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(71) Applicants (for all designated States except US):
AGENCY FOR SCIENCE TECHNOLOGY AND RESEARCH [SG/SG]; 20 Biopolis Way, #07-01, Centros, Singapore 138668 (SG). NATIONAL UNIVERSITY OF SINGAPORE [SG/SG]; 10 Kent Ridge Crescent, Singapore 119260 (SG).

(72) Inventors; and

(75) Inventors/Applicants (for US only): KHATIB, Oussama [US/US]; 616 Forest Ave., Palo Alto, CA 94301 (US). MA, Xin [CN/SG]; Blk 702 West Coast Road, #11-371,

Singapore 120702 (SG). NOWINSKI, Wieslaw, Lucjan [PL/SG]; 111 Clementi Road #10-06, NUS Kent Vale, Blk C, Singapore 129792 (SG). ANG, Marcelo Jr Huibonhoa [PH/SG]; Block 1E, Gilman Height #17-42, Singapore 104001 (SG). CHUI, Chee Kong [SG/SG]; Block 325 Yishun Central #12-373, Singapore 760325 (SG). LI, Zi Rui [CN/SG]; Blk 6 Holland Close #12-16, Singapore 271006 (SG).

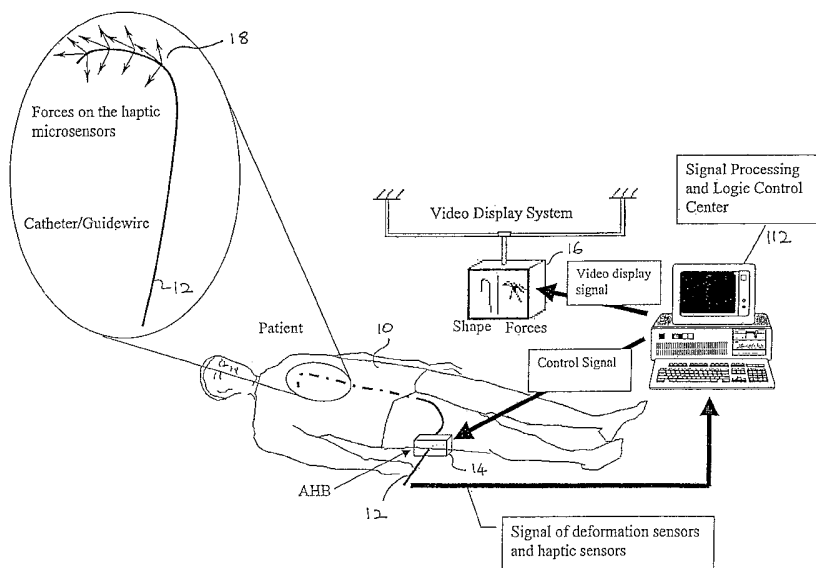
(74) Agent: POH, Chee Kian, Daniel; Lloyd Wise, Tanjong Pagar, P.O. Box 636, Singapore 910816 (SG).

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(54) Title: APPARATUS FOR MEDICAL AND/OR SIMULATION PROCEDURES



(57) Abstract: In a preferred embodiment, medical apparatus comprising a catheter (12) which operable to be inserted into a human subject (10) is disclosed herein. Haptic sensors (22, 24) and deformation sensors (26, 27) are connected to the catheter (12) and these are disposed at a plurality of locations along the length of the catheter (12). The haptic sensors measures 3D forces (18) acting on the catheter (12) at the disposed locations and these forces are provided to a haptic feedback device (14) which provides haptic feedback to, an interventional radiologist. The deformation sensors (26, 27) on the other hand, measures the deformation of the catheter (12) at the disposed locations and this information determines the shape of the catheter (12) which is represented on a display (16) for viewing by the radiologist.

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APPARATUS FOR MEDICAL AND/OR SIMULATION PROCEDURESBACKGROUND AND FIELD OF THE INVENTION

5 This invention relates to apparatus for medical and/or simulation procedures for interventional medicine.

In invasive medical procedures such as interventional radiology, interventional cardiology and interventional neuroradiology, an interventional medical specialist
10 (radiologist, cardiologist or neuroradiologist) needs to place a catheter at a target site in a patient by introducing the catheter through a blood vessel. Diagnostic images of the patient are taken before a procedure to provide the specialist with images of the blood vessel's structure. During the intervention procedure, the specialist relies mainly on the X-ray images and hand and eye coordination to navigate and position the catheter at the
15 target site and the procedure requires considerable skill and the development of haptic "feel", which comes with experience, so that the specialist can interpret feedback through the catheter to the specialist's hand of resistance to movement for example, that might be an indication of an obstruction and/or pressure being applied by the tip of the catheter to the blood vessel which might lead to the blood vessel being ruptured. To
20 avoid rupturing the blood vessel, when there is an indication of an obstruction, the specialist usually takes more X-ray images to ascertain the structure of the blood vessel and thus the patient and interventional staff are subjected to more radiation, which should be avoided.

It is an object of the invention to provide medical apparatus which can assist the specialist in such a procedure.

It is another object of the invention to provide medical apparatus which can be used in a
5 simulation procedure for training of such specialists.

SUMMARY OF THE INVENTION

In a first aspect of the invention, there is provided medical apparatus comprising an
10 elongate intervention device being operable to be inserted into a human or animal subject, and at least one force-measuring sensor connected to the intervention device and disposed at at least one location along the intervention device; the at least one force-measuring sensor being arranged to measure 3-D forces acting on the intervention device at the disposed locations.

15

Preferably, a force-measuring sensor is disposed near or at the insertion end of the intervention device. This measures the force acting on the tip of the device as the device is inserted into the subject and manoeuvred to the target site.

20 Preferably, a plurality of force measuring sensors is provided and disposed at different locations along the intervention device. The force-measuring sensors may be disposed at intervals, which may be uniform, along the whole or a part of the length of the intervention device. At each location, a plurality of coplanar sensors may be provided.

Each of these sensors measures the friction force between the intervention device and vascular walls of the human subject.

Preferably, the medical apparatus further comprises at least one deformation sensor
5 connected to the intervention device and disposed at at least one location along the
length for measuring the deformation of the intervention device at the disposed location.
The deformation information can be used to determine the shape of the intervention
device. Similar to the force-measuring sensors, at each location a plurality of coplanar
sensors may be provided.

10

Preferably, the deformation sensors and the force-measuring sensors are interleaved at
intervals with each other along the length direction of the intervention device. The
sensors may be interleaved at uniform intervals. The deformation sensors may be fibre
optic sensors and the force-measuring sensors may be haptic sensors. If the intervention
15 device is a catheter, then the sensors are connected to the catheter. Alternatively, the
intervention device may be a guide wire for a catheter and the sensors are connected to
the guide wire.

In a second aspect of the invention there is provided medical apparatus comprising
20 an elongate intervention device being operable to be inserted into a human or animal
subject; and at least one deformation sensor connected to the intervention device and
disposed at at least one location along the length direction of the intervention device, the
at least one deformation sensor being arranged to measure the deformation of the

intervention device at the disposed location. The deformation information can be used to determine the shape of the intervention device.

The apparatus is preferably connected to a processing means which determines, from
5 the sensors, details of the shape of and/or forces on the catheter/lead wire and displays the details and/or provides haptic feedback to the specialist. The processing means may further comprise means for displaying the shape of the intervention device.

According to a third aspect of the invention, there is provided haptic feedback apparatus
10 comprising force application means arranged to apply a force to an elongate intervention device, control means arranged to control the force applied to the intervention device by the force application means, the control means being connected to at least one sensor arranged to sense a remote force on the intervention device and the control means being arranged to calculate the applied force in accordance with the
15 remote force, the applied force being an amplification of the remote force.

Preferably, the force application means applies both an axial and a radial force to the catheter. The force application means may comprise a resilient member arranged to apply the said force to the intervention device. Preferably, the haptic feedback apparatus
20 further comprises a sensor arranged to detect frictional force between the resilient member and the intervention device. The detected frictional force may then be used to control the amount of applied force.

Preferably, the haptic feedback apparatus further comprises means for tracking the rotational and/or linear movement of the intervention device. Specifically, the tracking means may be in the form of a wheeled encoder.

- 5 The haptic feedback apparatus may further comprise means for comparing the remote force with a reference force. This may be used for training purposes under simulation environment since the comparison can be used to determine the catheterisation skills of an interventional radiologist. For example, if the reference force is the force that will rupture a blood vessel and if the detected remote force is more than the reference force,
- 10 this would mean that the radiologist would have ruptured a blood vessel if the procedure is real. In this case, the intervention device may be operable to be inserted into a simulated human model and the remote force may be generated using computer simulation.
- 15 Alternatively, in a real procedure, the intervention device is operable to be inserted into a human subject.

The at least one sensor may be disposed near or at a tip of the intervention device. Preferably, the control means is connected to a plurality of sensors disposed along the

20 length of the intervention device.

This invention also includes a method of using the medical apparatus in accordance with the first aspect and/or the second aspect of the invention and/or the haptic feedback apparatus in an interventional or simulated interventional procedure.

The described embodiment is for particular use in augmented interventional radiology in which an interventional device such as the catheter passes first through the haptic feedback apparatus and then is inserted into a blood vessel of a patient in a traditional way. The sensors transmit the signals back to the apparatus which magnifies the forces accordingly. This increases the accuracy of the interventional procedure. Furthermore, the force and other sensed information can be processed such that the tip of the catheter can be displayed in real time with respect to the blood vessel so that direction of the catheter's tip can be monitored. The described embodiment of the invention is also applicable as an interventional radiology simulator in which the forces from the sensors can be calculated from a physical and realistic model when using an interventional radiological simulator. The apparatus can then receive control signals based on the simulation for training purposes and to understand catheter-blood vessel interaction. In addition, information about the shape and location of the catheter can be used to guide model-data registration.

