handles parts 16a and 16b, from which the relative speed and displacement of the jaws 22, 24 can be derived. These measures of acceleration, speed and displacement are then used in the spring-viscosity-mass model described above to derive mass, viscosity and stiffness characteristics of the body part. The parameters of mass, viscosity and stiffness are used to characterise the type of tissue being sensed. As described above, when the appropriate fluctuation these parameters is observed, the surgeon can conclude that at least one artery is present within the body part being sensed. It is preferred that the system displays via a display unit a map depicting the sensed characteristics of the body part (for instance pulsation of a vessel).

It will be appreciated that in some embodiments, the accelerometer and the gyroscope are located in the gripper probe 14 where they measure relative acceleration (and thus speed and displacement) of the jaws 22, 24 directly.

In some embodiments, the tactile element may be rigid rather than deformable.

While the preferred embodiments make use of opposing arrays of sensor elements, the design of sensor array is considered to be advantageous in itself over prior art sensors and usable in other probes, including a probe utilising a single sensor array.

The concept of facing sensor arrays, in which the sensors preferably interdigitate, can be use with sensors other than the preferred pressure sensitive optical sensor structures used herein, that is to any pressure sensitive sensor.

The disclosure in British patent application number GB 1820240.8, from which this application claims priority, and in the abstract accompanying this application are incorporated herein by reference.

CLAIMS

1. A sensor for a surgical probe including a support unit having a plurality of channels disposed therewithin and a sensor face; there being disposed
5 in each channel a sensor element including a deformable section made of flexible material, a deforming member in contact with the deformable section, the deforming member being of a rigid material, a head extending beyond the sensor face and connected to the deforming member, and a reflective member disposed at an outlet of each channel; whereby pressure applied to the head causes
10 movement of the deformable element, deformation of the deformable section, and a change in shape of the reflective member.
2. A sensor according to claim 1, wherein the head is made of a rigid material.
15
3. A sensor according to claim 1 or 2, wherein the head and the deforming member are a unitary element.
4. A sensor according to claim 1, 2 or 3, wherein the head and the
20 deforming member are formed from the same material.
5. A sensor according to any preceding claim, wherein the head is hemispherical.
- 25 6. A sensor according to any preceding claim, wherein the deforming member is at least partially disposed in a recess within the deformable section so as to be at least partially embedded therein.
- 30 7. A sensor according to any preceding claim, wherein each channel includes a first portion extending substantially perpendicular to the sensor face, and each deforming member is cylindrical or frusto-conical.

8. A sensor according to any preceding claim, including a sprung return element coupled to each head and operable to bias the head and the deforming member to a non-pressed position.

5

9. A sensor according to any preceding claim, including wherein the sprung return element comprises a layer of elastomeric material disposed at the sensor face, the or each head having a portion extending over the return element.

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10. A sensor according to any preceding claim, wherein each channel has a uniform or tapering diameter along its length.

11. A sensor according to any preceding claim, wherein the channels are arranged in a two-dimensional array at the sensor face.

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12. A sensor according to preceding claim, wherein the support unit is in the form of a removable cartridge for a surgical probe.

13. A surgical probe including:

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a probe head provided with first and second probe arms movable relative to one another,

the first probe arm supporting a first array of sensor elements according to any preceding claim,

the second probe arm supporting a second array of sensor elements

25

according to any preceding claim,

wherein the first and second arrays of sensor elements are disposed in facing relationship to one another.

14. A surgical probe according to claim 13, wherein the sensor elements of the first and second arrays of sensor elements are disposed in interdigitating manner.

30

15. A surgical probe according to claim 13 or 14, wherein the sensor elements of the first and second sensor arrays are disposed in sets of spaced lines, wherein the sensor lines of the first and second arrays are disposed so as to interdigitate.

16. A surgical probe according to claim 13, 14 or 15, wherein the first and second probe arms are pivotally coupled together.

17. A surgical probe according to any one of claims 13 to 16, including a pressure sensor coupled to the first and second arms and configured to sense pressure applied between the first and second arms.

18. A surgical probe according to any one of claims 13 to 17, including an operator handle connected to the probe head and configured to control movement of the first and second arms.

19. A surgical probe according to claim 18, wherein the operator handle includes the or a pressure sensor for sensing pressure applied to the first and second arms.

20. A surgical probe according to any one of claims 13 to 19, including at least one of an accelerometer and a gyroscope.

21. A surgical probe according to any one of claims 13 to 20, wherein the probe is in the form of a surgical gripper.

22. A medical sensing system, comprising:
a surgical probe according to any one of claims 13 to 21;
a processing unit coupled to the first and second sensor arrays;

the processing unit including an input unit configured to receive pressure sensor signals from the sensor elements of the first and second arrays, a processor configured to generate from the received signals a map of sensor signals, the map being indicative of the characteristics of biological material disposed between the first and second sensor arrays, the processing unit including an output unit configured to generate an output representative of the generated map.

23. A medical sensing system according to claim 22, wherein the map is a pressure image based on pressure sensed by each sensor element of the first and second arrays.

24. A medical sensing system according to claim 22 or 23, wherein the processor is configured to determine at least one of acceleration, velocity and displacement at the first and second probe arms.

25. A medical sensing system according to claim 24, wherein the processor is configured to determine at least one of mass, viscosity and stiffness of biological material disposed between the first and second sensor arrays of the basis of determined acceleration, velocity and/or displacement of the first and second probe arms.

26. A medical sensing system according to claim 25, wherein the processor is configured to determine:

- (i) a tissue type based, and/or
- (ii) the presence of a vessel within the probe head, and/or
- (iii) the structure of a vessel within the probe head,

on the basis of at least one of measured mass, viscosity and stiffness.

27. A medical sensing system according to any one of claims 22 to 26, wherein the processor is configured to determine the presence and/or characteristics of fluid flow within a vessel on the basis of the generated map.

5 28. A medical sensing system according to claim 27, wherein the processor is configured to determine at least one of: direction of fluid flow, degree of fluid flow and/or fluid pressure within a vessel.

10 29. A method of characterising biological material using a surgical probe according to any one of claims 13 to 21, the method including the steps of:
 applying the first sensor array of the first probe arm to a first side of a volume of biological material;
 applying the second sensor array of the second probe arm to a second side of said volume of biological material, said second side facing the first side;
15 generating from signals from the sensor arrays a map of pressure signals orthogonal to the sensor faces, the map being indicative of the biological material disposed between the first and second sensor arrays, and generating an output representative of the generated map.

20 30. A method according to claim 29, including the step of determining at least one of acceleration, velocity and displacement at first and second probe arms.

25 31. A method according to claim 30, including the step of determining at least one of mass, viscosity and stiffness of biological material disposed between the first and second sensor arrays on the basis of determined acceleration, velocity and/or displacement of the first and second probe arms.

30 32. A method according to claim 31, including the step of:
 (i) determining a tissue type, and/or

(ii) the presence of a vessel between the first and second sensor arrays
and/or

(iii) the structure of a vessel
on the basis of at least one of the determined mass, viscosity and/or stiffness.

5

33. A method according to any one of claims 29 to 32, including the step of determining the presence and/or characteristics of fluid flow within a vessel on the basis of the determined map.

10

34. A method according to claim 33, including the step of determining at least one of: direction of fluid flow, degree of fluid flow and/or fluid pressure within a vessel.

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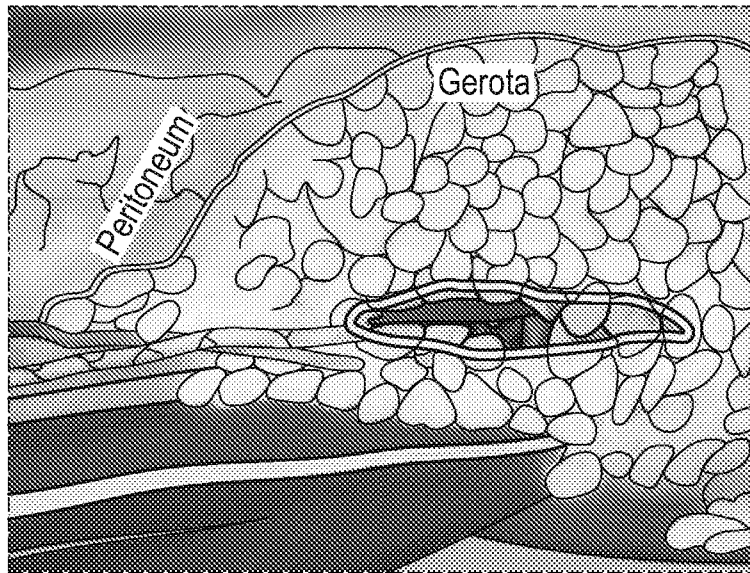