These approaches both real and simulated are also applicable for remote operations.

The actions of an interventional radiologist or other specialists can be also be measured by the sensors and compared to standard actions, for skill assessments and similarly a simulation system can be validated by measuring forces and torques produced by it in comparison to real life data.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings in which:

5

Figure 1 is a schematic overview of an interventional radiological procedure using the embodiment of the invention;

Figure 2a illustrates a catheter assembly with sensors applied to the catheter with Figure 2b illustrating a guide wire for a catheter including a plurality of sensors;

10

Figure 2c illustrates a method of embedding a sensor to an external wall and of a catheter;

Figure 2d illustrates a sensor being mounted at a tip of the catheter;

Figure 2e illustrates a sensor being mounted at a tip of the guide wire;

Figure 3 illustrates the forces on a catheter as this is fed through a blood vessel;

15

Figure 4 is a schematic diagram of a haptic feedback apparatus;

Figure 5 and Figure 6 illustrate the forces on a catheter, used in calculation of control signals for the haptic feedback apparatus of Fig. 4;

Figure 7 illustrates a detailed block diagram of a signal processing and logic control center;

20

Figure 8 illustrates a deformation sensor in the form of a microgyroscope;

Figure 9 shows a side view of the microgyroscope of Figure 8 mounted on a glass substrate;

Figure 10 is a block diagram depicting a processing circuit connected to the microgyroscope of Figure 8;

Figure 11 depicts how micro-wires are used to transmit signals from the sensors attached to the catheter of Figure 2a to a signal processing and logic control unit for further processing;

Figure 12 illustrates a feedback loop used in the haptic feedback apparatus of
5 Figure 4;

Figure 13 shows how detection of the constraint forces in the catheter determines the shape of a catheter;

Figure 14 is a block diagram depicting an overview of the different components of the first embodiment of the invention; and

10 Figure 15 illustrates a variation of one of the sensors of Figure 2.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to Fig. 1, a general overview of an interventional radiology procedure
15 using an embodiment of the invention is illustrated. In such a procedure an interventional radiologist (a specialist medical doctor) inserts an elongate intervention device 12 such as a catheter 20, which at the entry stage is provided with a guide wire (not shown) to give the intervention device 12 a more solid structure, into a blood vessel of the patient and the device 12 is threaded through the vessel to a treatment location in
20 the patient's body 10. The intervention device 12 is passed through a haptic feedback device 14 before entry to the patient 10. The intervention device 12 is of a special form being provided with a plurality of force sensors along its length which sense forces acting thereon. These sensors are connected to a control processor forming part of the haptic feedback device 14 which controls the operations of the device 14 and also sends

data to a display 16 upon which the shape of the intervention device 12 in the patient's body and forces on the intervention device 12 can be displayed. The forces measured by the sensors are schematically illustrated in Fig. 1 by three orthogonal force vectors 18 at the locations of the sensors.

5

Two variations of an intervention device 12 in the form of a catheter 20 and a guide wire 30 are shown in Figs. 2a and 2b respectively. In Fig. 2a, a catheter 20 is shown in which a plurality of haptic sensors 22, 24 are embedded in the catheter wall 23. Haptic sensors 22, 24 are of the same type with four such sensors being equi-angularly
10 disposed in the same radial plane of the catheter 20 at intervals D of preferably 5 mm, so that each sensor 22,24 can sense three dimensional forces on the catheter 20 at that location and feedback these sensory values to the radiologist via hair-thin cables to the distal end of the catheter 20 and to the haptic feedback device 14 which acquires the data.

15

The second type of sensors embedded in the walls of the catheter 20 or the guide wire 30 are a plurality of deformation sensors in the form of fibre optic sensors 26,27. These deformation sensors 26,27 are disposed in the same manner as the haptic sensors 22,24 but are positioned in different radial planes so that these deformation sensors 26,27 are
20 interleaved between the haptic sensors 22,24 as shown in Figure 2a. Preferably, if the distance D between two sets of haptic sensors is 5mm, then the distance between a haptic sensor 22,24 and a deformation sensor 26,27 is 2.5mm. These deformation sensors 26,27 detect the orientation or shape of the catheter 20 so that an interventional radiologist could more intuitively navigate the catheter 20 in a human body. When the

detected shape of the catheter 20 is displayed, this allows the radiologist to monitor the direction of movement of the catheter 20 as the catheter 20 is being manoeuvred in the human body.

5 A second variation of an intervention device is shown in Fig. 2b. As noted with reference to Fig. 1, the catheter 20 when inserted may be provided with a guide wire 30 and the haptic and deformation sensors 22,24,26,27 shown in Fig. 2a can be disposed on the guide wire instead of in the catheter 20. A guide wire 30 is shown in Fig. 2b which is generally made of plastic or suitable metal and has a flexible body for steerability and
10 is provided with haptic sensors 22, 24 and deformation sensors 26,27 disposed on the external surface of the guide wire 30.

There are two methods of embedding or connecting the micro-sensors 22,24,26,27 to the catheter 20 (it should be apparent that the methods also apply to the guidewire) and
15 Figure 2c shows a first method [1] in which the sensors are mounted along the catheter walls. In this method, the first step is to form wiring 32 on the outer wall to carry signals picked up by the sensors to the distal end of the catheter 20 and an electrical conductive layer is first formed on the outer catheter wall by vacuum evaporation. The wiring 32 is next patterned using excimer laser processing. In this case, as shown in
20 Figure 2c, the wiring 20 is helical in shape so as to conform to the shape of the catheter 20 to enhance flexibility.

After the wiring process, the conductive layer is electroplated with copper to reduce electrical resistance. Preferably, the catheter 20 is also coated with polyurethane resin to protect the wiring against bending or abrasion.

5 To embed each sensor to the outer catheter wall, receptacles 34 and electrodes 36 are formed. Each receptacle 34 is formed using the excimer laser process for patterning the wiring 32 and electroplating technique is used to mount a sensor within the receptacle 34. The sensor is then bonded to the receptacle using adhesive agent such as polyurethane resin. The electrodes 36 are then electrically connected to the sensor's
10 leads.

Mounting the sensors and forming the receptacles, electrodes and wiring on the outer catheter walls has advantages, for example the catheter's diameter can be reduced and the catheter is more flexible when compared with locating the sensors and wiring along
15 the "lumina" of the catheter 20.

A second method [2] is for mounting a sensor near or at the catheter or guide wire's tip. Figure 2d shows side and end views of a catheter 20 with a tactile sensor 22 mounted along the rim of the catheter's tip. Figure 2e, on the other hand, illustrates side and end
20 views of a guide wire 30 with a tactile sensor being mounted at the tip of the guide wire. In both cases, wiring and electrode for connecting to the sensor's leads are formed using the process described earlier. Next, the sensor is attached to the tip of the catheter (or guide wire, as the case may be) using a suitable adhesive and silicon rubber 38 to form a

contact portion which provides good contact with the blood vessels for enhanced sensing when the catheter/guide wire is in use.

In both variations of the intervention device, the haptic sensors 22,24 are fabricated using MEMS technology such as that described in a publication "Silicon-based three axial force sensor for prosthetic applications" [3] which describes a three axial force sensor to sense normal and shear force components at a particular contact point. In the present embodiment, as shown in Figure 3, the haptic sensor 22,24 are used to detect the forces on a catheter 20 at a particular point of contact with the internal wall of a blood vessel. The force acting on the catheter 20 at location can be resolved into three force components F_x , F_y , F_z . The forces F_x and F_y are resolved in a direction tangential to the catheter with the force component F_z being orthogonal to the plane of the forces F_x , F_y . The forces F_x and F_y , in combination, represent the frictional force between the catheter and the vessel wall, and the force F_z normal to the sliding direction causes problems of direct puncturing of the vessel walls. The vector sum of these forces ($F = F_x + F_y + F_z$) at a particular contact is the friction force in the opposite direction to the motion of the catheter and is used for the calculation of the haptic feedback on the catheter.

ΣF represents summation of all the friction forces F detected by each haptic sensor 22,24 along the body of the catheter/guide wire. This summation force ΣF is then processed by the Signal Processing and Logic Control Center and provided to the haptic feedback device 14 so that the effect is more readily felt by a specialist's hand. For example, if the ΣF is 5N and this force is augmented five times to 25N (denoted as F'),

this means that 25N of force will be fed back to the radiologist's hand. In this way, the force sensors can thus detect the force components and to provide tactile feedback based on piezoresistive effect. The operation of the haptic feedback device 14 will be described in more detail below.

5

Fiber optic sensors 26,27 are suitable for use as deformation sensors because of their high resolution, accuracy and immunity to electromagnetic interference. In this embodiment, fiber optic tactile-based microgyroscopes are used as deformation sensors and Figure 8 shows an example of a "comb-drive single mass" microgyroscope 90. The microgyroscope 90 comprises a resonator 92 (proof mass) made of silicon and
10 suspended by four flexures or beams 94 as shown in Figure 9. The resonator 92 is driven by electrostatic forces generated by DC and AC bias voltages across comb actuators 96 coupled to the resonator 92. When the suspended resonator 92 is vibrating, angular rate around the y-axis induces Coriolis force F_c which is proportional to the
15 proof mass "m", the vibration velocity "v" and the angular rate. This Coriolis force F_c causes the proof mass (resonator) to vibrate in the z direction.

To set up the microgyroscope 90 as a deformation sensor 26,27, the four beams 94 are anchored on a glass substrate 98 and Figure 9 shows a cross-sectional view of this
20 arrangement. The glass substrate 98 is then supported by two fiber alignment structures, preferably made of silicon. An optical fiber 102 with a suitable diameter such as 50/125 μm (core/clad) is communicatively coupled to the glass substrate 98 via a fiber optic coupler 104 - fused coupler, split ratio 1:1 (not shown).