Fig. 1

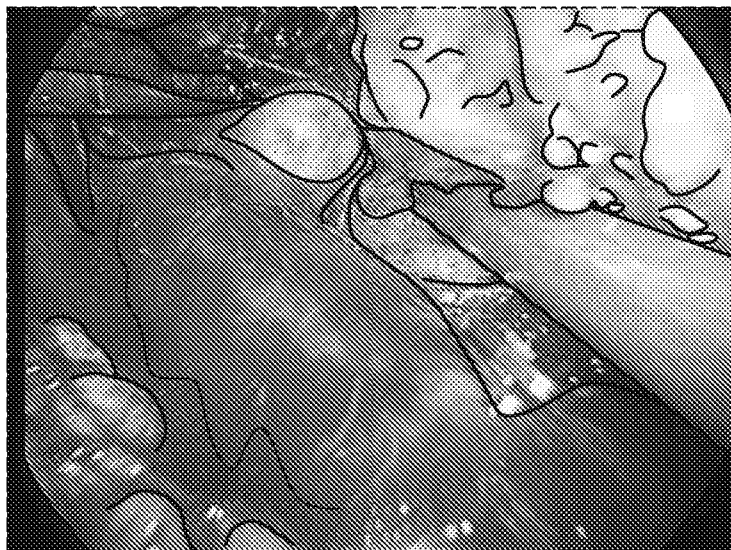
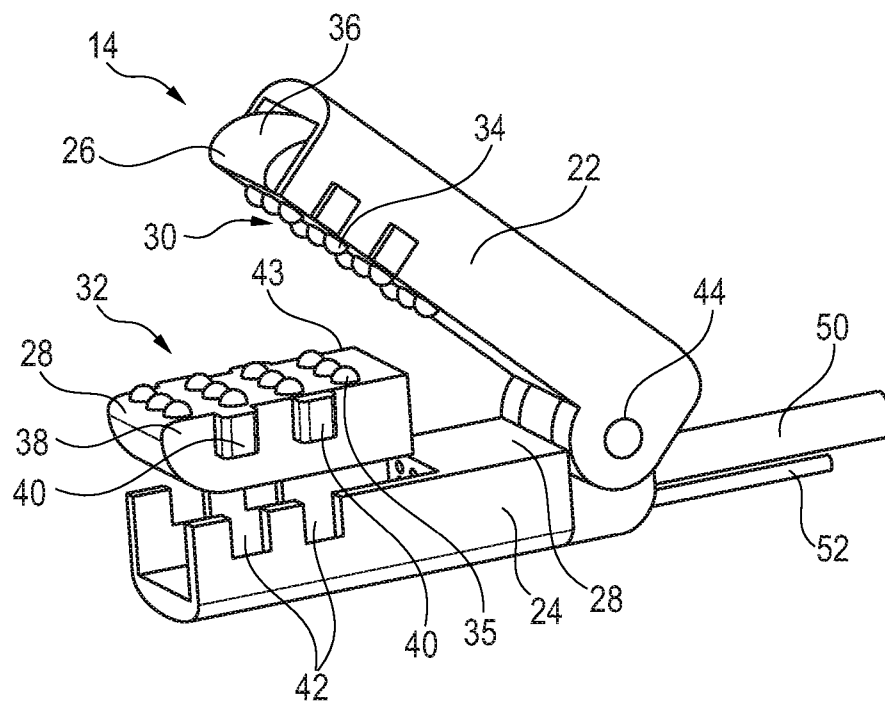
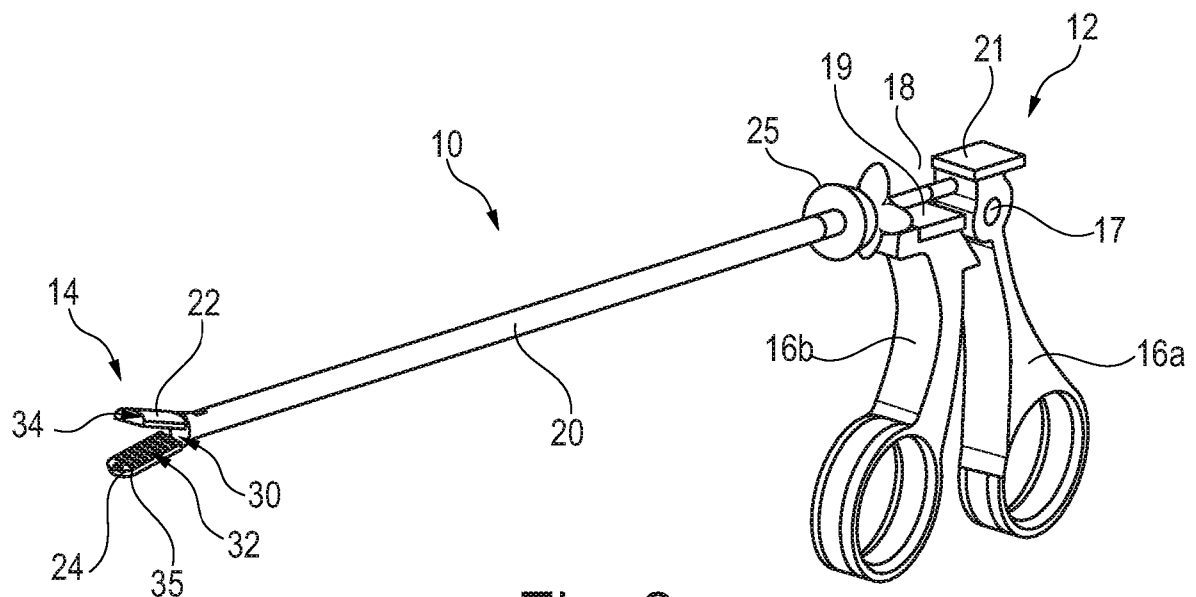


Fig. 2

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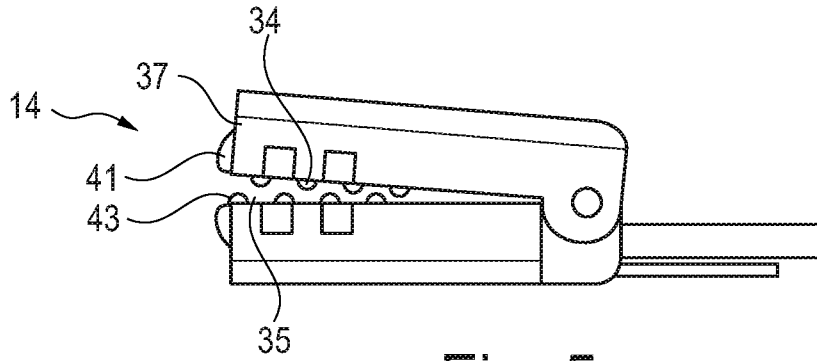


Fig. 5

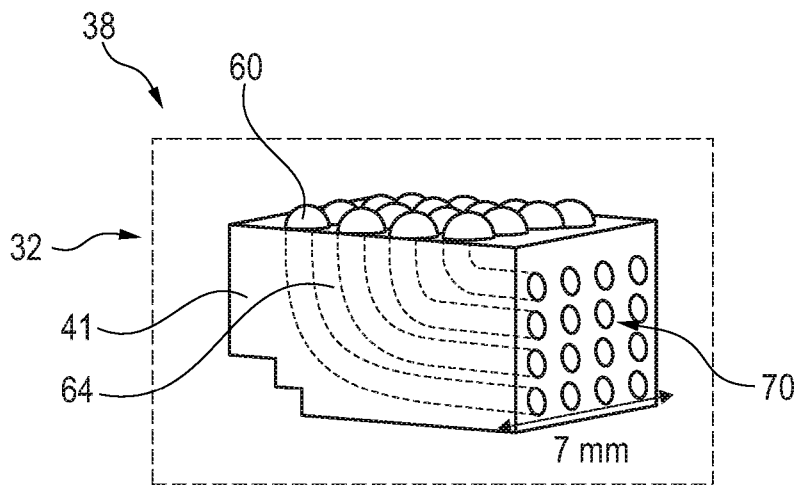


Fig. 6

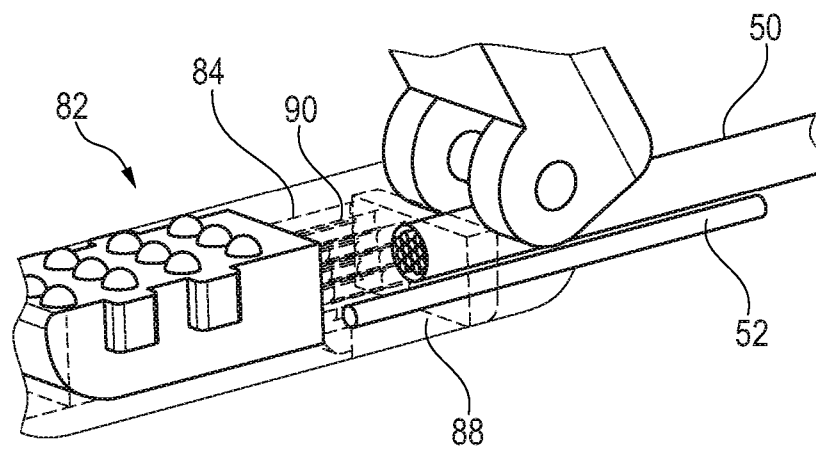


Fig. 7

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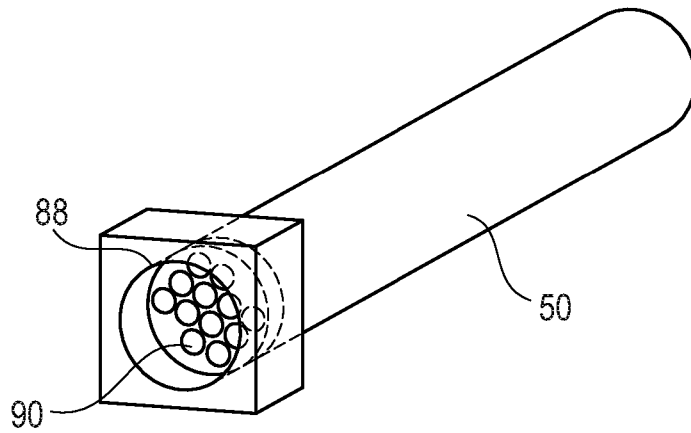


Fig. 8

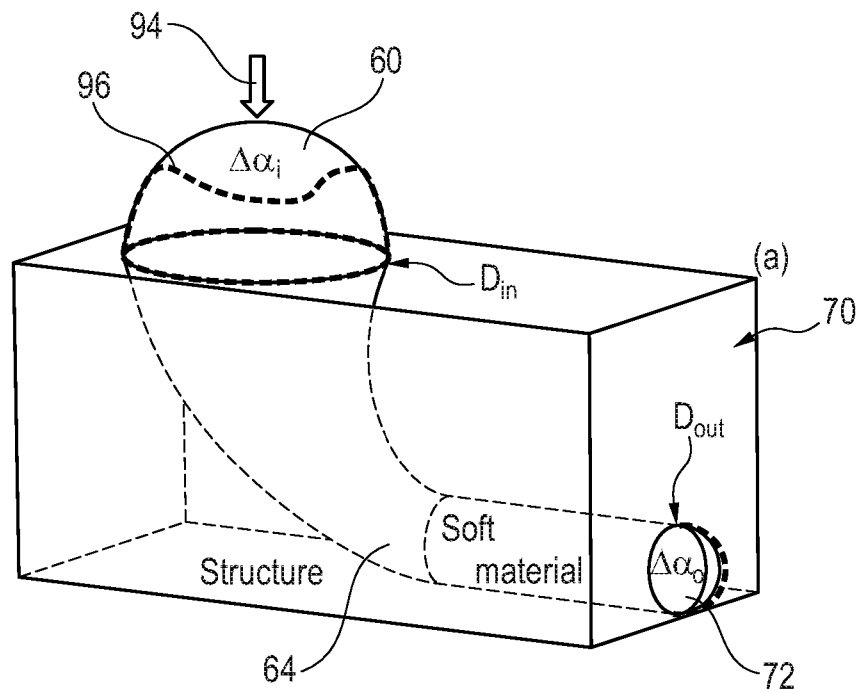


Fig. 9

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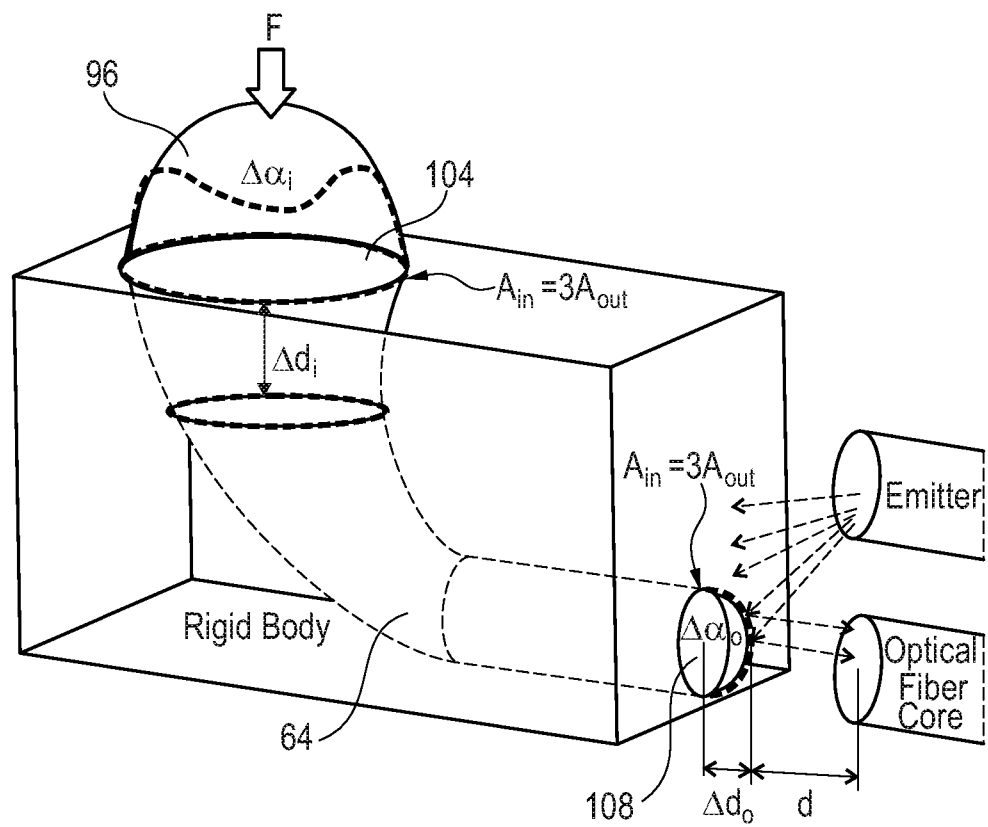


Fig. 10

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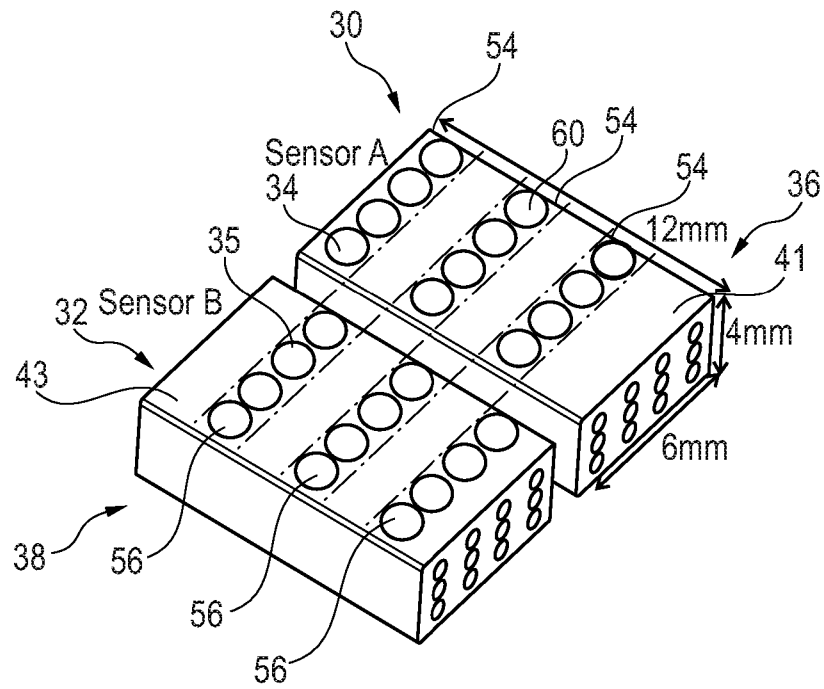


Fig. 11

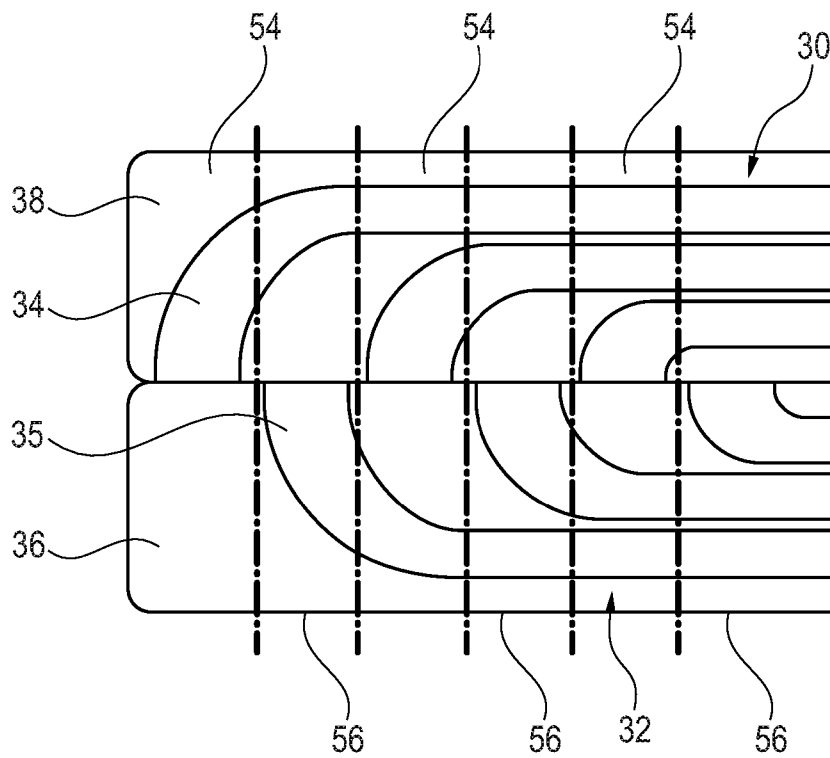


Fig. 12

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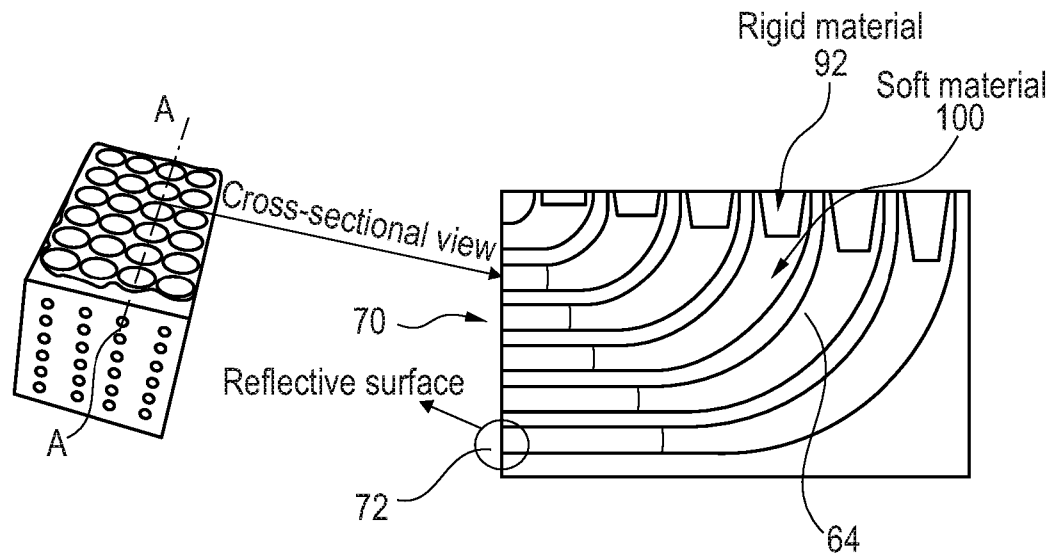