The sensing method [4] used is modulation of the light intensity since intensity of the light source changes due to the vibration of the resonator 92 located in front of the glass substrate 98 which also acts as a “fiber stopper”. This means the resonator 92 acts like a mirror reflecting the light source that is beamed to the resonator’s underside and the reflected light is processed to obtain perturbation experienced by the resonator 92. Accordingly, the fiber optic coupler 104 needs to re-transmit the light to the resonator 92 and also receive back the reflected light.

Figure 10 is a schematic diagram showing how the reflected signal is being processed thereafter. A light source 106 such as a LED is used to provide a light beam 106a through the optical fiber 102 and to a receive port of the fiber optic coupler 104. The fiber optic coupler re-transmits the light 106a to the resonator 92 which is vibrating. The light reflected by the resonator 92 at a particular intensity in response to the vibration is transmitted back through the fiber optic coupler 104 to a detector 108 connected to the other output port of the fiber optic coupler 104. In this example, a photodiode 108 is used as the detection means to detect the light level since we are concerned with the intensity of the reflected light. A photodiode reference 109 may also be derived from the coupler 104 which can be used for calibration of the resonator 92. The detected signal level is processed by the Signal Processing and Logic Control Center 112 and this includes a Signal Conditioning Circuitry 112a which comprises filtering and amplification circuits. The conditioning circuitry 112a filters unwanted noise from the detected signal level and, if need be, amplifies the signal so that the detected signal is suitable for acquisition by the Data Acquisition Unit 112b. This unit can use normal data acquisition circuits available off the shelf such as that from National Instruments.

The acquired data is then provided to a computing unit 112c for translating the data into amount of displacement of the resonator 92. As mentioned earlier, there is a plurality of deformation sensors 26,27 disposed along the length of the catheter 20 and
5 displacement information from these sensors 26,27 provide the shape of the catheter 20. As shown in Figure 11, when the displacement information of three of the deformation sensors 26,27 are obtained, the Signal Processing and Logic Center 112 can use known mathematical tools such as line segmentation, circle segmentation or splines (requires displacement information of at least four points), to determine the shape of the catheter
10 20.

After obtaining the shape information, a real-time graphics representation of the catheter 20 can be displayed on a monitor, for example, using one of several known graphics display rendering methods such as centerline model, wireframe model, surface rendered
15 model or volume rendered model.

In this way, the fiber optic sensors 26,27 disposed along the length of the catheter 20 provide local deformation information which is used to determine and display the shape of the catheter. This is represented schematically in Figure 14. This allows the
20 radiologist to observe the orientation of the catheter 20 in the event that the tip of the catheter 20 bends backwards which causes the catheter to move in the opposite direction. Without the shape information, it may not be possible to detect this scenario if the radiologist does not feel any obstruction when inserting the catheter 20.

In addition, the radiologist when manoeuvring the catheter 20 will be able to monitor the orientation (shape) of the catheter 20 when, for example, the catheter 20 turns left or right branching into an auxiliary blood vessel, and thus the interventional specialist can observe this through a tactile video display 16 (See Figure 1).

5

Wiring formed on the outer catheter walls transmit signals (detected forces) picked up by the sensors 22,24,26,27 for further processing to the Signal Processing and Logic Control Centre 112.. Alternatively, in the case of the fiber optic microgyroscope, fiber optic micro cables may be used to carry such information from the catheter 20. Figure

10 11 shows a simplified sensor arrangement in a catheter which has two haptic sensors 22,24 and three deformation sensors 26,27 disposed along a particular length. To send signals from the sensor locations to the signal conditioning circuitry or directly to the logic and control center 112, each sensor is provided with a wire or cable. In this case, there is a total of six wires/cables with an additional wire for a ground signal.

15

Having described the deformation sensors 26,27 in detail, the haptic sensors 22,24 will now be described together with how the remote forces detected by the sensors 22,23 are felt by the radiologist.

20 In Figs. 2a and 2b, only a small section of the catheter/guide wire is shown but in practice the sensors 22, 24 (or 32, 34) will be repeated along the length of the catheter 20 to provide force information along the whole length of the catheter 20 as this is inserted into the blood vessel of a patient. In addition, a haptic sensor (see Figure 2d) is preferably provided at the tip of the catheter 20 to detect the force at the tip of the

catheter 20 which can be used to determine the rupturing force against the wall of a blood vessel [5].

It is very important for the radiologist to be able to feel these forces since they are
5 indicative of potential damage to the blood vessel wall. However, the actual magnitude of these forces is very small and in the described embodiment the sensors are used in two ways, firstly to display the force information for the specialist's benefit (as in the deformation sensors 26,27) and also to provide augmented haptic feedback (as in the haptic sensors 22,24) so that the specialist can feel the nature of the forces more clearly.

10

To allow the specialist to feel the forces more clearly, the frictional forces F detected by the sensors are processed by the signal conditioning circuit 112a, data acquisition unit 112b and the computing unit 112c. The computing unit 112c calculates the augmented force F' and generate a signal to drive the haptic feedback device 14. This
15 also allows the radiologist to adjust the amount of amplification via the computing unit to adapt to the feel of different radiologists.

Further, the frictional forces can be transformed into images to provide a visual image/picture of forces for the radiologist to better visualise the forces. (see for
20 example, publication at http://page.inf.fu-berlin.de/~kurze/publications/chi_97/mk-hapt.htm). Thus, in addition to the haptic feel, the forces can also be displayed on a display.

The haptic feedback device 14 of Figure 1 is shown in more detail in Fig. 4. The catheter 20 (guide wire) is fed through the middle of the device 14 and several control mechanisms act on the catheter 20 to apply an augmented force on the catheter 20 as the catheter 20 passes through the body. On one side of the catheter 20 a reaction device is provided which includes a first wheeled encoder 40 connected to a shaft 42. The other end of the shaft 42 is connected to a stationary support 44 via a ball and socket joint 48. Biasing means 70 in the form of a spring is included, as shown in Figure 4, to ensure contact between the first wheeled encoder 40 and the catheter 20. The first wheeled encoder 40 is used to monitor and track the linear movement of the catheter 20. When the tip of the catheter 20 passes through the first wheeled encoder 40, an initial encoder value is initialised which corresponds to the tip of the catheter 20. When the catheter 20 advances through the haptic feedback device 14 and into the vessel, the encoder value changes which is proportionate to the amount the catheter's tip has advanced past the first wheeled encoder 40 and into the blood vessel. In this way, the length of the catheter 20 that is inserted into the human body can be calculated.

On the other side of the catheter 20 a force supplying device is provided which includes a servo motor 50 connected to a shaft 52. At the other end of the shaft 52, a gear box 54 is provided which converts the rotational motion of the shaft 52 into a translational motion towards or away from the catheter 20. The gear box 54 and the shaft 52 may be a "rack and pinion" structure to translate the rotational force of the shaft into the required translational motion. The part of the gear box 54 which engages the catheter 20 is provided with a surface 56 made of resilient material, such as rubber, to apply a

variable force normal to the catheter's length direction on the catheter 20. Other suitable surfaces may be used which provides such a resilient force.

A force sensor 57 (see Figure 12) is embedded within the surface 56 to detect the
5 amount of pressure "P" being asserted on the catheter 20. An example of such a force
sensor is a "Single Axis Force Sensor" from "Applied Robotics"
(www.arobotics.com/forcesensors.htm). Let's assume that the contact between the
catheter 20 and the surface 56 creates a friction coefficient of "k". A friction force "f"
acting on the catheter 20 is then calculated as " $f = kP$ ". In this way, it is possible to
10 detect the amount of force that is to be applied on the catheter 20. However, to control
this force "f" (applied by the servo motor 50) in relation to the augmented force F' (as
derived from the sensors 22,24 embedded in the catheter wall) a feedback loop can be
used and an example of which is shown in Figure 12.

15 As mentioned earlier, the augmented force F' is provided by the computing unit 112c of
the Signal Processing and Logic Control Center 112 and in this embodiment since a
servo motor 50 is used to drive the shaft 52, the augmented force F' may be in the form
of a square wave to control the servo motor 50. It is apparent that this can be realised in
a number of ways.

20

If the augmented force $F' > f$, a servo motor amplifier 114 increases the amount of
voltage V to the servo motor 50 to drive the gear box 54 so that the friction force "f"
applied on the catheter 20 increases. The increased in friction force "f" acts on the
catheter 20 to resist the advance of the catheter 20 and thus the radiologist experiences

increased resistance. On the other hand, if $F' < f$, the amplifier reduces the voltage V to the servo motor so that the friction force “ f ” acting on the catheter 20 is reduced. This allows the catheter 20 to advance with greater ease. If $F' = f$, then voltage V will be maintained and f will not change. In this way, the correct amount of force “ f ” is applied
5 on the catheter 20 without causing any damage to the vessel walls. Preferably, this force “ f ” (and the augmented force F') is computed continuously so that the variable force “ f ” is continuously updated to ensure the correct amount of force is applied onto the catheter 20. Alternatively, this variable force “ f ” may be computed only at regular intervals when used in a less critical application such as in a simulation experiment.

10

A second wheeled encoder 60 is also provided in the haptic feedback device 14 which encodes the rotational movement of the catheter 20. On the other side of the catheter 20 a biasing arrangement comprising a support 62, a spring 64 coupled to the support 62 at one end and a contact member 66 resiliently attached to the other end of the spring 64,
15 is used to ensure contact between the catheter 20 and the second wheeled encoder 60 as the catheter 20 advances through the haptic feedback device 14. In this embodiment, the contact member 66 is in the form of a ball which rotates freely and is biased by the spring 64 so that the catheter 20 is always in contact with the second wheeled encoder 60 to track the rotational movement of the catheter 20. Similar to the first wheeled
20 encoder 40, the second wheeled encoder 60 is initialised to a reference position of the catheter 20 so that any subsequent rotational movement may be registered.