Fig. 13

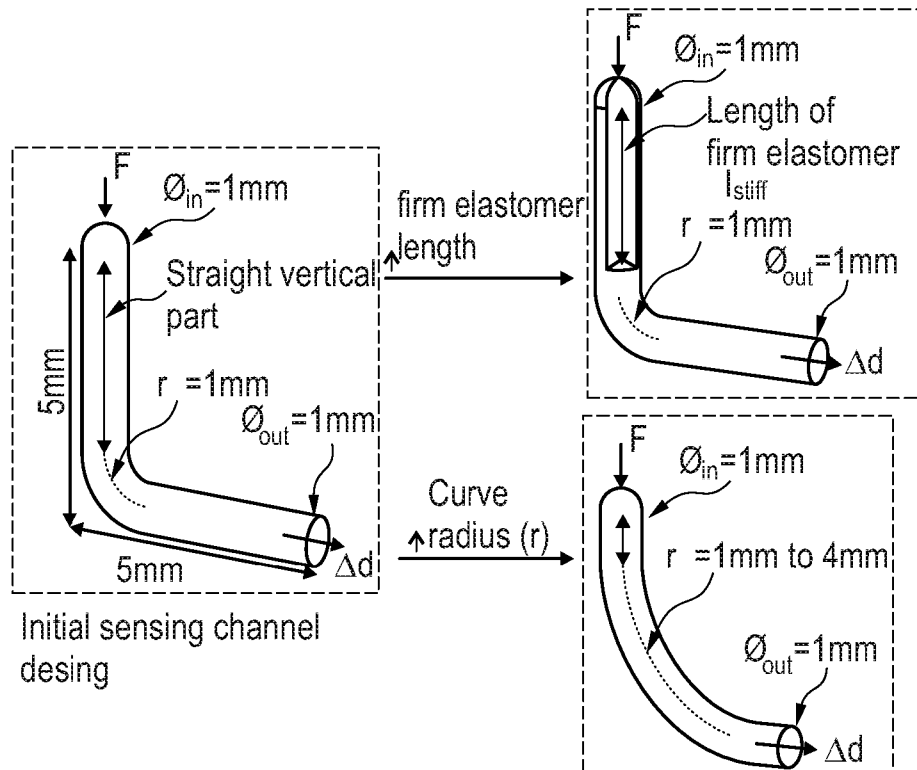


Fig. 14

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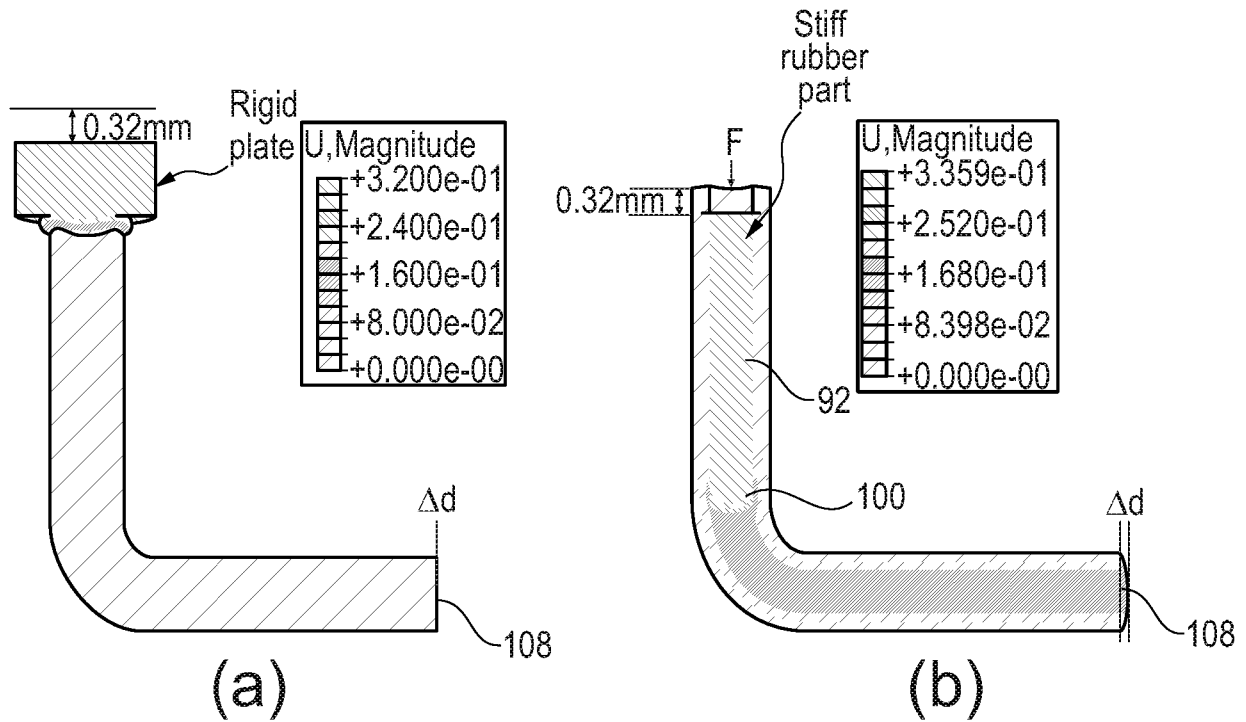
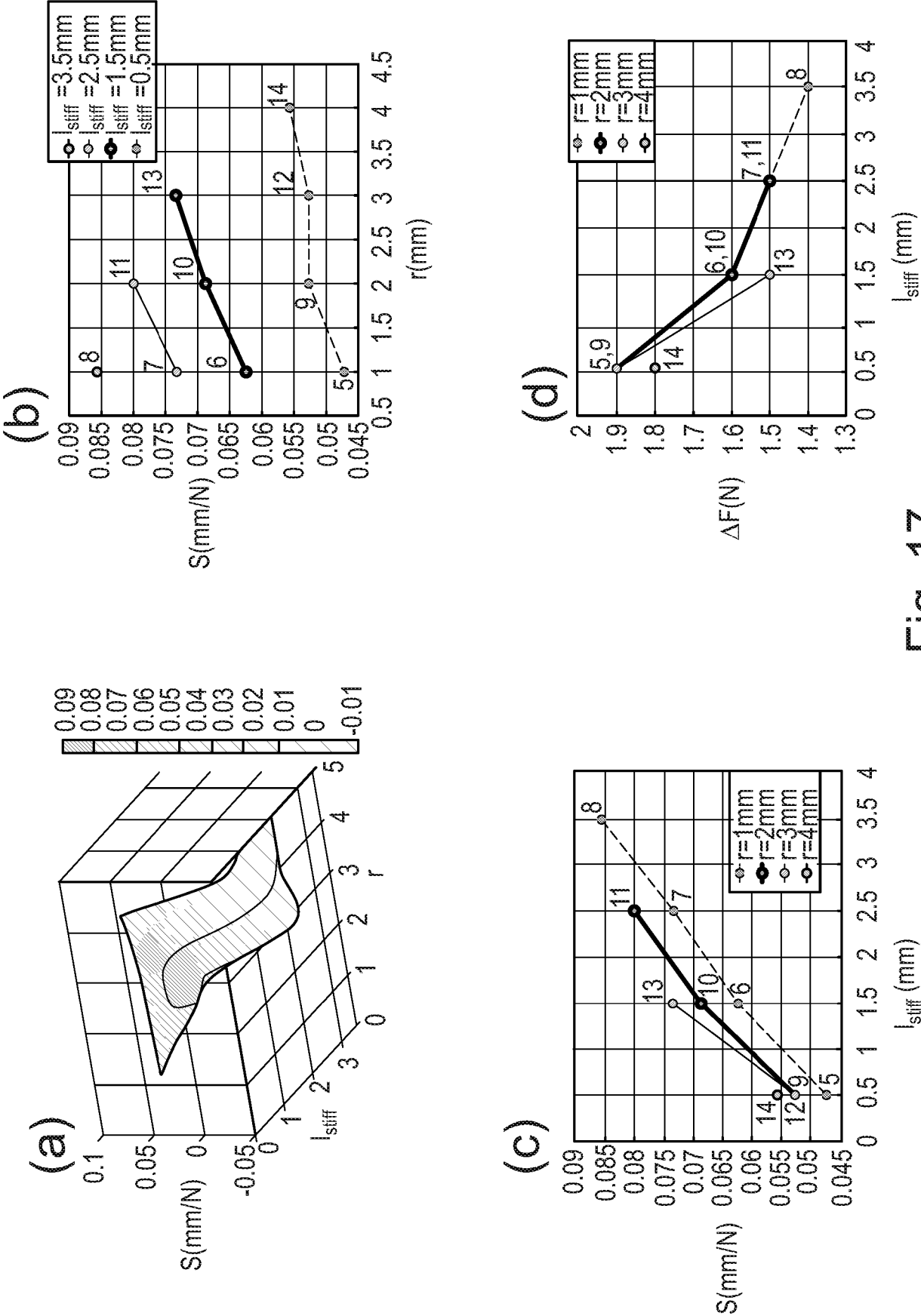


Fig. 15

No	I_{stiff}	r	S	$\Delta F_{(N)}$	$\Delta d_{(mm)}$	No	I_{stiff}	r	S	$\Delta F_{(N)}$	$\Delta d_{(mm)}$
1	None	1mm	0.15	0.14	0.021	8	3.5mm	1mm	0.09	1.4	0.12
2	None	2mm	0.17	0.14	0.024	9	0.5mm	2mm	0.05	1.9	0.1
3	None	3mm	0.17	0.14	0.024	10	1.5mm	2mm	0.07	1.6	0.11
4	None	4mm	0.17	0.14	0.024	11	2.5mm	2mm	0.08	1.5	0.12
5	0.5mm	1mm	0.05	1.9	0.09	12	0.5mm	3mm	0.05	1.9	0.1
6	1.5mm	1mm	0.06	1.6	0.1	13	1.5mm	3mm	0.07	1.5	0.11
7	2.5mm	1mm	0.07	1.5	0.11	14	0.5mm	4mm	0.06	1.8	0.1

Fig. 16



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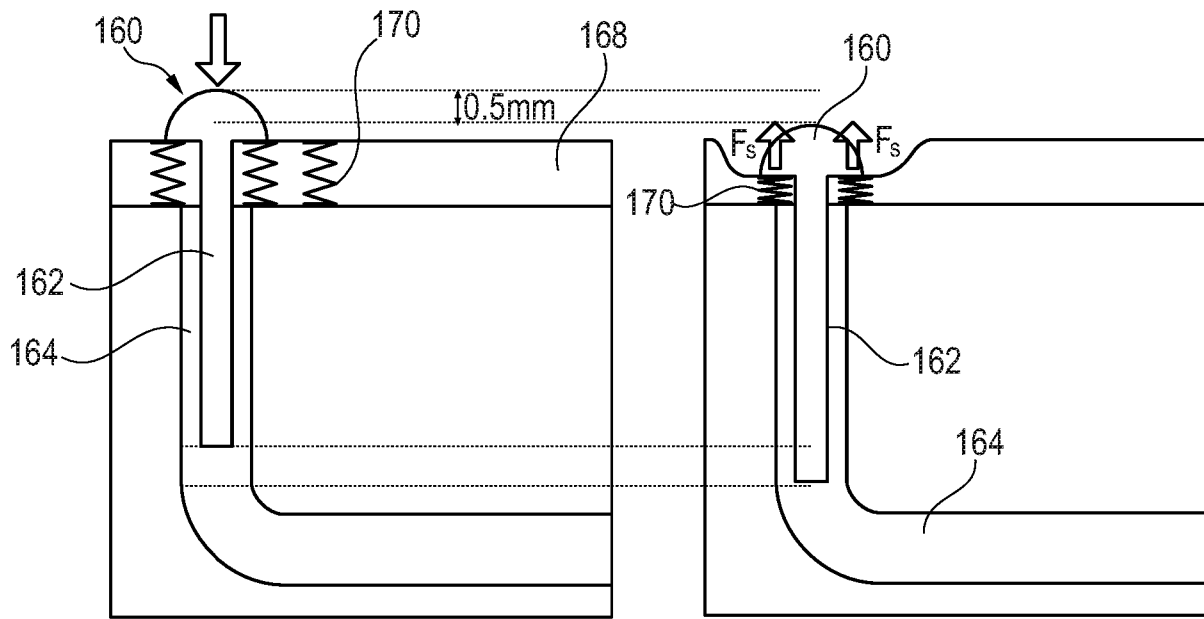


Fig. 18A

Fig. 18B

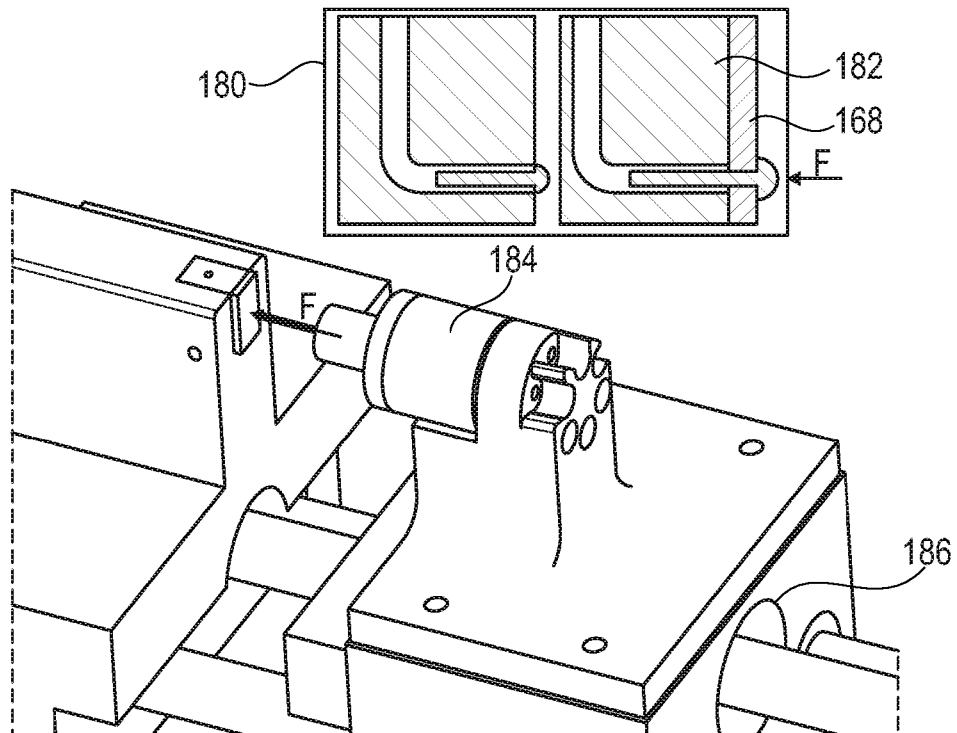


Fig. 19

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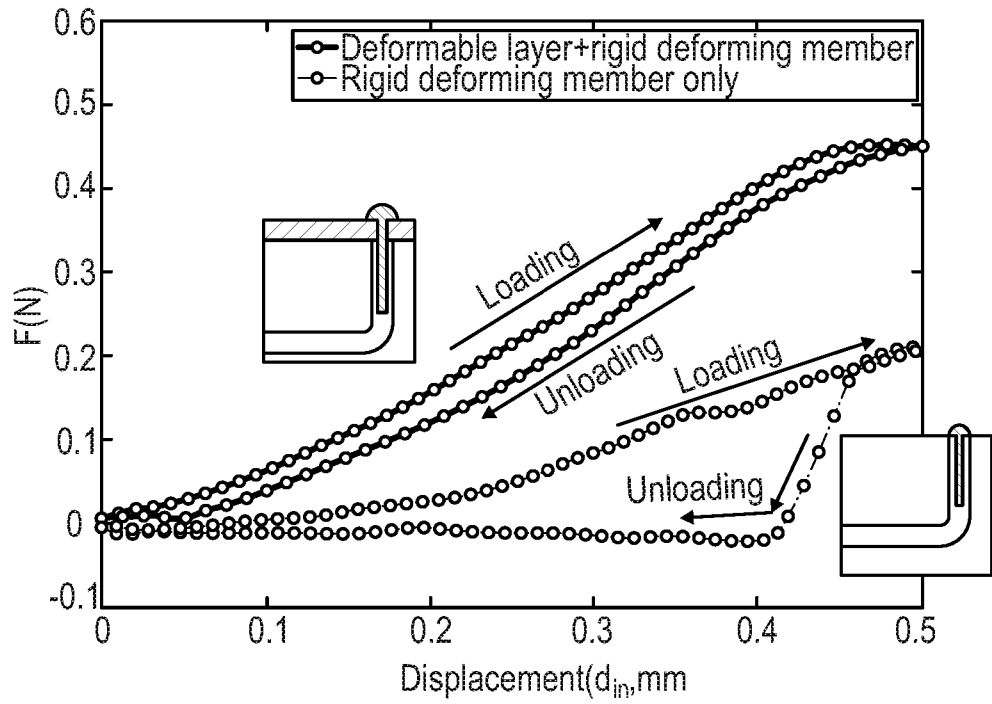