In use, if the catheter 20 experiences increased friction as sensed by the sensors 22, 24 when the catheter 20 travels through a blood vessel, the haptic feedback device 14 acts

on the catheter 20 to amplify that force to make it more noticeable to the specialist. Specifically, with an increase in sensed resistance, the device 14 causes the surface 56 to approach the catheter 20 which, due to increased friction between the catheter 20, wheel 40 and the surface 56 increases the degree of resistance that the specialist will
5 feel when feeding the catheter into the blood vessel. In this way, the specialist feels an augmented force F' when operating the catheter 20. Similarly, if the catheter starts to twist in the body, the rotation is picked up by the second wheel encoder 60 and this rotation can be recorded. For example, when the catheter 20 reaches a branch, the user of the catheter may need to rotate the catheter to change the direction of motion. By
10 recording this information, the direction of the catheter can be obtained.

If the specialist wants to pull back the catheter/guide wire 20,30 force sensors detect a decrease in pressure and feeds this change to the servo motor 50 which rotates the shaft 52 clockwise thus releasing the normal force " F " on the catheter 20.

15

Figure 14 depicts an overall block diagram according to the first embodiment and illustrates how the various components are connected to each other. The haptic sensors 22,24 are arranged to determine the three dimensional frictional forces acting on the catheter 20 as the catheter 20 navigates through a blood vessel. This information is
20 processed by the control center 112 which provides an augmented force F' via the feedback control device 14 to the body of the catheter 20. In this way, as the radiologist pushes or rotates the catheter 20 into the blood vessel, the remote force picked up by the haptic sensors 22,24 are amplified and provided to the catheter 20 so that the radiologist can interpret or feel more clearly any possible obstruction to alleviate rupturing of the

blood vessel. This allows the radiologist to better “localise” the catheter’s movement within the blood vessel. The control center 112 also obtains displacement information from the fiber optic deformation sensors 26,27 which can be translated into shape of the catheter for visual observation by the radiologist.

5

In combination, the shape of the catheter and the haptic feedback helps the radiologist to perform the catheterisation procedure with greater accuracy and convenience alleviating a need to take X-ray images of the patient whenever there is an indication of obstruction of the catheter.

10

The first embodiment of the present invention may also be used for simulation training in which the blood vessel or vasculature is simulated virtually. For this purpose, the human subject may be replaced by a FEM model such as that disclosed in PCT/SG01/00111, the contents of which are incorporated herein by reference. However, 15 unlike a real patient, the sensors 22,24,26,27 on the catheter 20 will not detect the actual forces and thus the haptic feedback force needs to be calculated and provided to the specialist navigating the catheter via the haptic feedback device 14 in order to provide a “life-like” catheterisation procedure.

20 Instead of detecting the constraint forces F_x , F_y and F_z , the simulation model calculates and provides simulated constraint forces F_1, F_2 for display and this will be described with reference to Figs. 5 and 6. Vectors F_1 and F_2 are constraint forces from two contacting points (in actual simulation there would be many of these since in practise there are also a plurality of constraint forces). If the catheter is moving, friction forces

f_1 , f_2 in Fig. 5 are also generated. The force feedback F_0 and the twisting torque T_0 will be equal to the sum of the constraint forces and frictional forces from all of the contact points.

- 5 By measuring the force and torque on the catheter 20 along its length, the feedback force and torque F_0 , T_0 can be estimated and for processing by the signal processing and logic unit 112 which subsequently provides amplified versions of the force via the haptic feedback device 14 to the catheter 14 in the same way as a real procedure.
- 10 The detection of the simulated forces experienced by the catheter 20 are computed from a computer model of a simulated vasculature and the computation method and processing are known as explained in "Real-Time Interactive Simulator for Percutaneous Coronary Revascularization Procedures" [8]. Thus, this will not be further elaborated here.
- 15
- Similar to a real procedure, when the radiologist interacts in the virtual environment, the forces experienced by the radiologist may be displayed using for example haptics rendering as explained in "Dynamic Models for Haptic Rendering Systems" [9].
- 20 The third embodiment of the invention envisages using the invention according to the second embodiment to assess the skills of a practitioner such as an intervention radiologist.

In a catheterisation procedure, such as peripheral, cardiac or neuro catheterisation, the success rate may depend on the skills of the interventional radiologist. Complications may result from such procedures if the vascular walls are damaged which may be caused by the use of excessive force when steering or navigating the catheter through the vessels.

For the third embodiment, a database would first be set up which contains a permissible range of forces that may be exerted on a specific region of an artery or a blood vessel without causing damage. Such biomechanical measurements may be obtained from prior literatures [6],[7] and an example of such a database is shown below: a

Table 1:

Tissue	Density (ton/m ³)	Bulk modulus (Gpa)	Shear modulus (Gpa)	Poisson ratio
Bridging veins	1.133	EA=1.9N		0.45

The maximum force or stress that the vein (or vessel wall) can sustain can then be determined using finite element analysis. An example is to model the vein using eight nodes brick elements and assuming a linear model, the minimum force required to damage the vein can be estimated using a finite element solver such as ABACUS. In this example, the above vein parameter translate to a force of less than 1N that can be exerted on the particular vein without causing damage.

As described in the second embodiment, the haptic sensors 22,24 of the catheter 20 are arranged to measure the various simulated forces acting on the catheter at that point. Therefore, these forces can be determined and compared with the data in the database above for the skills assessment. From the comparison, a score may then be assigned

depending on how well the radiologist manages to control the catheter such that the force exerted on that portion of the vessel is within that of the collected range in the database.

- 5 In a fourth embodiment, the invention may be used as a tool for validation of catheterisation simulators.

Catheterisation simulators are important in the training of interventional specialists, particularly their “motor skills”, which is the interventional specialist’s ability to
10 manipulate or guide the catheter/guidewire to the target area of the patient’s body. A typical software simulator measures the amount of contrast dye and X-ray used and the time taken for a targeted navigation. Such simulators also compute the forces experienced by the catheter during the procedure and feedback such forces to a force feedback device and to an interventional radiologist participating in the simulation. The
15 accuracy of the computation and the resultant tactile force is critical and thus there is a need to validate these parameters.

The fourth embodiment of the invention proposes the use of the force measuring sensors and the catheter to validate such a catheterisation simulation. An in-vivo experiment
20 may be conducted using human subjects so that forces at various points of an artery or blood vessel may be measured and recorded. These forces are then compared with the corresponding computed forces from the simulator. If, for example, the forces experienced by the tip of the catheter at a particular section along a artery have a scalar

quantity of 0.002N, then the measured forces at the same section should have approximately the same value.

The described embodiments should not be construed as limitative. For example, in
5 Figures 2a and 2b, four haptic sensors are used to detect three dimensional force acting on a particular point. Alternatively, more sensors can be arranged to cover the whole surface of the catheter which would improve the accuracy of the measurement. However, this will make the catheter more complex and may increase the difficulty of manufacturing.

10

In another variation, other suitable light source may be use, for example a laser diode, for use by the microgyroscope. Other parameters of the reflected light can also be measured to understand the perturbation experienced by the resonator other than measuring the intensity of the reflected light.

15

The described embodiment uses a catheter 20 as an example but it will be apparant that what is described can similarly be applied to a guide wire. In the described embodiment, the catheter 20 is arranged to be inserted into a human subject but the same interventional procedure may be used on an animal body.

20

Instead of providing a plurality of deformation sensors along the catheter 20, a “distributed sensor” 23 such as that shown in Figure 15 may be used to determine the shape of the catheter 20 at that location. The distributed sensor 23 includes a plurality of

micro sensors and together these micro sensors determine the deformation of the catheter 20 similar to that described earlier.

References

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- [9] Diego Ruspini and Oussama Khatib; “*Dynamic Models for Haptic Rendering
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CLAIMS

1. Medical apparatus comprising
an elongate intervention device being operable to be inserted into a human or
5 animal subject, and
at least one force-measuring sensor connected to the intervention device and
disposed at at least one location along the intervention device; the at least one
force-measuring sensor being arranged to measure 3-D forces acting on the
intervention device at the disposed location.
10
2. Medical apparatus according to claim 1, wherein a said force-measuring sensor
is disposed near or at the insertion end of the intervention device.
3. Medical apparatus according to claim 1 or claim 2, further comprising a plurality
15 of force-measuring sensors connected to the intervention device and disposed at
locations along the intervention device.
4. Medical apparatus according to claim 3, wherein the plurality of force-
measuring sensors are disposed at intervals along the whole or a part of the
20 length of the intervention device.
5. Medical apparatus according to claim 4, wherein the plurality of force-
measuring sensors are disposed at uniform intervals.

6. Medical apparatus according to any one of claims 3 to 5, wherein at each location a plurality of coplanar force-measuring sensors is provided.
7. Medical apparatus according to any one of the preceding claims, further
5 comprising at least one deformation sensor connected to the intervention device and disposed at at least one location along the length of the intervention device for measuring the deformation of the intervention device at the disposed location.
- 10 8. Medical apparatus according to claim 7, wherein the at least one sensor and the at least one force-measuring sensor are interleaved at intervals with each other along the length direction of the intervention device.
9. Medical apparatus according to claim 8, wherein the sensors are interleaved at
15 uniform intervals.
10. Medical apparatus according to any one of claims 7 to 9, further comprising a plurality of deformation sensors connected to the intervention device and disposed at locations along the length of the intervention device.
20
11. Medical apparatus according to claim 10, wherein at each location a plurality of coplanar deformation sensors are provided.