Fig. 20

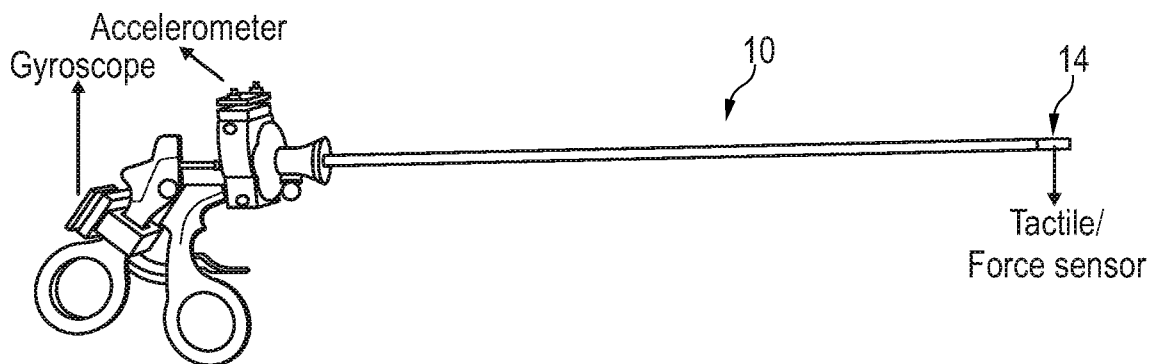


Fig. 21

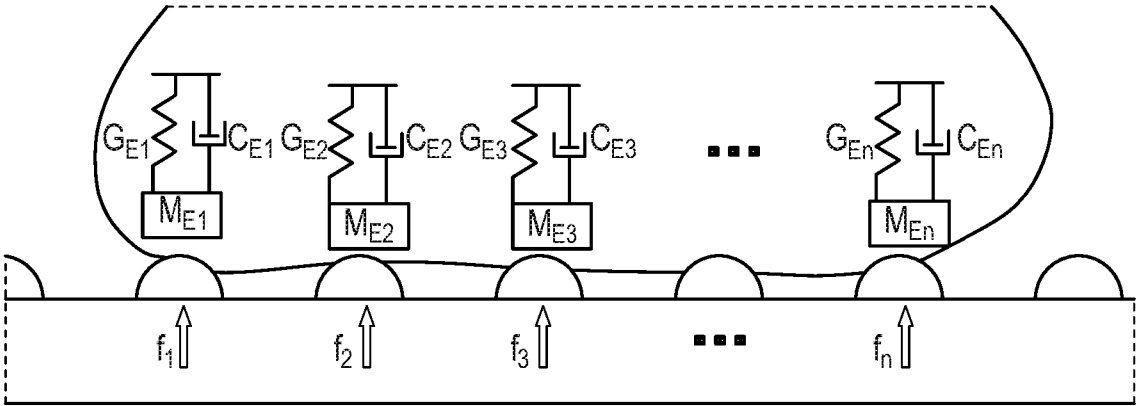


Fig. 22

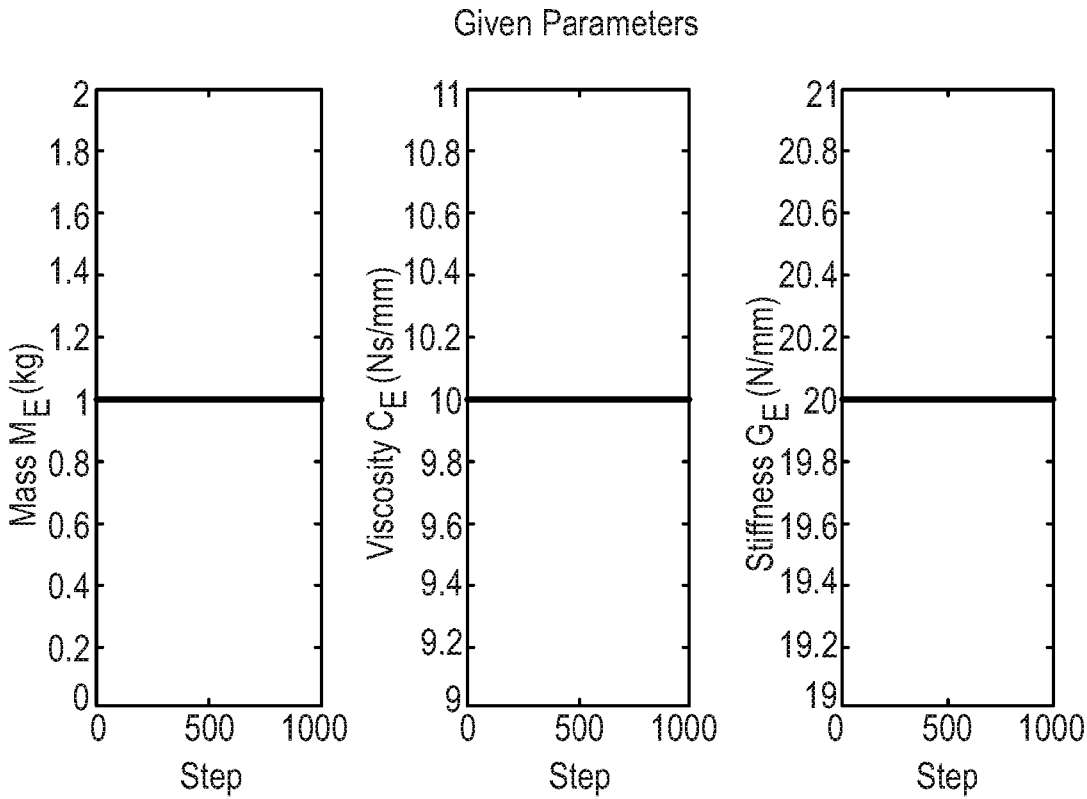


Fig. 23

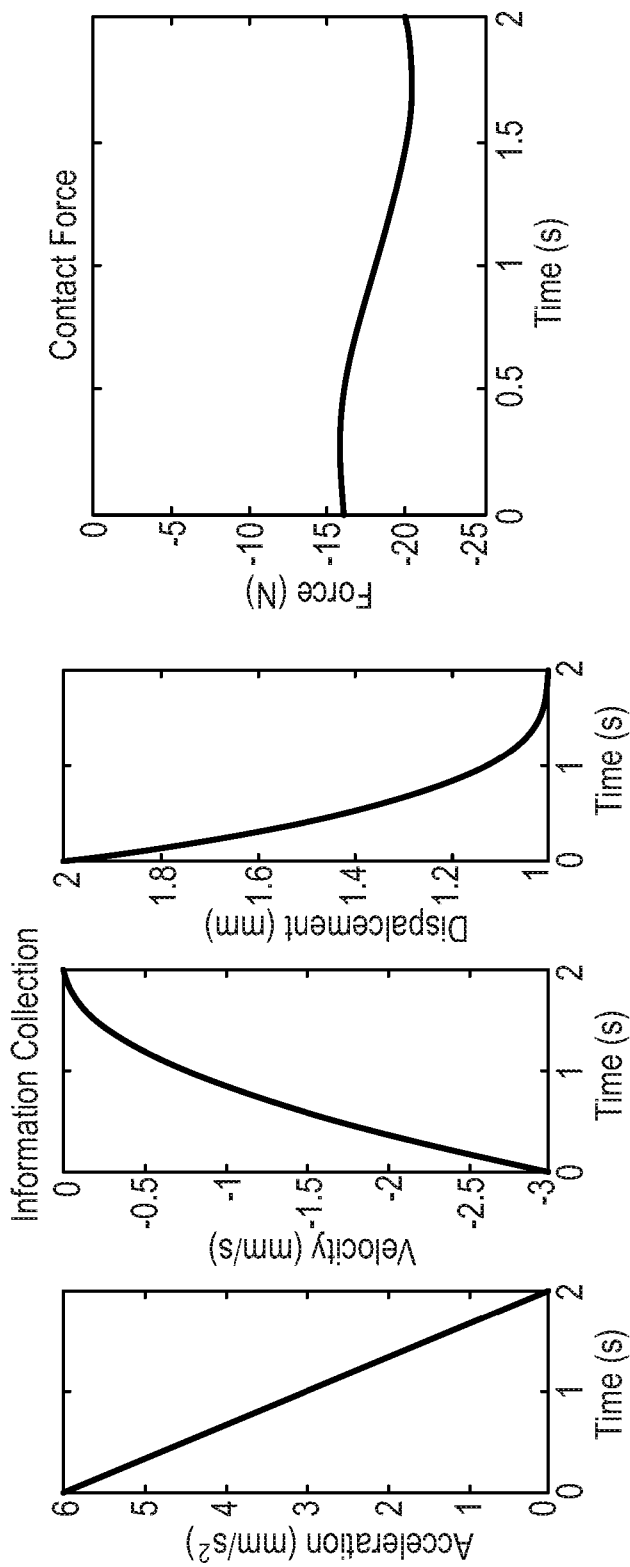


Fig. 24

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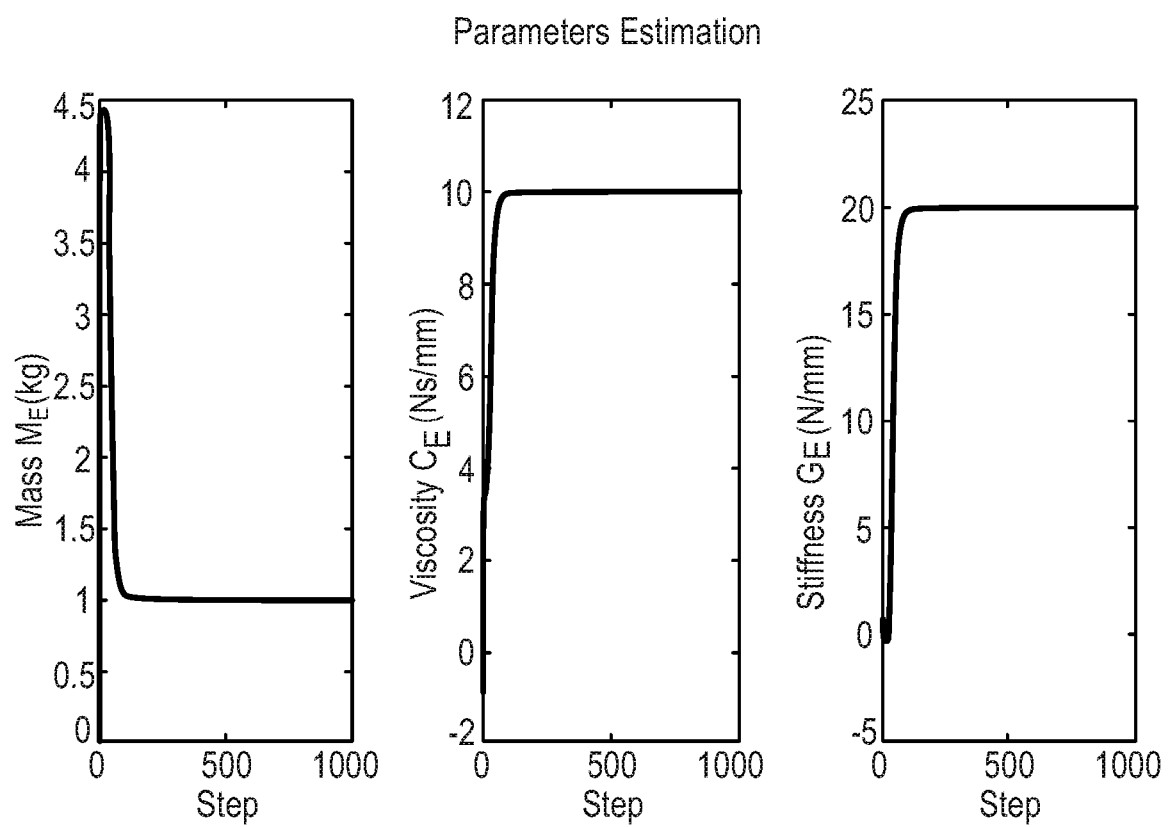


Fig. 25

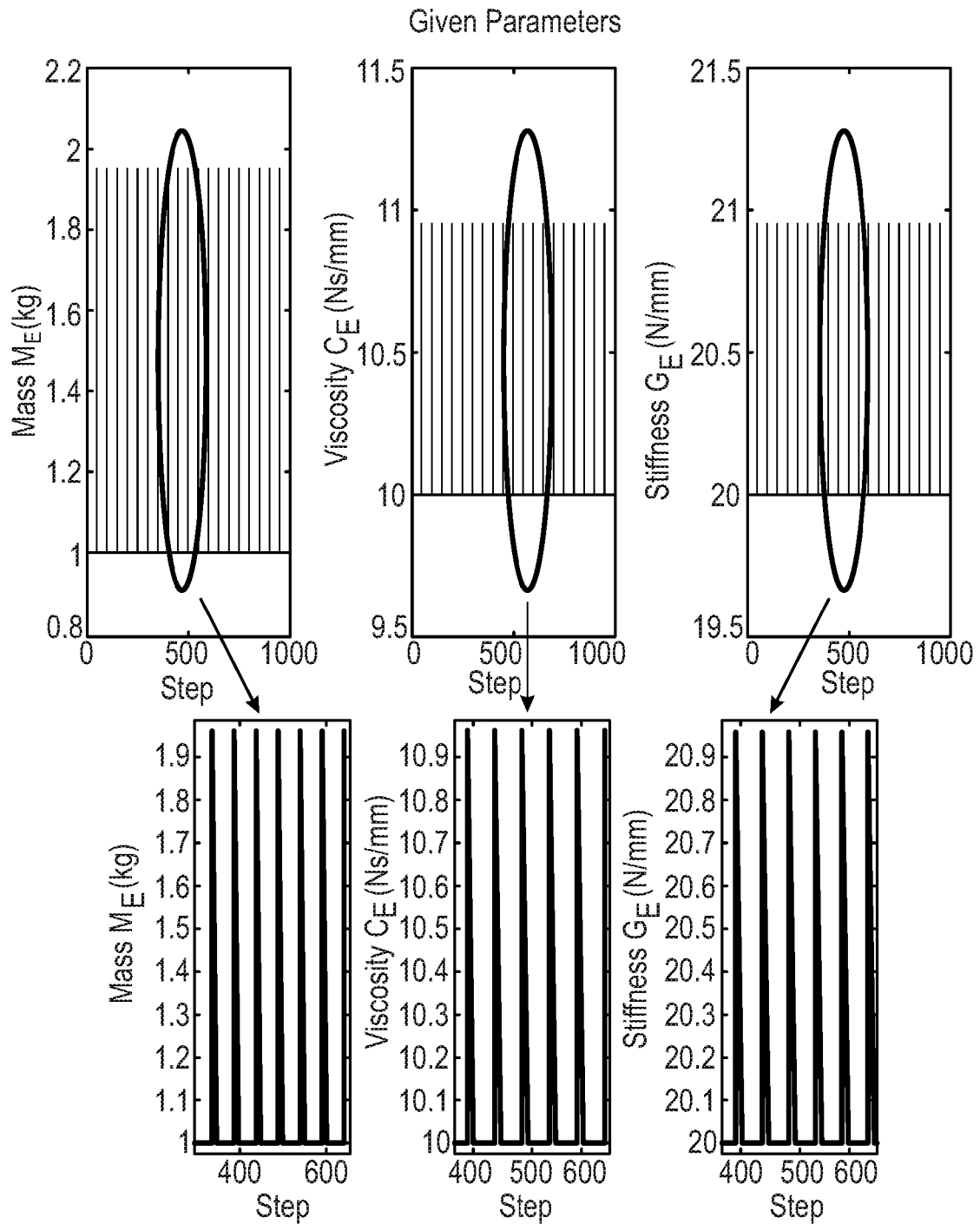


Fig. 26

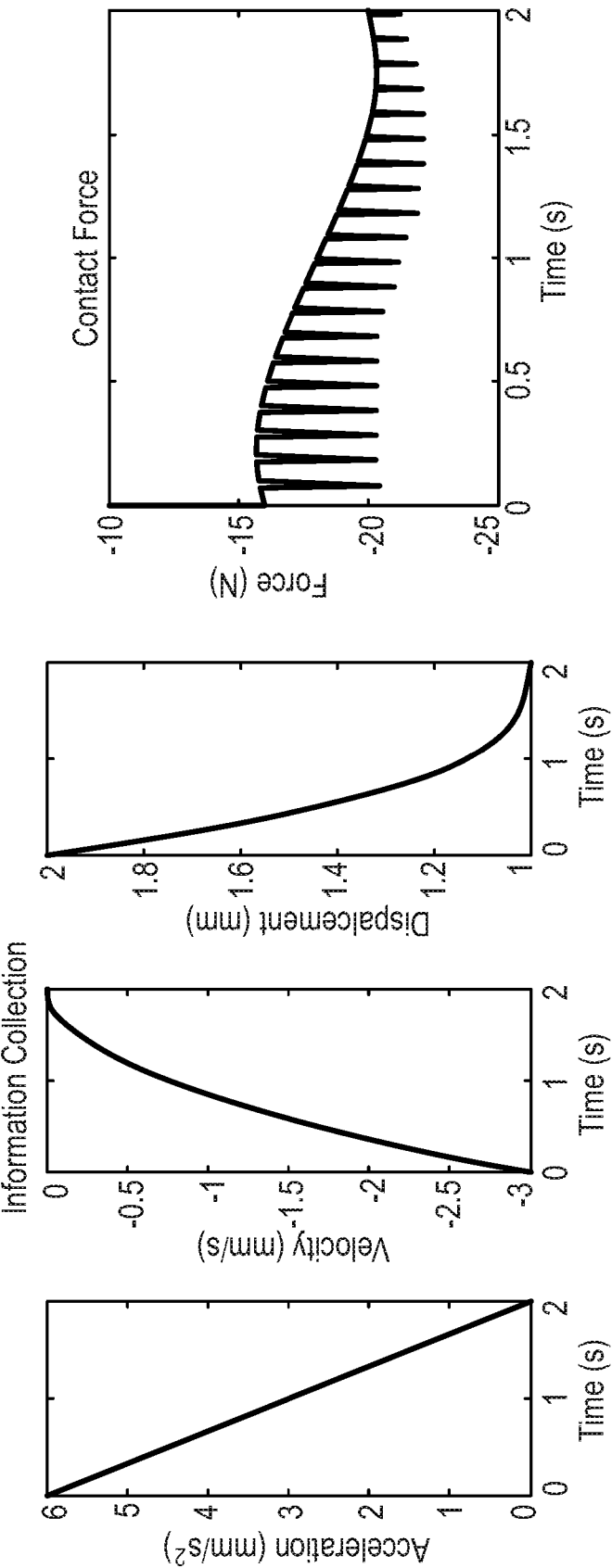


Fig. 27

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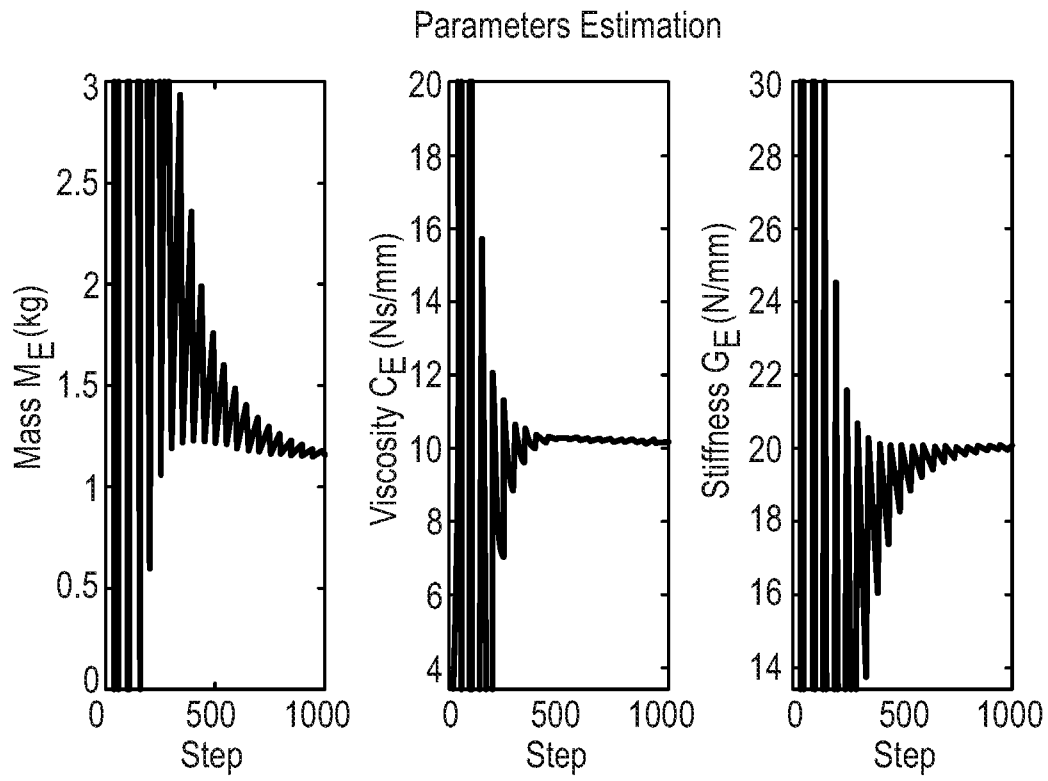


Fig. 28

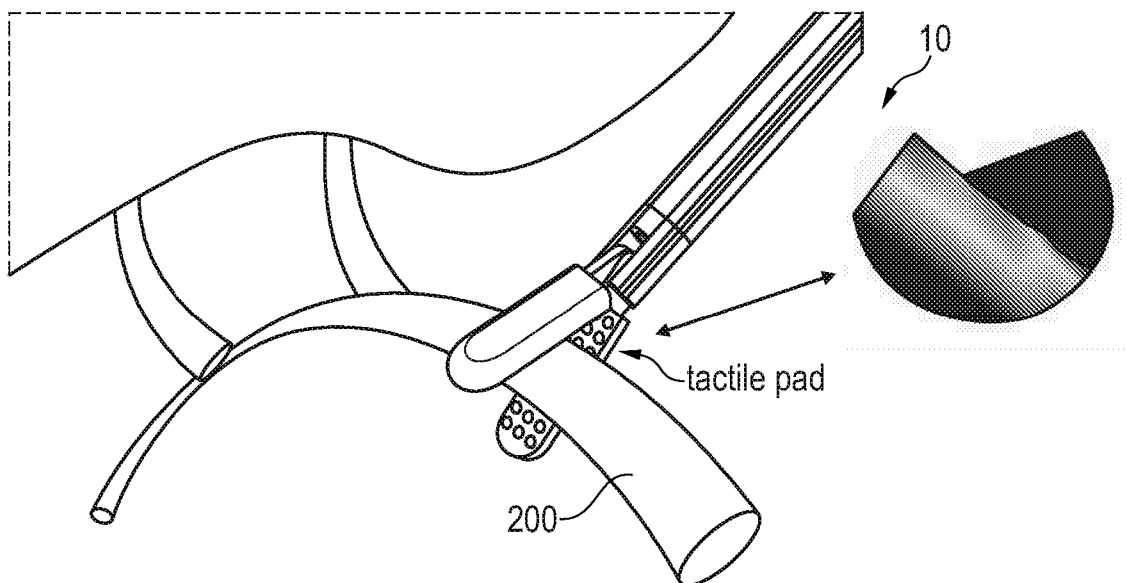
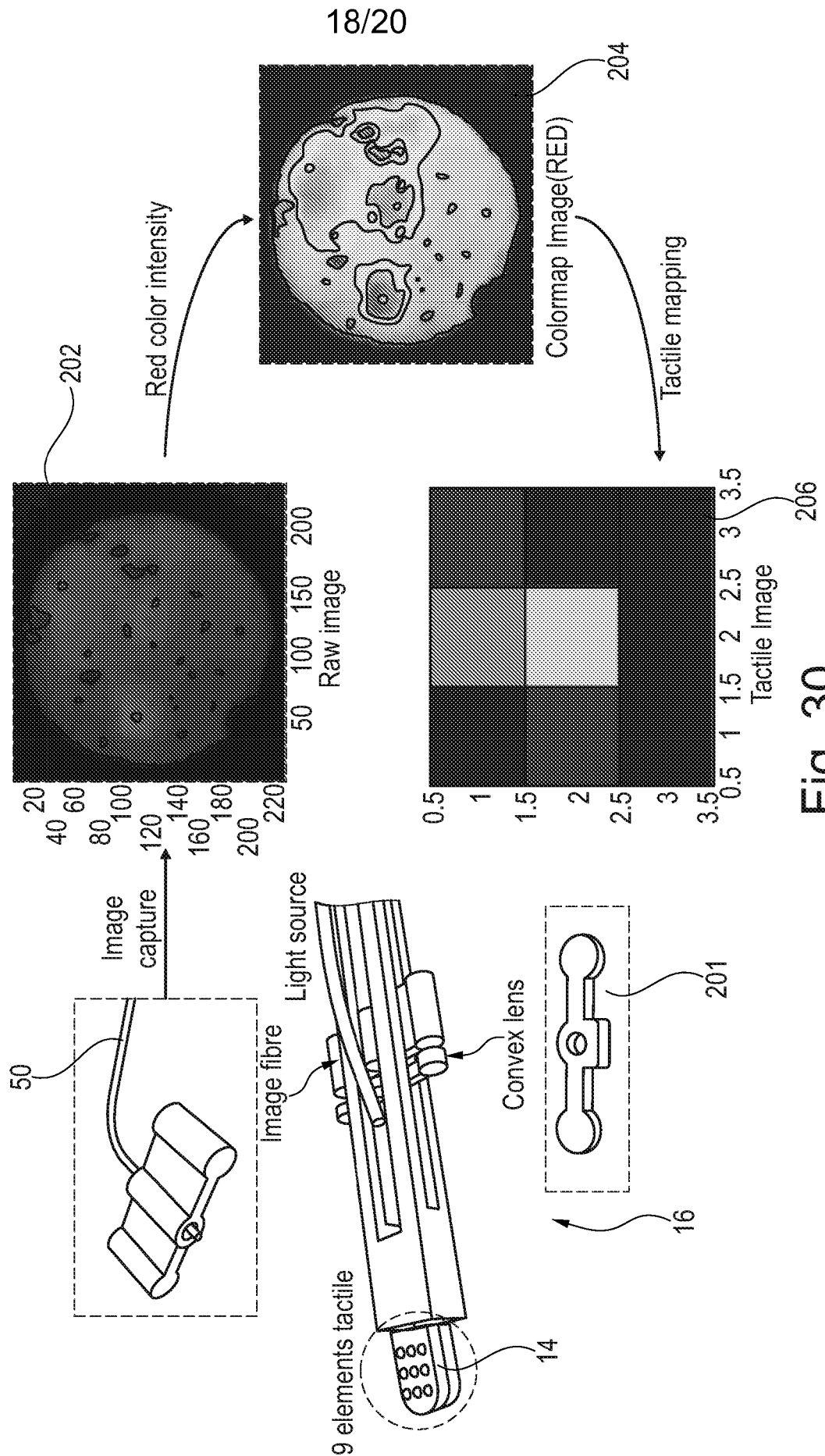


Fig. 29



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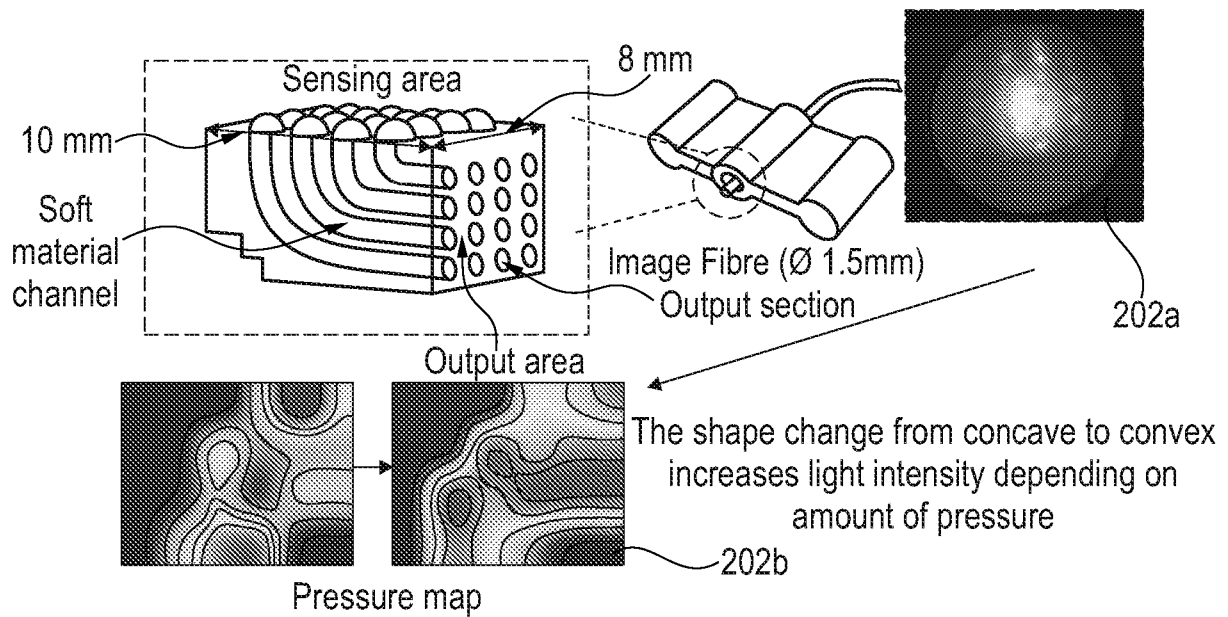