12. Medical apparatus according to any one of the preceding claims, wherein the deformation sensors are in the form of fiber optic sensors.
13. Medical apparatus according to any one of the preceding claims, wherein the
5 force-measuring sensors are in the form of haptic sensors.
14. Medical apparatus according to any one of the preceding claims, wherein the intervention device is a catheter and the sensors are connected to the catheter.
- 10 15. Medical apparatus according to any one of claims 1 to 14, wherein the intervention device is a guide wire for a catheter and the sensors are connected to the guide wire.
16. Medical apparatus comprising
15 an elongate intervention device being operable to be inserted into a human subject or animal subject; and
at least one deformation sensor connected to the intervention device and disposed at at least one location along the length of the intervention device, the at least one deformation sensor being arranged to measure deformation of the
20 intervention device at the disposed location.
17. Medical apparatus according to claim 16, wherein at each location a plurality of coplanar deformation sensors are provided.

18. Medical apparatus according to claim 16 or 17, further comprising a plurality of deformation sensors connected to the intervention device and disposed at locations along the length of the intervention device.
- 5 19. Medical apparatus according to any one of claims 16 or 18, wherein the deformation sensors are in the form of fiber optic sensors.
20. Medical apparatus according to any one of claims 16 to 19, wherein the intervention device is a catheter and the sensors are connected to the catheter.
- 10 21. Medical apparatus according to any one of claims 16 to 20, wherein the intervention device is a guide wire for a catheter and the sensors are connected to the guide wire.
- 15 22. In combination, medical apparatus according to any one of claims 16 to 21, and processing means for determining the shape of the intervention device based on the deformation measurement
- 20 23. A combination according to claim 22, wherein the processing means further comprises means for displaying the shape of the intervention device.
24. Haptic feedback apparatus comprising force application means arranged to apply a force to an elongate intervention device, control means arranged to control the force applied to the intervention

device by the force application means, the control means being connected to at least one sensor arranged to sense a remote force on the intervention device and the control means being arranged to calculate the applied force in accordance with the remote force, the applied force being an amplification of the remote force.

5

25. Haptic feedback apparatus according to claim 24, wherein the force application means comprises a resilient member arranged to apply the said force to the intervention device.

10

26. Haptic feedback apparatus according to claim 25, further comprising a sensor arranged to detect frictional force between the resilient member and the intervention device.

15 27. Haptic feedback apparatus according to claim 26, wherein the detected frictional force is used to control the amount of applied force.

28. Haptic feedback apparatus according to any one of claims 24 to 27, further comprising means for tracking the rotational movement of the intervention device.

20

29. Haptic feedback apparatus according to any one of claims 24 to 28, further comprising means for tracking the linear movement of the intervention device.

30. Haptic feedback apparatus according to any one of claims 24 to 29, further comprising means for comparing the remote force with a reference force.
- 5
31. Haptic feedback apparatus according to any one of claims 24 to 30, wherein the intervention device is operable to be inserted into a simulated human model.
32. Haptic feedback apparatus according to claim 31, wherein the remote force is
10 generated using computer simulation.
33. Haptic feedback apparatus according to any one of claims 24 to 32, wherein the intervention device is operable to be inserted into a human subject.
- 15 34. Haptic feedback apparatus according to any one of claims 24 to 33, wherein the at least one sensor is disposed near or at a tip of the intervention device.
35. Haptic feedback apparatus according to any one of claims 24 to 34, further comprising a plurality of sensors disposed along the length of the intervention
20 device and the control means is connected to each of the plurality of sensors.
36. In combination, medical apparatus according to any one of claims 1 to 15 and haptic feedback apparatus according to any one of claims 24 to 35.

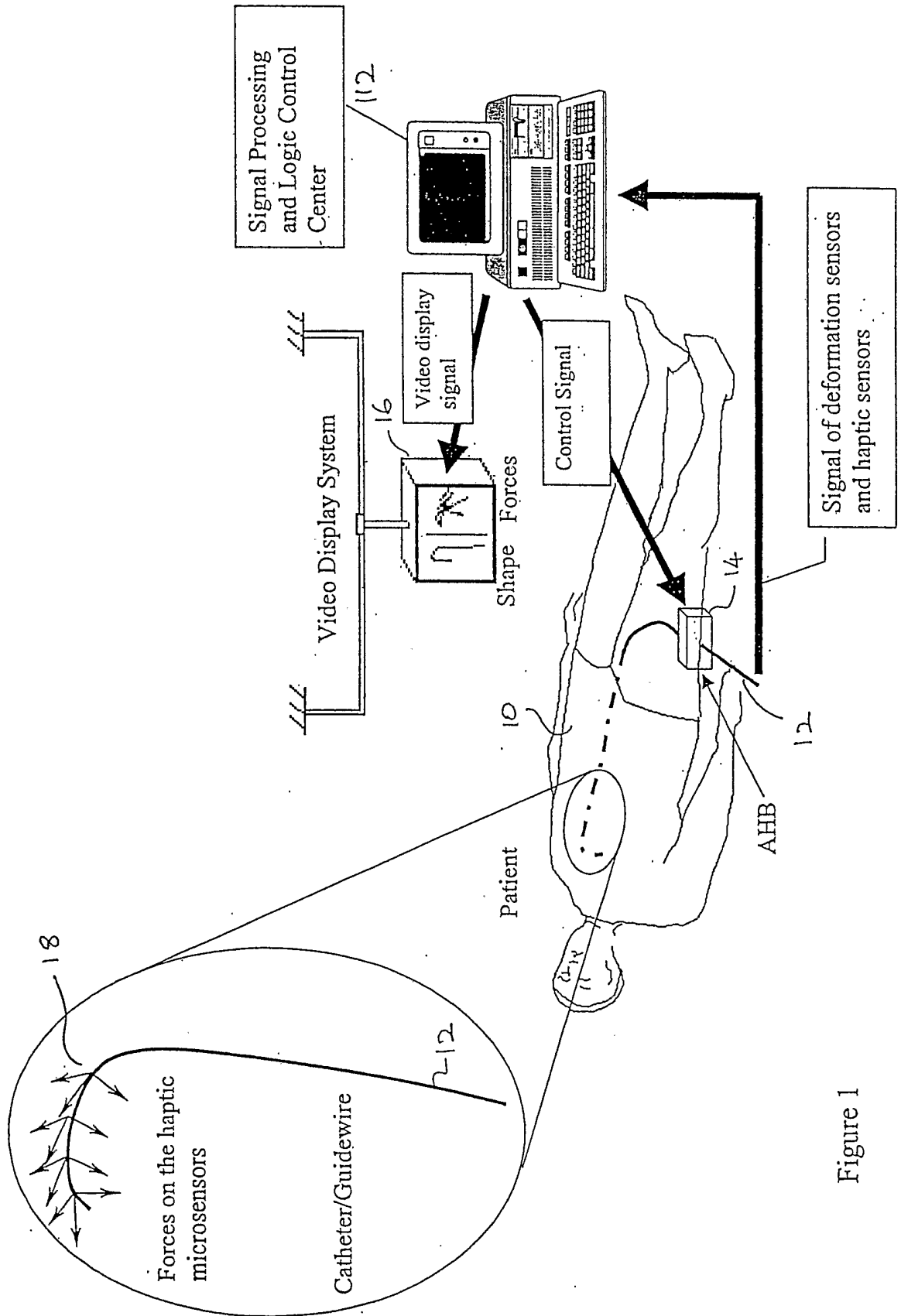
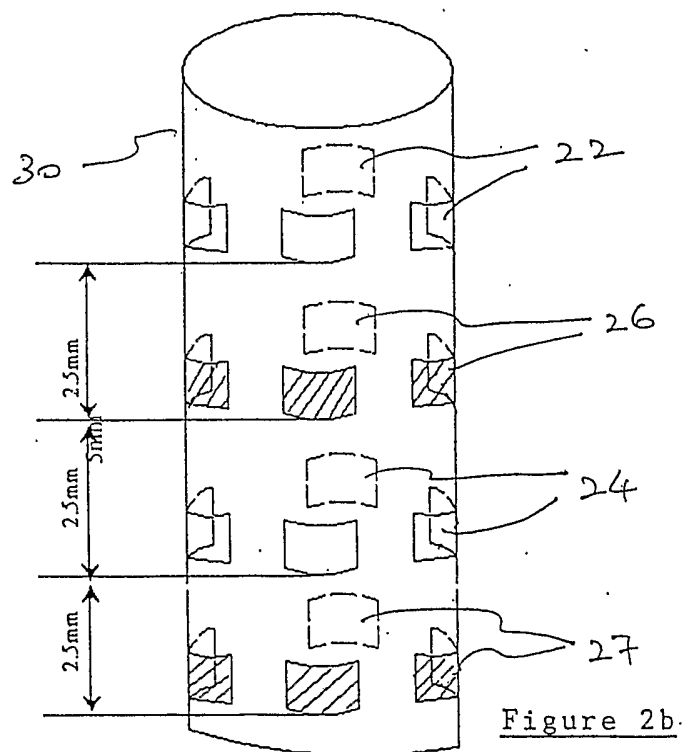
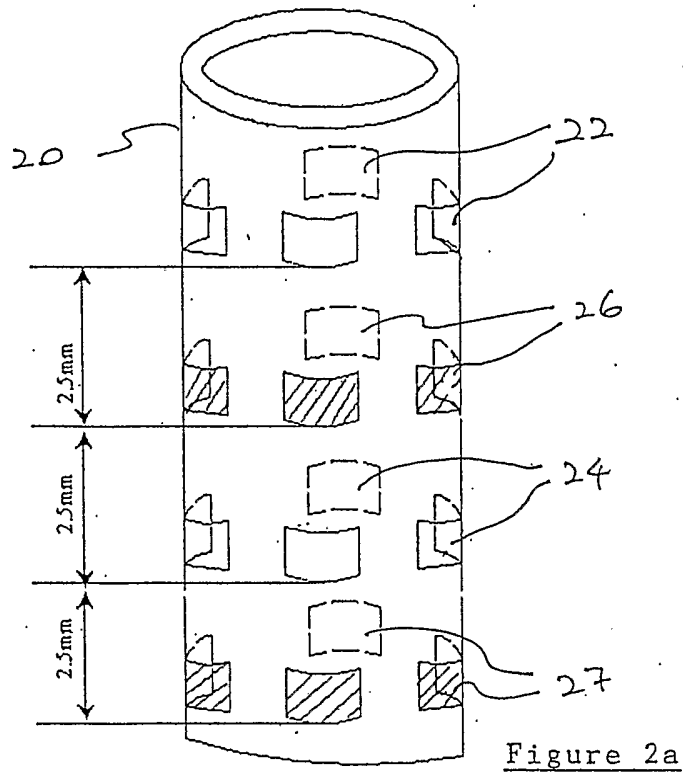