Fig. 31

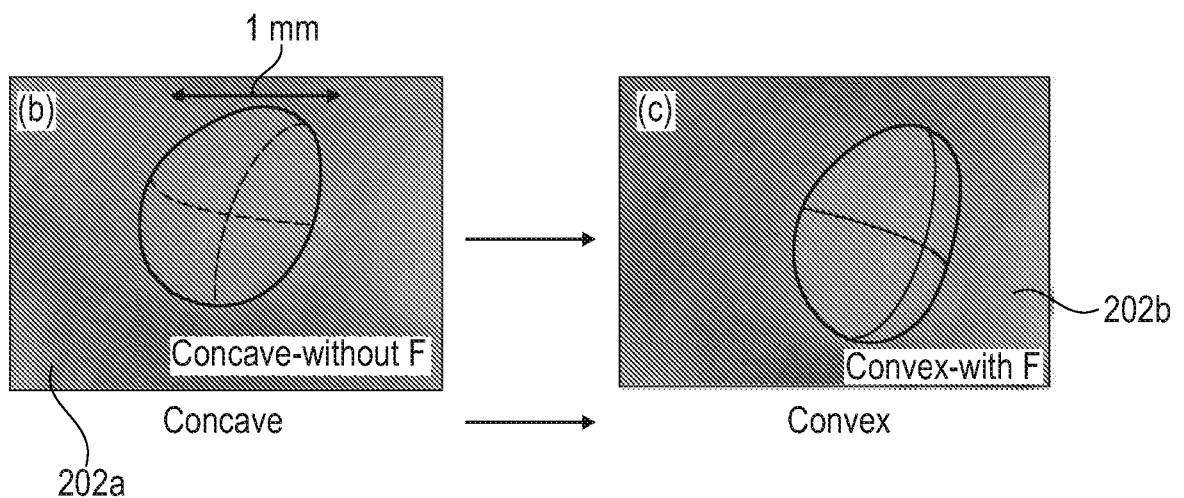


Fig. 32

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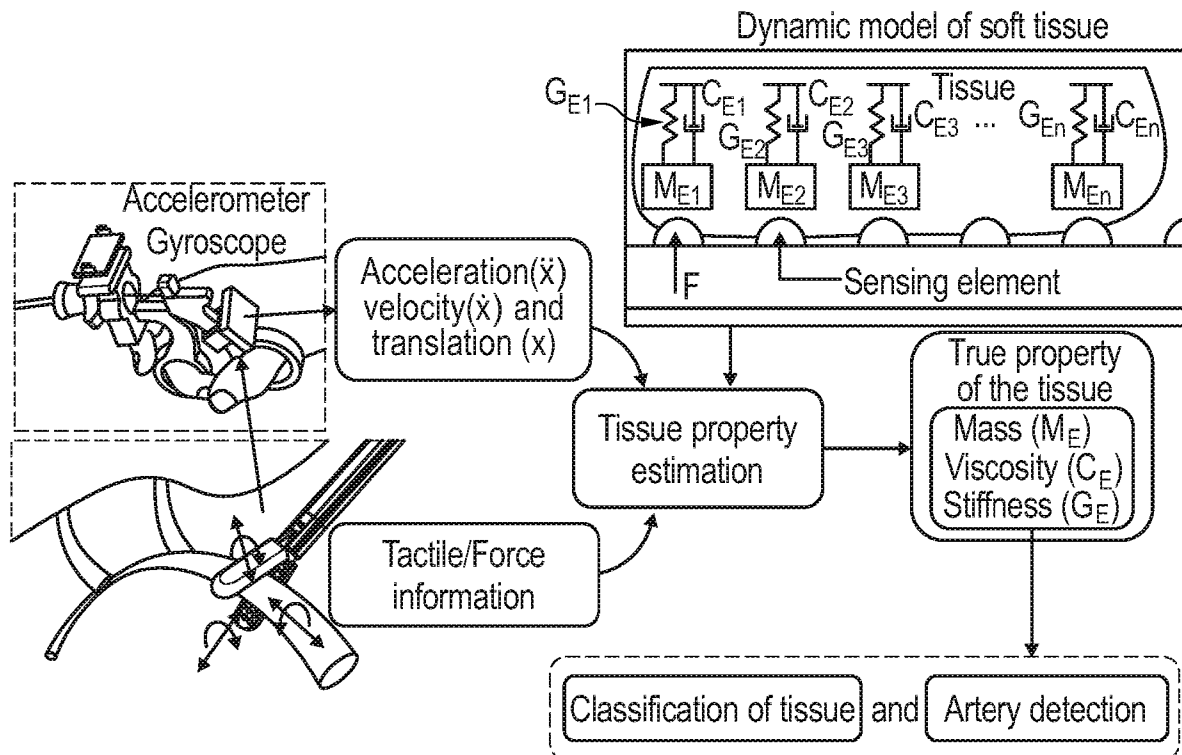


Fig. 33

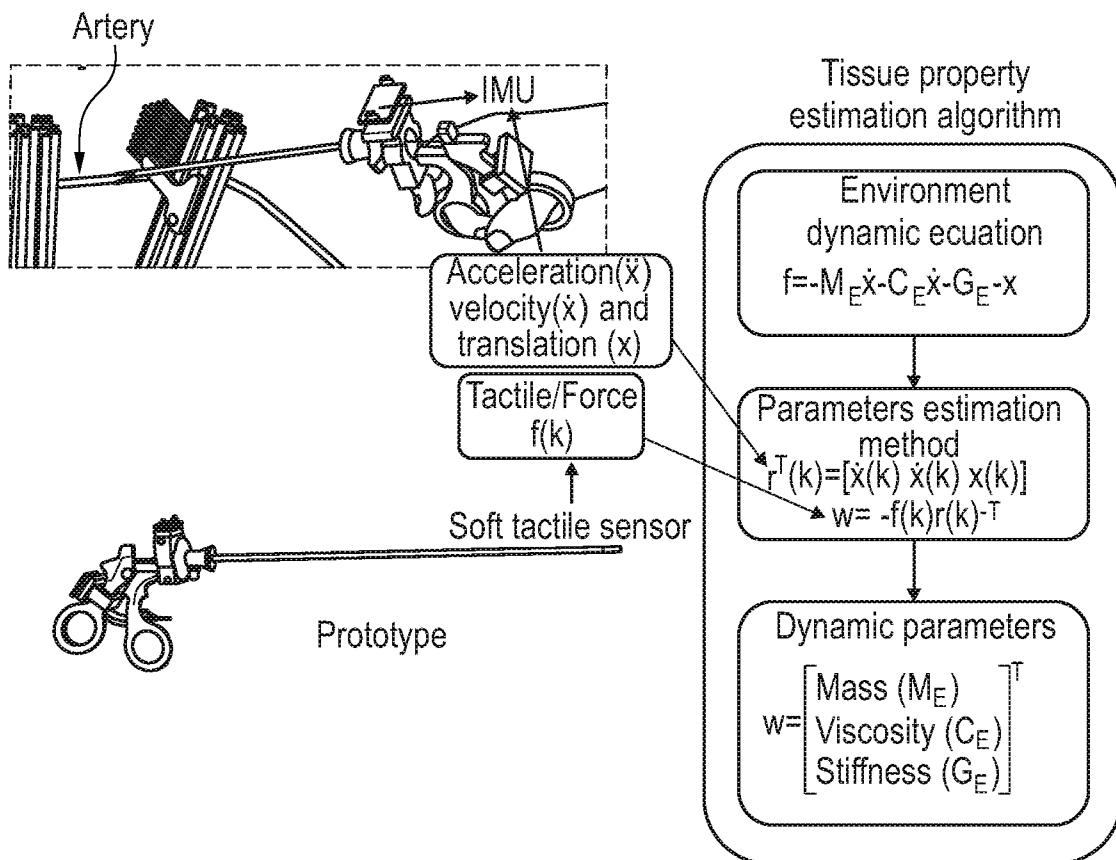


Fig. 34

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RJ/N34432-WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/GB2019/053508	International filing date (<i>day/month/year</i>) 11 December 2019 (11-12-2019)	(Earliest) Priority Date (<i>day/month/year</i>) 12 December 2018 (12-12-2018)
Applicant GUY'S AND ST. THOMAS' NHS FOUNDATION TRUST		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6**bis**(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
- ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 6
- ☐ as suggested by the applicant
- ☐ as selected by this Authority, because the applicant failed to suggest a figure
- ☒ as selected by this Authority, because this figure better characterizes the invention
- b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2019/053508

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/00 A61B5/0215 A61B17/29 A61B18/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Hui Xie: "Magnetic resonance compatible tactile force sensing using optical fibres for minimally invasive surgery", King's College London Research Portal 1 June 2014 (2014-06-01), XP055675716, Retrieved from the Internet: URL:https://core.ac.uk/download/pdf/83947297.pdf [retrieved on 2017-11-06] page 3 - page 4 page 50 - page 107 page 141 - page 145 figures 3-5,3-6,4-1,4-4 ----- -/-	1-13,22



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

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

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

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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

11 March 2020

Date of mailing of the international search report

18/03/2020

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Van der Haegen, D

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2019/053508

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007/078484 A1 (TALARICO JOSEPH [US] ET AL) 5 April 2007 (2007-04-05) paragraph [0005] - paragraph [0006] paragraph [0029] - paragraph [0032] paragraph [0043] paragraph [0045] -----	1,13, 16-19, 21,22
A	WO 2012/055024 A1 (VALORBEC SOC EN COMMANDITE [CA]; PACKIRISAMY MUTHUKUMARAN [CA] ET AL.) 3 May 2012 (2012-05-03) abstract paragraph [0007] paragraph [0050] - paragraph [0064] paragraph [0080] figures 2,9 -----	1,13,22
A	US 5 065 010 A (KNUTE WALLACE L [US]) 12 November 1991 (1991-11-12) abstract column 2, line 46 - line 64 column 3, line 52 - column 4, line 43 figures 1,3A-B -----	1,13,22
A	WO 2010/149651 A1 (IMEC [BE]; UNIV GENT [BE] ET AL.) 29 December 2010 (2010-12-29) abstract page 3, line 15 - line 23 page 4, line 29 - page 5, line 3 figure 1 -----	1,13,22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2019/053508

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007078484	A1	05-04-2007	NONE
WO 2012055024	A1	03-05-2012	US 2013220032 A1 29-08-2013 US 2016265989 A1 15-09-2016 WO 2012055024 A1 03-05-2012
US 5065010	A	12-11-1991	NONE
WO 2010149651	A1	29-12-2010	EP 2446238 A1 02-05-2012 US 2012160031 A1 28-06-2012 WO 2010149651 A1 29-12-2010