Figure 1



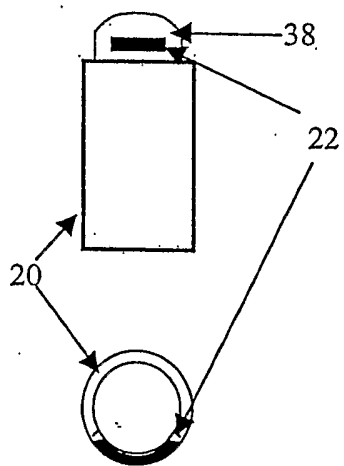


Figure 2d

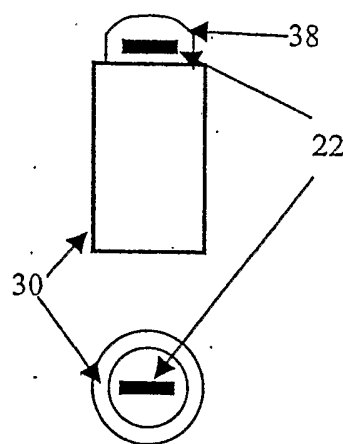


Figure 2e

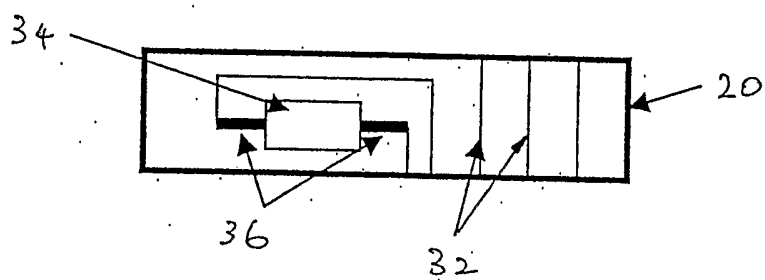


Figure 2c

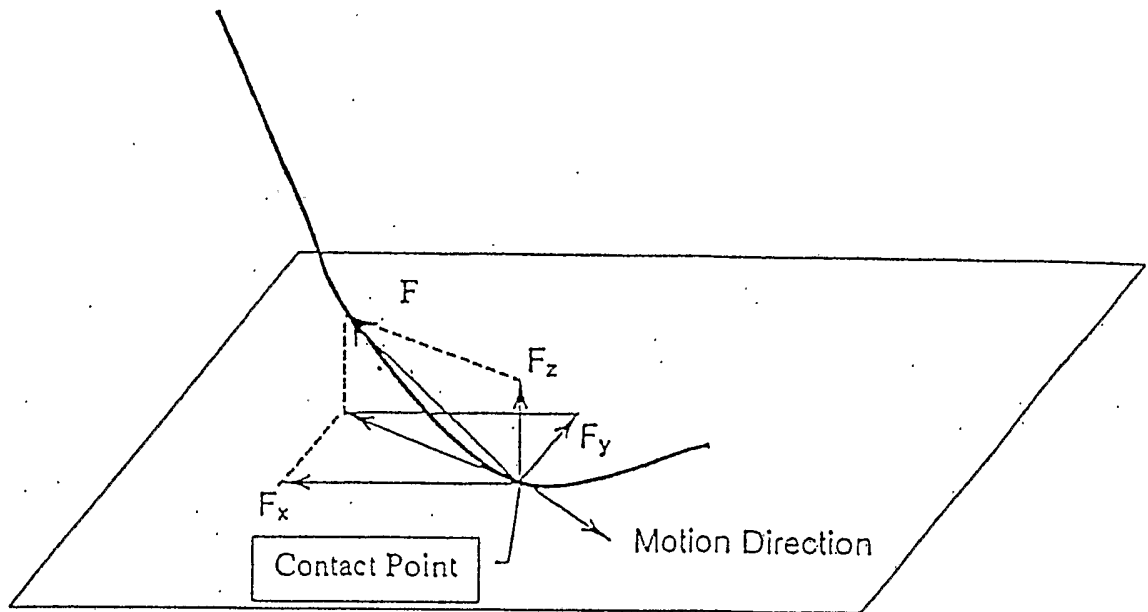


Figure 3.

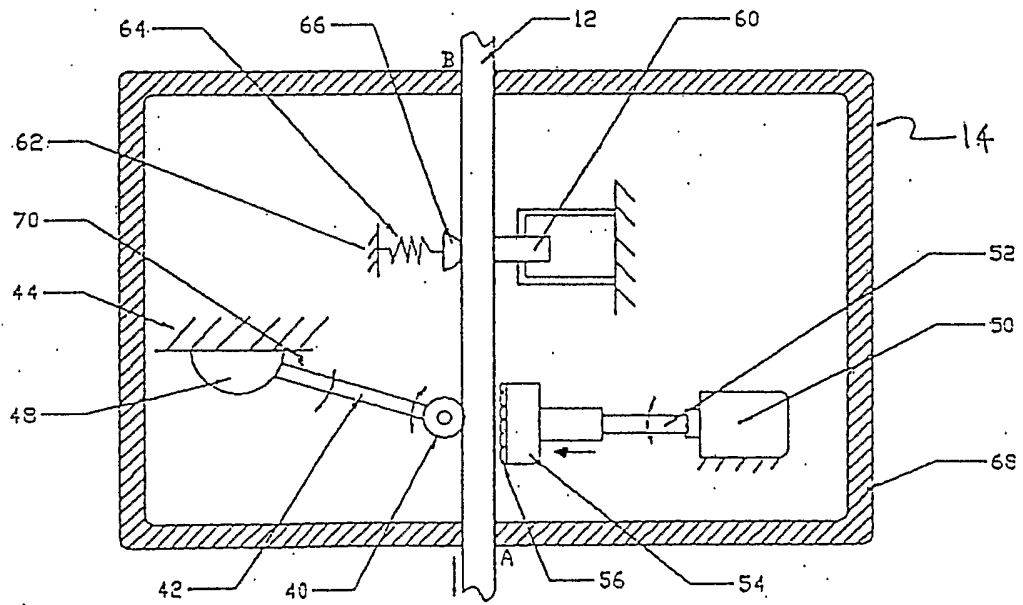


Figure 4.

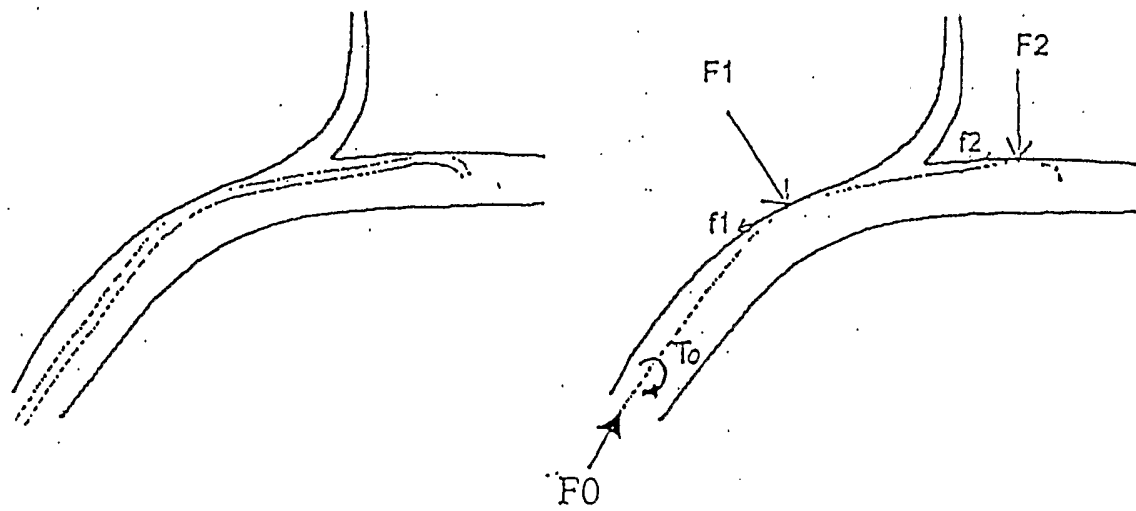


Figure 5

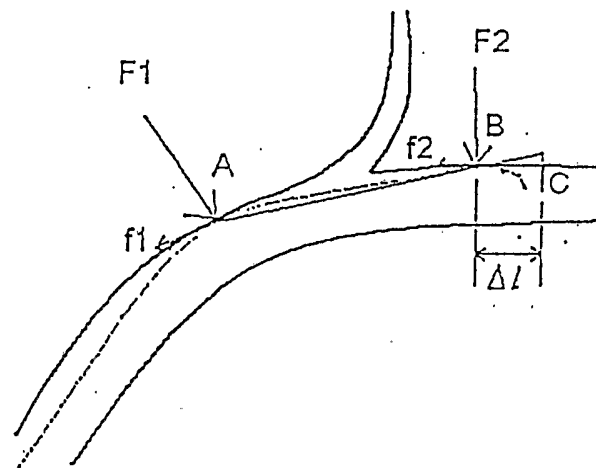


Figure 6

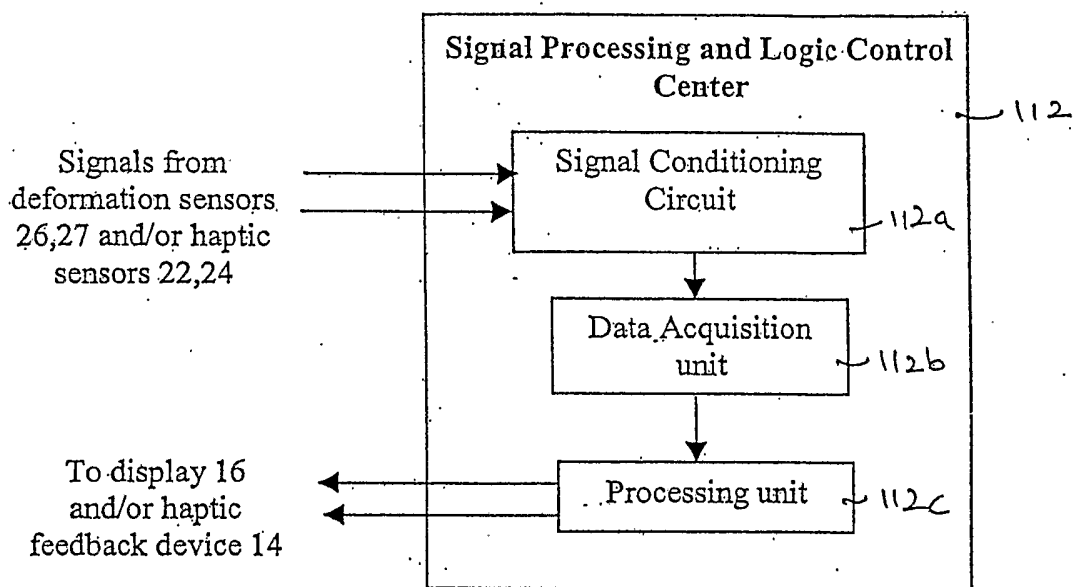


Figure 7

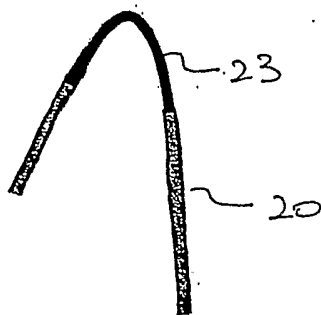


Figure 15

7/10

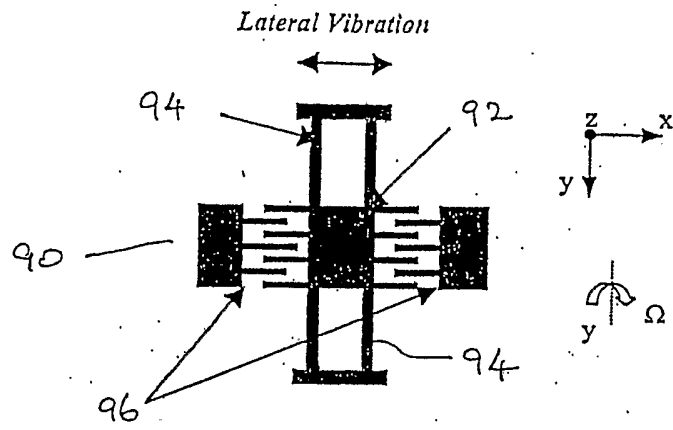


Figure 8

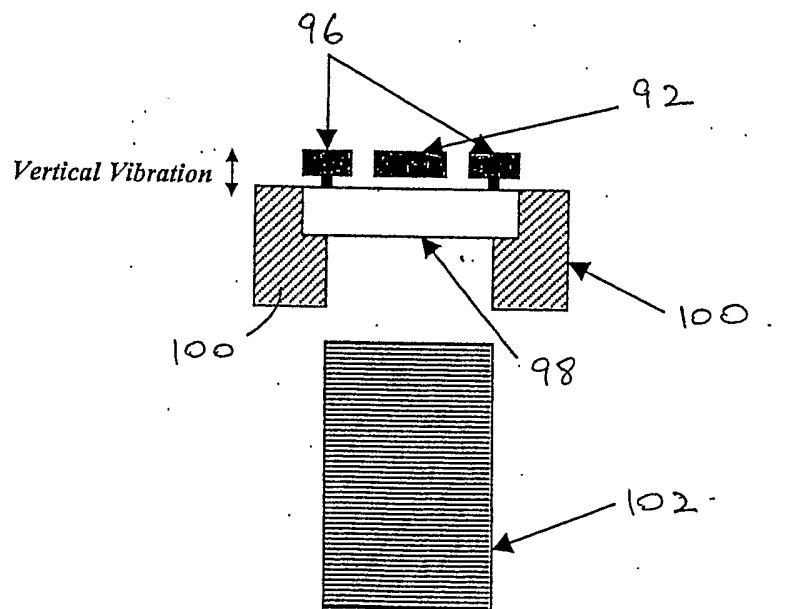


Figure 9

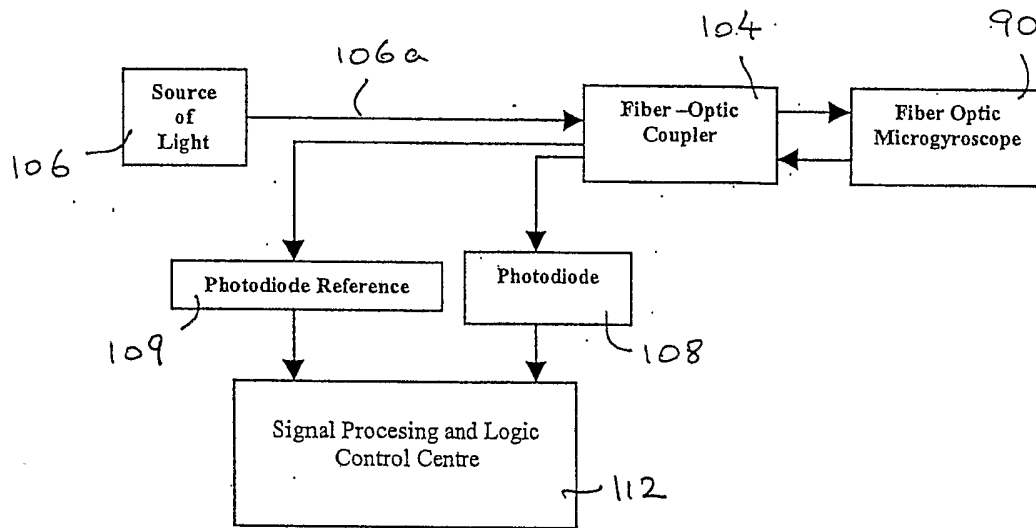


Figure 10

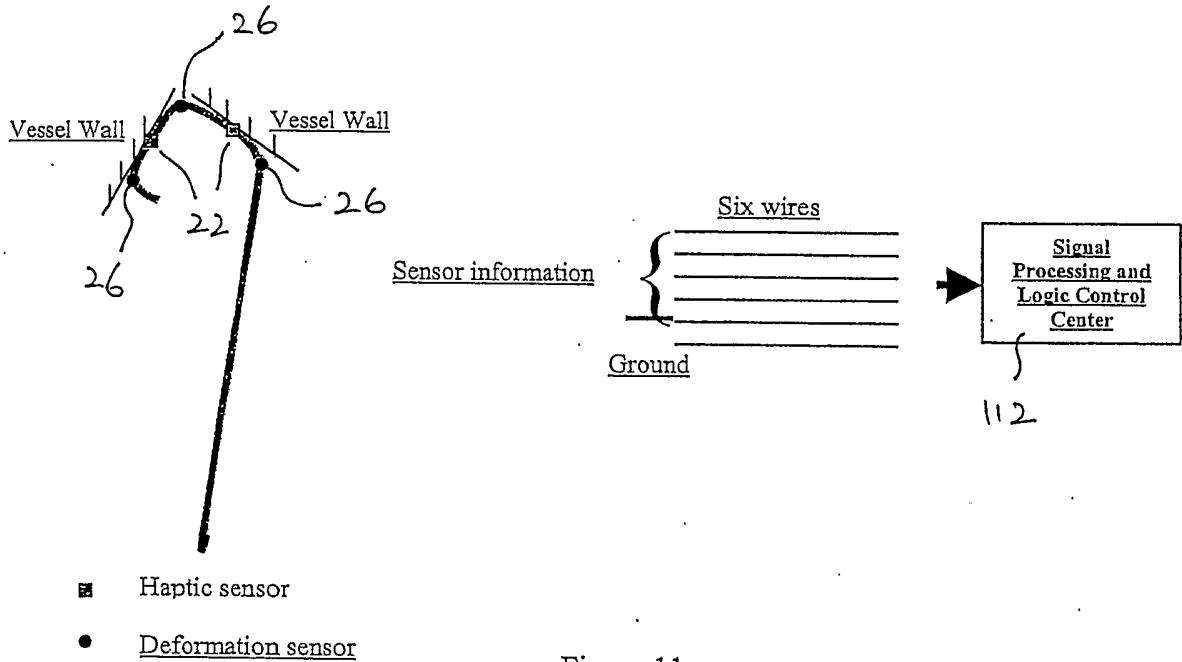


Figure 11

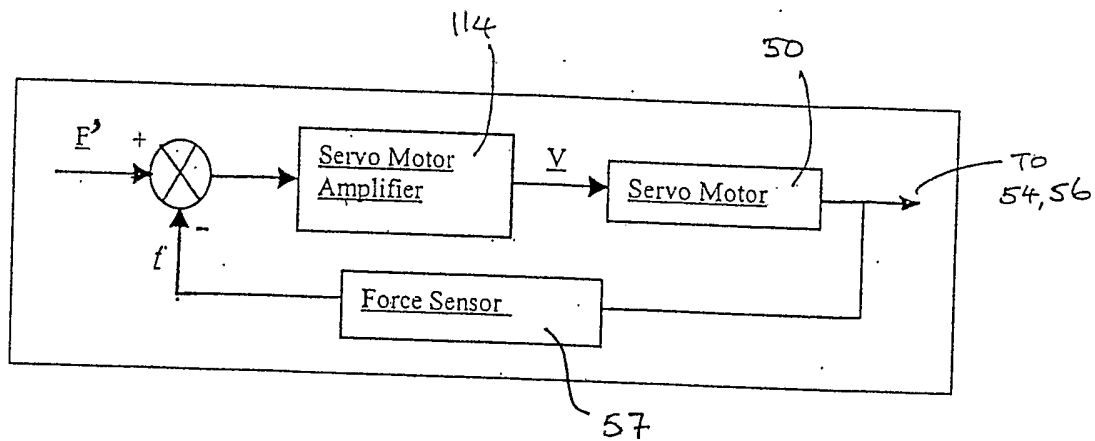


Figure 12

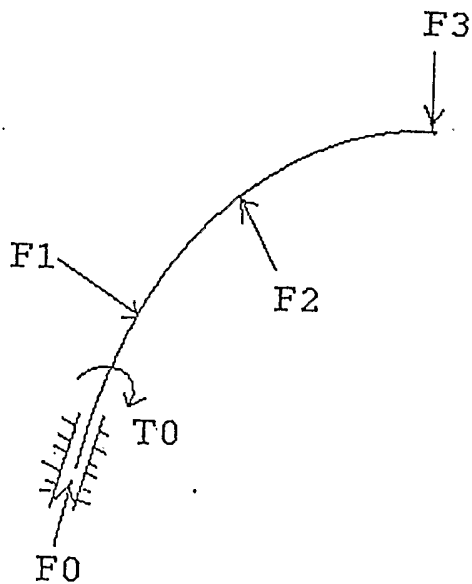


Figure 13

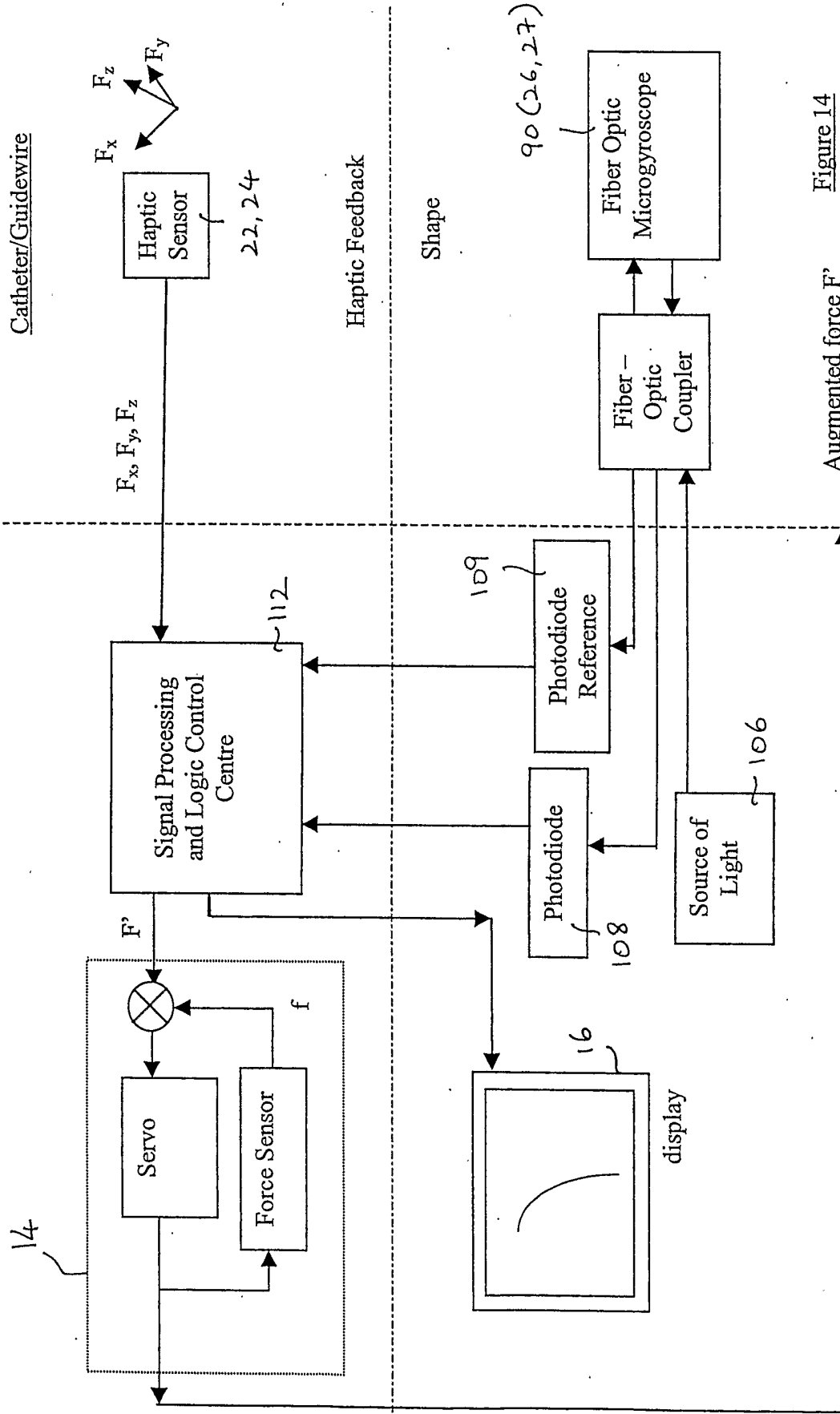



Figure 14

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2005/000063

A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. ⁷ : A61B 5/103 A61B 1/00 A61M 25/00 G01L 1/24 G01L 1/10		
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)		
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) DWPI JAPIO USPTO: A61B A61F A61M medical patient surgery force friction strain stress resist load probe cannula catheter scope handpiece elongate device operate direct insert slide displace move travel motion obstruct impeded resist defelct block hinder bend sense meter transduce gauge		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4366810 A (SLANETZ) 4 January 1983 Figures, column 2 lines 35 to 64, column 5 line 18 to column 6 line 6, column 6 lines 42 to 63.	1-36
X	US 4873990 A (HOLMES et al) 17 October 1989 Column 4 lines 15 to 23, figure 1, claims	1-23
X	JP 6-190050 A (MITSUBISHI CABLE IND. LTD.) 12 July 1994 Abstract and figures	16-36
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> 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	"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
"E"	earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"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 12 May 2005		Date of mailing of the international search report 20 MAY 2005
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustrialia.gov.au Facsimile No. (02) 6285 3929		Authorized officer  MATTHEW FORWARD Telephone No: (02) 6283 2606

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2005/000063

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5339799 A (KAMI et al) 23 August 1994 Figures, claims.	24-27, 30-35
X	WO 1997010746 A1 (UNIVERSITY OF WALES COLLEGE OF MEDICINE) 27 March 1997 Page 2 line 28 to page 3 line 15, page 5 line 5 to page 6 line 3	1-23
A	JP 9-192230 A (TOSHIO et al) 29 July 1997 Figures	1, 16, 24
X	WO 1999033392 A1 (SKRABAL et al) 8 July 1999 Abstract and figure 1	1-23
X	US 5957833 A (SHAN) 28 September 1999 Entire document	1-23
X	WO 2002007617 A2 (VERIMETRA, INC.) 31 January 2002 Entire document	24-35
X	US 6612992 B1 (HOSSACK et al) 2 September 2003 Entire document	1-23
P, X	WO 2005011511 A1 (TECHNISCHE UNIVERSITAT DARMSTADT) 10 February 2005 Abstract, figures 1 and 2	16-23
P, X	DE 10303270 A1 (TECHNISCHE UNIVERSITAT DARMSTADT) 5 August 2004 Figures	16-35

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2005/000063

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

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

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

- Remark on Protest**
- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 15 define medical apparatus with an elongate intervention device with one or more force measuring sensors being arranged along the device to measure 3-D forces acting on the device. It is considered that using force measuring sensors to measure 3-D forces comprises a first "special technical feature".
2. Claims 16 to 23 define a medical apparatus of an elongate intervention device and one or more deformation sensors on the length of the device arranged to measure deformation of the intervention device. It is considered that measuring deformation of an intervention device using such sensors comprises a second special technical feature.
3. Claims 24 to 35 define a haptic feedback system of a means to apply force to an elongate intervention device, control means to control the force applied, one or more sensors connected to the control that sense a "remote force on the intervention device" and the control means calculating an applied force in accordance with an amplification of the remote force. It is considered that using an amplification of the remote force to determine the applied force is a third special technical feature.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

However all these concepts could be searched without the need to an extra fee.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/SG2005/000063

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member		
US 4366810	US 4469091		
US 4873990			
JP 6190050			
US 5339799	DE 4213426 JP 5076482	JP 4324409	JP 5038327
WO 1997010746	AU 69934/96	EP 0862380	US 6117091
JP 9192230			
WO 9933392			
US 5957833	US 5728044		
WO 2002007617	AU 77081/01 US 2002116022	EP 1303220	US 6494882
US 6612992			
WO 2005011511			
DE 10303270	WO 2004067053		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX