



(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention
of the grant of the patent:
09.11.2005 Bulletin 2005/45

(51) Int Cl.⁷: **A61B 5/0205**

(21) Application number: **02710734.1**

(86) International application number:
PCT/CA2002/000140

(22) Date of filing: **05.02.2002**

(87) International publication number:
WO 2002/065903 (29.08.2002 Gazette 2002/35)

(54) **APPARATUS FOR ASSESSMENT OF CARDIAC FUNCTION BY MONITORING MOVEMENT OF THE TRACHEA**

GERÄT ZUR STEUERUNG VON HERZFUNKTION DURCH ÜBERWACHUNG VON LUFTRÖHREBEWEGUNGEN

DISPOSITIF PERMETTANT D'ÉVALUER LA FONCTION CARDIAQUE PAR UNE SURVEILLANCE DU MOUVEMENT DE LA TRACHÉE

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE TR**

(72) Inventor: **KOBLANSKI, John**
Vancouver, B.C. V6M 1R9 (CA)

(30) Priority: **22.02.2001 US 791518**

(74) Representative: **Specht, Peter et al**
Loesenbeck.Stracke.Specht.Dantz,
Patentanwälte,
Jöllnbecker Strasse 164
33613 Bielefeld (DE)

(43) Date of publication of application:
19.11.2003 Bulletin 2003/47

(73) Proprietor: **Texon Technologies Ltd.**
Vancouver, British Columbia V6C 2T8 (CA)

(56) References cited:
US-A- 4 383 534 **US-A- 4 530 354**
US-A- 5 263 478 **US-A- 5 964 223**
US-B1- 6 171 258

Description

[0001] This invention relates to an apparatus to assess cardiac function in a subject.

[0002] Non-invasive methods of determining cardiac functioning include the following:

a) Mechanical methods that include pulse recording of the jugular, carotid artery or apexcardiogram. This group also includes sound recordings, for example, use of the stethoscope and phonocardiographic techniques.

b) Electrical techniques which are best exemplified by the electrocardiogram (ECG).

c) Relatively more recent techniques include imaging techniques, for example echocardiography, nuclear cardiography, radiographic techniques and magnetic resonance imaging (MRI).

[0003] All of the above the mechanical methods, which rely on vibration and sound recording, involve measuring the movements of the body resulting from cardiac activity. This means that the mass of the body is part of the recording means. This is not desirable. Chest movements, for example, are dependent upon chest shape, and sound recording is dependent upon the amount of fat and the condition of the lung tissue for its amplitude. An accurate trace pattern is difficult to achieve and these techniques are therefore of limited diagnostic value.

[0004] Electrical methods measure only the electrical field generated by the heart. This cannot provide a direct measure of the cardiac forces generated by the heart and therefore these methods are incapable of evaluating the heart's function as a pump.

[0005] Imaging techniques have limited ability to evaluate the force of the heart's contraction.

[0006] Thus none of the above methods is capable of measuring the force of the heart's contraction. As a result the evaluation of the condition of the myocardium is not possible. Heart attack risk cannot be determined by any known non-invasive method. A patient may be diagnosed as normal and yet die of a heart attack shortly after the diagnosis.

[0007] Relevant literature includes the following text books: Clinical Phonocardiography and External Pulse recording by Morton E. Tavel, 1978 Yearbook, Medical publishing Inc.; Non-Invasive Diagnostic Techniques in Cardiology by Alberto Benchimol, 1977, The Williams and Wilkins Co.; and Cardiovascular Dynamics by Robert F. Rushmer, 1961, W.B. Saunders Company.

[0008] Rushmer first postulated that acceleration and deceleration of the various structures of the heart and blood explain heart sounds as well as their modifications with changing dynamic conditions. As acceleration is a function of force, the aortic blood acceleration is a man-

ifestation of the force that sets the cardiac structures in motion. Other forces originate from the pressure gradient between the aorta and the left ventricle, which acts over the closed semilunar valve. The valve behaves like a circular, stretched membrane in which the thin, flexible leaflets can be stretched in all directions by the differential aorta - ventricular pressure. The energy of the rapid ejection phase of the left ventricle expands the aorta and the stored energy is in direct relationship to its wall elasticity. Measurement of the amplitude of the wave created after the maximum ejection rate, is a measure of the elasticity of the wall of the aorta. The elasticity of the aortic valve can also be measured by measuring the amplitude of the wave created after the valve is closed. The most sensitive indicators of performance are the rates of change of momentum as indicated by changes in velocity of the blood and heart mass. This acceleration is directly indicative of myocardial contractility which is one of the most difficult parameters to measure. In 1964 Rushmer established a direct relationship between the initial ventricular impulse and the peak flow acceleration during the systolic ejection - see Circulation - volume 29: 268-283 1964.

[0009] Commonly owned United States Patent No. 5,865,759 discloses a method and apparatus for measuring cardiac function using an external sensor positioned against the thyroid cartilage in the neck. The sensor detects the response of the thyroid cartilage to heart function and generates a signal that is fed to a signal processing unit to generate a waveform signal characteristic of heart function for assessment by a user. The apparatus and method of United States Patent No. 5,865,759 provide reliable, accurate and inexpensive assessment of cardiac function.

SUMMARY OF THE INVENTION

[0010] The present invention provides an improved apparatus for assessment of cardiac activity by directly measuring the movement of the trachea. The apparatus rely on introduction of a sensing apparatus into the throat of the user to engage with the trachea. This arrangement is sensitive to very small movement forces and permits accurate measurement of cardiac function with even finer details.

[0011] Accordingly, the present invention provides an apparatus as defined in claim 1.

[0012] The probe can be a hollow tube having an internal passage to deliver air to the subject and whereby movement of the hollow tube serves to transmit the movement of the trachea.

[0013] Alternatively, the apparatus can employ an endotracheal tube for housing the probe in which case the probe comprises a tubular member having an inner end adapted to protrude from the endotracheal tube and engage against the carina region at which the trachea bifurcates into the lungs.

[0014] In a preferred embodiment the present inven-

tion provides an apparatus to assess cardiac function in a subject comprising:

a tube insertable into the mouth of a subject such that a first end extends into the trachea and a second end protrudes from the mouth;

a flexible support extendable from the tube to engage the trachea and suspend the tube within the trachea for movement of the tube along the longitudinal axis of the tube;

a rigid anchor extendable from the tube to engage the trachea and transmit movement of the trachea due to cardiac function to the tube;

a sensor to sense the movement of the tube and generate a signal indicative of the movement of the trachea; and

a signal processing unit to receive the signal from the sensor and generate a waveform signal characteristic of the cardiac function.

[0015] The apparatus of the present invention is intended to be used primarily with human patients, however, the subject matter also finds application with animal subjects. The apparatus can be used with a conscious subject or when the subject is anaesthetised, for example, during surgery.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Aspects of the present invention are illustrated, merely by way of example, in the accompanying drawings

Figure 1 is a schematic view of a first embodiment of the apparatus of the present invention which relies on movement of a tube within the trachea to transmit movement of the trachea due to cardiac function;

Figure 1a is a detail view showing the manner of attachment of the sensor to the tube of Figure 1;

Figure 2a is a detail view of the anchor for coupling the tube to the trachea in the folded position;

Figure 2b is a detail view of the anchor in the expanded position;

Figure 3 is a detail view of the retaining strap for holding the tube of the first embodiment in place;

Figure 4 shows a second embodiment of the apparatus of the present invention which relies on a probe inserted through an endotracheal tube to measure the

movement of the carina region of the trachea;

Figure 5 is a detail section view through the mounting assembly that supports one end of the probe of the second embodiment via a movable carriage;

Figure 5a is a detail view of an alternative sensor that can be used in apparatus of the second embodiment;

Figure 5b is a detail view taken along line 5-5 in Figure 5 showing the wheel arrangement that permits movement of the carriage;

Figure 6 shows an endotracheal tube used with the probe of the second embodiment;

Figures 7a and 7b show the probe with an inner end having locating fingers in a collapsed position to facilitate insertion through the endotracheal tube and an extended position to locate the inner end on the carina region;

Figure 8 shows the probe and mounting assembly of the second embodiment prior to insertion into the endotracheal tube of Figure 6; and

Figure 9 is a schematic view of the display unit used with the apparatus of the present invention to show typical cardiac events and inputs from the sensors.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0017] The apparatus of the present invention is directed to a new system for assessing cardiac function in a subject. Essentially, the apparatus of the present invention comprises a probe 4 insertable and supportable in the trachea of a subject to transmit movement of the trachea due to cardiac function. The transmitted movement of the trachea is detected by a sensor which generates a signal indicative of the trachea movement. This signal is passed to a signal processing unit which generates a waveform signal characteristic of the cardiac function. Details of the processing of the signal are disclosed in commonly owned United States Patent No. 5,865,759 which also discloses externally monitoring the movement of the thyroid cartilage in order to monitor heart function. The present invention is directed to an improved system which relies on internal monitoring of the movement of the trachea to provide an even more accurate picture of the heart function. The trachea is the passage reinforced by rings of cartilage through which air reaches the bronchial tubes from the larynx.

[0018] Figures 1-3b illustrate a first embodiment of the apparatus of the present invention in which the probe is a hollow tube 4 insertable through the mouth and throat of a user into the trachea and supportable therein.

Movement of the tube itself serves to transmit the movement of the trachea.

[0019] Referring to Figure 1, hollow tube 4 has a structure similar to a conventional intubation device in that there is a hollow interior 6 that extends between an outer end 8 and an inner end 10 formed with a structure known as a Murphy Eye which ensures that the inner end does not become blocked. Tube 4 is insertable into the mouth of a subject such that inner end 10 extends into the trachea and outer end 8 protrudes from the mouth. Outer end 8 includes an attachment for ready connection to a ventilator unit (not shown) which can deliver air through tube interior 6 to inner end 10 and the trachea to allow a subject to breathe while the tube is in place.

[0020] A flexible support in the form of inflatable cuffs 14 and 16 are extendable from the tube to engage the anatomy of the subject and suspend tube 4 within the trachea for longitudinal movement. Lower cuff 14 is positioned to engage with the trachea. Upper cuff 16 is positioned within the mouth of the subject to prevent opposition to tube motion by mouth structures such as the teeth or tongue. Cuffs 14 and 16 are shown in their inflated state in Figure 1 extending radially outwardly from tube 4. As with a conventional intubation device, the side walls of tube 4 include sealed embedded air passages to permit inflation and deflation of cuffs 14 and 16. A separate syringe 18 or 20 is connected via line 18' or 20', respectively, to embedded air passages for independent control of each cuff. Syringes 18 and 20 include a check valve 19 to ensure that the cuffs remain inflated. Cuffs 14 and 16 are formed from soft, pliable plastic and dimensioned to be inflatable to a diameter that securely engages with the walls of the trachea or the mouth of the subject to reliably suspend tube 4 in place within the trachea. Two spaced cuffs 14 and 16 are shown supporting each end of tube in Figure 1, however, it will be readily apparent to a person skilled in the art that additional cuffs may be used intermediate the ends of the tube.

[0021] Cuffs 14 and 16 are sealably mounted to the external surface of tube 4 by annular end walls 22 that extend generally radially from the external surface. Transverse flexing of end walls 22 permits longitudinal movement of tube 4 in the direction indicated by arrow 24 within the trachea. On deflation, cuffs 14 and 16 collapse against external surface of tube 4 to permit ready insertion or removal of tube 4 from the trachea and mouth of the subject.

[0022] In order to ensure that tube 4 moves with the trachea in response to cardiac function, tube 4 also includes a rigid anchor in the form of at least two hinged flanges 30 that are extendable radially outwardly from the external surface of tube 4 to engage the trachea. Each flange 30 is pivotally connected via a hinge joint to collar 32 which encircles tube 4. Preferably, an inflatable bladder 34 is provided inside flanges 30 between the flanges and tube 4. Bladder 34 acts to pivot the flanges between a folded position against the tube and a radially expanded position extending between the tube

and the trachea. Figure 1 and Figure 2a show flanges 30 in the folded position in which the flanges lie substantially flat against the side of tube 4. Figure 2b shows the flanges in the radially expanded position due to inflation of bladder 34. When in the expanded position, flanges 30, which are preferably formed from a rigid plastic, engage against the walls of the trachea to anchor tube 4 to the trachea such that tube 4 moves with the trachea. Tube 4 is supported by cuffs 14 and 16 within the trachea for longitudinal movement so that any movement of the trachea due to beating of the heart is transmitted by flanges 30 to tube 4. Inflation of cuff 34 is controlled manually by syringe 36 via line 36' (Figure 1). A check valve 19 is also provided. Alternatively, a small air pump 38 can be programmed under computer control to vary pressure in bladder 34 so that the pressure is increased to a predetermined value for a period and reduced to a different pressure for another period. Operating in this manner prevents tissue necrosis in the trachea due to pressure of rigid flanges 30 against the trachea for extended periods.

[0023] When inserted into the trachea, tube 4 has a tendency to move outwardly and must be restrained from doing so. In the apparatus of the present invention, a retainer member 39 is preferably provided adjacent outer end 8 of tube 4 to prevent excess outward movement of tube 4. Figure 3 shows retainer 39 in the form of a strap and buckle connectable about the neck of the subject. The strap includes a circular opening 41 dimensioned to permit free movement of outer end 8 of tube 4 therethrough while preventing passage of cuff 16. Therefore, abutting of cuff 16 against the strap serves to prevent excess outward movement of tube 4.

[0024] Movement of tube 4 is detected by sensor 40 attached to the outer end 8 of tube 4. As best shown in Figure 1a, sensor 40 can be clipped to the tube via arms 40a to permit convenient interchange of sensors. In all cases, sensor 40 is selected to generate a signal indicative of movement of the tube and thus the trachea. Sensor 40 is preferably an accelerometer which senses the acceleration or velocity of tube 4. Alternatively, sensor 40 can be selected to measure displacement of tube 4. The signal generated by sensor 40 is sent via data line 42 to a data acquisition unit 44. The data acquisition unit includes a signal processing unit 45 to receive the signal from sensor 40 and generate a waveform signal characteristic of cardiac function. Signal processing unit 45 includes an amplifier to amplify the signal from the accelerometer and a digitizer to digitize the amplified signal. A signal analysis unit is then used to analyze the amplified signal and generate a waveform signal characteristic of cardiac function. The resulting waveform signal is displayed on a monitor 46 for ease of inspection. The data acquisition unit 44, signal processing unit 45 and display unit 46 are preferably organized into a control unit 50. Control unit 50 includes a computer with keyboard 55 running appropriate software to acquire, manipulate, store and display the data provided by sen-

sor 40. As shown in Figure 9, control unit 50 can also include inputs for additional sensor data and electrocardiogram (ECG) readings for simultaneous display on monitor 46 for comparison purposes.

[0025] In use, tube 4 is lubricated and manipulated according to standard procedures of intubation to insert the tube through the mouth of the user into the trachea with cuffs 14 and 16 collapsed and flanges 30 in the folded position. Cuffs 14 and 16 are then inflated using syringes 18 and 20. Cuff 16 is located in the mouth and cuff 14 seals the airway between the tube and trachea. Together the cuffs co-operate to suspend tube 4 within the trachea for free vibratory movement in response to movement of the trachea. Flanges 30 are moved to the expanded position to contact the trachea and lock the tube and trachea together so that tube 4 transmits any movement of the trachea due to the heart's motion. Movement of tube 4 is sensed by sensor 40 clipped to the outer end of the tube. Sensor 40 is used to generate a waveform signal based on movement of the tube which is used to determine cardiac function. By inserting a tube directly into the trachea and using the tube itself to detect movement of the trachea, more accurate and reliable data regarding cardiac function can be acquired than was previously possible.

[0026] Figures 4-8 illustrate a second embodiment of the present invention in which the probe for insertion into the trachea comprises a tubular member 8 which is inserted through an endotracheal tube 50 to directly engage and monitor the movement of the carina region 52 where the trachea 54 bifurcates into the bronchial tubes 56.

[0027] Referring to Figures 4 and 5, the apparatus of the second embodiment includes a mounting structure comprising a box housing 60 that supports one end of tubular member 8 to manipulate and manoeuvre the tubular member for insertion into the trachea of a subject via the mouth. Housing 60 includes tubular port 61 from which tubular member 8 protrudes. Housing 60 also includes an encircling clamp 62 and ball joint coupling 63 for connecting the housing to mounting bracket 64. Bracket 64 supports the entire apparatus and permits the apparatus to be oriented for ease of insertion of tubular member 8 into the trachea of a subject.

[0028] Figure 5 is a detail section view through housing 60. Housing 60 includes a movable carriage 66 to receive the outer end 74 of tubular member 8. Carriage 66 is movably supported by wheels 68 on rails 70 to permit adjustment of the position of tubular member 8 so that the member is biased against carina region 52 of the subject as will be explained in more detail below. To further support tubular member 8, wheels 68 are preferably mounted to the tubular member in the region of tubular port 61 to engage rails 70 mounted to the inner walls of the port. Fig. 5b is a section view taken along line 5-5 of Figure 5 showing details of a preferred arrangement in which each wheel 68 includes a central clannel to engage rail 70.

[0029] Tubular port 61 includes a window 61a to monitor the position of an indicator 100 fixedly mounted to tubular member 8. Indicator 100 in window 61a allows a user to determine the position of tubular member 8 within housing 60.

[0030] Referring to Figure 6, there is shown an endotracheal tube 50 used with the apparatus of the present embodiment. Tube 50 includes an inflatable cuff 15 that is controlled by syringe 53 via line 53' to retain tube 50 in the trachea of a subject. Tube 50 includes a main port 57 to receive end 72 of tubular member 8. Tubular member 8 is fed through the interior of endotracheal tube 50 via port 57 to protrude from end 58 for positioning against the carina. Endotracheal tube 50 also includes an auxiliary port 59 connectable to a ventilator for providing air to the subject through the interior of tube 50. As best shown in Figure 4, port 57 of endotracheal tube 50 is releasably connectable to tubular port 61 of housing 60 to form a continuous passage to house tubular member 8 when inserted into the trachea of a subject.

[0031] As best shown in Figure 5, the positioning of movable carriage 66 and thus the position of the tubular member in the trachea of the subject is preferably controlled by a spring biasing system. In the illustrated embodiment, the biasing system relies on spring loaded clamps 65 arranged in opposed pairs at each end of housing 60. Each clamp 65 controls a line connected to movable carriage 66. Fixed length lines 67 (preferably of nylon cord) extend from one side of carriage 66 while elastic lines 69 extend from the opposite side to exert a biasing force that tends to move the carriage and the attached tubular member 8 toward the subject. Lines 67 are connected to handle 73. Each clamp 65 includes a control knob 71 that is normally biased inwardly to grip and hold the line extending through the clamp. Pulling the control knob releases the clamp to allow movement of the lines. In use, the clamps controlling lines 67 are released and handle 73 is pulled to move carriage 66 and tubular member 8 to a predetermined position as shown by indicator 100 in port window 61a. Carriage 66 is moved against the return force exerted by stretching of elastic cords 69. The clamps for lines 67 are then engaged to hold the lines in place. This procedure locks the movable carriage 66 into a parked position for initial insertion of the tubular member into the trachea of a subject via endotracheal tube 50. After insertion of tubular member 8, the clamps 65 controlling lines 67 are released with the result that tubular member 8 mounted to carriage 66 will be biased against the carina of the subject by the tension force in stretched elastic lines 69. The clamps 65 controlling elastic lines 69 are provided to permit adjustment of the tension in the elastic lines.

[0032] As best shown in Figures 7a and 7b, tubular member 8 comprises an inner end 72 adapted to protrude from the endotracheal tube 50 and engage against carina region 52, and outer end 74 supported in movable carriage 66 of housing 60. Tubular member 8 has sub-

stantially rigid side walls 76 defining a sealed interior filled with a fluid 78 communicating the inner and outer ends. Preferably, side walls 76 include a bendable region 80 formed with corrugations to accommodate curvature of the trachea.

[0033] Inner end 72 and outer end 74 of tubular member 8 include resilient surfaces 82 and 84, respectively, that communicate via the fluid in sealed interior 78. Movement of resilient surface 82 at inner end 72 due to movement of the carina region 52 is transmitted by fluid 78 to resilient surface 84 at outer end 74. To assist in locating inner end 72 of tubular member 8 on the carina region, collapsible locating fingers 86 are provided. Fingers 86 are movable between a collapsed position shown in Figure 7a and an extended position shown in Figure 7b. In the collapsed position, fingers 86 are aligned with the side walls of tubular member 8 to facilitate insertion through endotracheal tube 50 and the trachea. In the extended position, fingers 86 are positioned to engage the carina region to maintain resilient surface 82 on the carina region.

[0034] Fingers 86 are movable between the collapsed and extended positions by hydraulic pressure created by withdrawing fluid 78 from or injecting fluid 78 into the interior of tubular member 8. The inner and outer ends of tubular member 8 are formed as collapsible bulbs 77 and 79 that include resilient surfaces 82 and 84. A syringe 87 with check valve 19 communicates with the interior of tubular member 8 via line 87' to withdraw or inject fluid to collapse or inflate the bulbs. At inner end 72, bulb 77 acts to bias fingers 86 between the collapsed and extended positions.

[0035] As best shown in Figure 5, resilient surface 84 of outer end 74 of tubular member 8 is positioned against sensor 90 which is mounted to carriage 66 by resilient lines 87. Any movement of resilient surface 82 at inner end 72 of member 8 is transmitted by fluid 78 to resilient surface 84 for detection by sensor 90. In Figure 5, sensor 90 comprises an accelerometer to measure the acceleration and velocity of resilient surface 84 in response to movement of resilient surface 82 at the carina region. Alternatively, as shown in Figure 5a, sensor 90 can be a pressure transducer mounted directly to the end of tubular member 8 to replace bulb 84 and to detect pressure changes at the inner end 74.

[0036] In the arrangement of the second embodiment, it is also possible to include an additional sensor 94 mounted to the rigid side walls of tubular member 8 to detect acoustic energy transmitted through the side walls of the tubular member by the beating heart. In this manner, the sounds associated with cardiac function can also be recorded.

[0037] The various sensors 90 and 94 of the second embodiment are connectable via data lines 90' and 94' to the data acquisition unit shown in Figure 9 for analysis and display of the collected data relating to cardiac function. As best shown in Figure 4 and 8, housing 60 is provided with ports 96 to permit syringe line 87' and data

lines 90' and 94' to extend from the interior of housing 60 to the exterior. Syringe line 87' connects to syringe 87 via check valve 19.

[0038] Using the apparatus of the second embodiment involves lubricating endotracheal tube 50 with a water soluble gel and intubating the subject in a conventional manner. When cuff 51 is well within the trachea and within a few centimeters of the carina, the cuff is inflated by syringe 87. Tubular member 8 is positioned within housing 60 using handle 73. Figure 8 shows the apparatus prior to insertion of tubular member 8 into endotracheal tube 50 with fingers 86 in the collapsed position. Tubular member 8 is inserted through endotracheal tube via port 55. The inner end 72 of tubular member 8 is pushed forward until the end exits the endotracheal tube about 2cm at which point the endotracheal tube 50 is connected to tubular port 61 of housing 60. Fluid 78 is injected into tubular member 8 by syringe 87 via line 87' resulting in fingers 86 separating. Clamps 65 controlling lines 67 are slowly released and movable carriage 66 is moved by the biasing force of elastic lines 69 to carry tubular member 8 into engagement with the carina region. Resilient surface 82 of tubular member 8 abuts the carina while fingers 86 contact the sides of the carina region to assure proper positioning. Global movement of the heart is transmitted by the carina to the resilient surface 82. As the carina moves in response to the forces of the heart, resilient membrane 82 transmits its acceleration and deceleration through fluid 78 to resilient surface 84 at outer end 74. Accelerometer 90 is elastically attached and outputs to the data acquisition unit. An additional accelerometer sensor 94 having a higher frequency response outputs the acoustic energy received through the rigid walls 76 of tubular member 8. This sound energy is fed to the data acquisition system via data line 94'.

[0039] When using the apparatus of the present invention, certain body positions are preferable for optimal recording of cardiac functions as follows:

- 1) Head bent slightly towards the chest. This position frees the trachea for movement.
- 2) Diaphragm pushed upwards. This position forces the heart against the bronchus for better transmission.
- 3) Sitting Position with the feet placed up on a rail 4" higher than chair. This position compresses the diaphragm. The head is preferably bent towards the chest to free the trachea for movement.
- 4) Supine Position
- 5) On back with cushion under head inflated bag around abdomen with knees up.
- 6) Decubitus Position - legs folded against abdo-

men.

[0040] Although the present invention has been described in some detail by way of example for purposes of clarity and understanding, it will be apparent that certain changes and modifications may be practised within the scope of the appended claims.

Claims

1. Apparatus for assessing cardiac function in a subject comprising:

a probe (4) insertable and supportable in the trachea for transmitting movement of the trachea in response to cardiac function through the probe (4);
a sensor (40) for detecting the transmitted movement of the trachea and generate a signal indicative of the movement of the trachea; and
a signal processing unit (45) for receiving the signal from the sensor (40) and generating a waveform signal characteristic of the cardiac function.

2. Apparatus as claimed in claim 1 in which the probe is a hollow tube (4) having an internal passage to deliver air to the subject and whereby movement of the hollow tube (4) serves to transmit the movement of the trachea.
3. Apparatus as claimed in claim 2 including a flexible support (14, 16) extendable from the tube to engage the trachea and suspend the tube (4) within the trachea for movement of the tube (4) along the longitudinal axis of the tube (4).
4. Apparatus as claimed in claim 2 including a rigid anchor extendable (30) from the tube (4) for engaging the trachea and transmit movement of the trachea in response to cardiac function to the tube.
5. Apparatus as claimed in claim 3 in which the flexible support comprises at least two spaced, inflatable cuffs (14, 16) extending about the tube (4), each cuff (14, 16) being inflatable from a collapsed position against the tube (4) to an inflated position with the trachea or mouth region of the subject.
6. Apparatus as claimed in claim 1 including an endotracheal tube for housing the probe.
7. Apparatus as claimed in claim 6 in which the probe (4) comprises a tubular member (8) having an inner end adapted to protrude from the endotracheal tube (50) and engage against the carina region (52) at which the trachea bifurcates into the lungs and an

outer end supported in a mounting structure for positioning the inner end against the carina region (52).

8. Apparatus as claimed in claim 7 in which the tubular member (8) has substantially rigid side walls (76) defining a sealed interior filled with a fluid communicating the inner and outer ends (72, 74).
9. Apparatus as claimed in claim 8 in which the side walls of the tubular member (8) include a bendable region (80) to accommodate curvature of the trachea.
10. Apparatus as claimed in claim 8 in which the inner and outer ends (72, 74) include resilient surfaces that communicate via the sealed interior whereby movement of the resilient surface at the inner end due to movement of the carina region (52) is transmitted by the fluid to the resilient surface at the outer end.
11. Apparatus as claimed in claim 10 in which the inner end (72) includes collapsible locating fingers (86) movable between a collapsed position aligned with the side walls of the tubular member to facilitate insertion through the endotracheal tube and an extended position to grip the carina region (52) to maintain the resilient surface at the inner end in engagement on the carina region.
12. Apparatus as claimed in claim 11 in which the collapsible fingers (86) are moved between the collapsed and extended positions by withdrawing fluid from or injecting fluid into, respectively, the interior of the tubular member.
13. Apparatus as claimed in claim 11 including a syringe communicating with the interior of the tubular member to withdraw or inject fluid.
14. Apparatus as claimed in claim 10 in which the resilient surface at the outer end engages the sensor (90).
15. Apparatus as claimed in claim 14 in which the sensor (90) comprises an accelerometer which detects acceleration of the resilient surface.
16. Apparatus as claimed in claim 14 in which the sensor (90) comprises a pressure transducer which detects pressure changes at the resilient surface.
17. Apparatus as claimed in claim 14 including an acoustic sensor (94) associated with the tubular member to detect acoustic energy transmitted through the side walls of the tubular member.

18. Apparatus as claimed in claim 10 in which the mounting structure includes a movable carriage to support the outer end of the tubular member for movement of the tubular member to bias the resilient surface at the inner end against the carina region (52). 5
19. Apparatus according to claim 2, in which the second end of the tube (4) is adapted to be connected to a ventilator unit. 10
20. Apparatus according to claim 1, in which the sensor (40) is an accelerometer positioned to sense the acceleration and velocity of the tube. 15
21. Apparatus as claimed in claim 4 in which the rigid anchor comprises a hinged flange (30) pivotable between a folded position against the tube and a radially expanded position extending between the tube (4) and the trachea. 20
22. Apparatus as claimed in claim 21 in which the hinged flange (30) includes an inflatable bladder (34) positioned between the tube (4) and the flange (30) such that inflation of the bladder (34) moves the flange (30) to the expanded position and deflation of the bladder (34) moves the flange (30) to the folded position. 25
23. Apparatus according to one of the preceding claims in which the signal processing unit (45) includes: 30
- an amplifier to amplify the signal from the accelerometer;
 - a digitizer to digitize the amplified signal;
 - a signal analysis unit to analyze the amplified signal and generate the waveform signal characteristic of the cardiac function; and
 - a display to show the waveform signal. 35
24. Apparatus according to claim 2 including a retainer member attachable to the second end of the tube (4) to assist in maintaining the position of the tube (4) in a subject. 40
25. Apparatus as claimed in claim 24 in which the retainer member comprises a strap attachable to the tube (4) adjacent the second end and extendable about the neck of the subject. 45
26. Apparatus according to claim 1, in which the probe is a tube (4) and is insertable into the mouth of a subject such that a first end extends into the trachea and a second end protrudes from the mouth. 50

Patentansprüche

1. Gerät zur Bestimmung der Herzfunktion in einer Person, umfassend:
 - eine in der Trachea einführbare und festmachbare Sonde (4) zur Übertragung der Bewegung der Trachea als Reaktion auf die Herzfunktion durch die Sonde (4);
 - einen Sensor (40) zum Erfassen der übertragenen Bewegung der Trachea und zum Erzeugen eines die Bewegung der Trachea anzeigenden Signals; und
 - eine Signalverarbeitungseinheit (45) zum Empfangen des Signals vom Sensor (40) und zum Erzeugen eines für die Herzfunktion kennzeichnenden Wellensignals.
2. Gerät nach Anspruch 1, in dem die Sonde eine Hohlröhre (4) mit einem inneren Durchgang ist, durch den Luft zu der Person befördert wird und wobei die Bewegung der Hohlröhre (4) dazu dient, die Bewegung der Trachea zu übertragen.
3. Gerät nach Anspruch 2, das eine flexible Halterung (14, 16) besitzt, welche von der Röhre ausgefahren werden kann, um eine Verbindung mit der Trachea einzugehen und damit die Röhre (4) innerhalb der Trachea zur Bewegung der Röhre (4) entlang der Längsachse der Röhre aufgehängt werden kann.
4. Gerät nach Anspruch 2, einen starren Anker (30) umfassend, der von der Röhre (4) ausgefahren werden kann, um eine Verbindung mit der Trachea einzugehen und die Bewegung der Trachea als Reaktion auf die Herzfunktion auf die Röhre zu übertragen.
5. Gerät nach Anspruch 3, bei dem die flexible Halterung mindestens zwei beabstandete, aufblasbare Manschetten (14, 16) umfasst, die sich um die Röhre (4) erstrecken, wobei jede Manschette von einer schlaffen Position gegen die Röhre (4) in eine aufgeblasene Position im Trachea- oder Mundbereich der Person aufgeblasen werden kann.
6. Gerät nach Anspruch 1, das einen Endotrachealtubus zur Unterbringung der Sonde besitzt.
7. Gerät nach Anspruch 6, wobei die Sonde (4) ein Röhrenelement (8) besitzt, von dem ein Innenende so ausgeführt ist, dass es von der Endotrachealröhre (50) vorragt und eine Verbindung mit dem Carina-Bereich (52) eingeht, wo sich die Trachea in die Lungen hinein gabelt, und ein Außenende in einer Befestigungsstruktur gehalten wird, um das Innenende in Verbindung gegen den Carina-Bereich (52) zu positionieren.

8. Gerät nach Anspruch 7, wobei das Röhrenelement (8) im Wesentlichen starre Seitenwände (76) besitzt, die einen abgeschlossenen Innenraum begrenzen, der mit einem Fluid gefüllt ist, welches das Innen- mit dem Außenende (72, 74) verbindet. 5
9. Gerät nach Anspruch 8, wobei die Seitenwände des Röhrenelements (8) einen biegsamen Bereich (80) umfassen, der dazu dient, die Biegung der Trachea aufzunehmen. 10
10. Gerät nach Anspruch 8, bei dem die Innen- und Außenenden (72, 74) elastische Oberflächen besitzen, die über den abgeschlossenen Innenraum miteinander kommunizieren, wobei die Bewegung der elastischen Oberfläche am Innenende infolge der Bewegung des Carina-Bereichs (52) durch das Fluid auf die elastische Oberfläche am Außenende übertragen wird. 15
11. Gerät nach Anspruch 10, bei dem das Innenende (72) einziehbarer Lokalisierungsfinger (86) besitzt, die zwischen einer eingezogenen Position in Anpassung an die Seitenwände des Röhrenelements zur Ermöglichung des Einführens durch die Endotrachealröhre und einer ausgefahrenen Position zum Ergreifen des Carina-Bereichs (52), um die elastische Oberfläche am Innenende in Verbindung mit dem Carina-Bereich zu halten, gewechselt werden können. 20
12. Gerät nach Anspruch 11, bei dem die einziehbaren Finger (86) zwischen der eingezogenen und der ausgefahrenen Position gewechselt werden, indem Fluid aus dem Innenraum des Röhrenelements entnommen bzw. in diesen eingespritzt wird. 25
13. Gerät nach Anspruch 11, das eine Spritze besitzt, die mit dem Innenraum des Röhrenelements in Kommunikationsverbindung steht, um Fluid zu entnehmen oder einzuspritzen. 30
14. Gerät nach Anspruch 10, bei dem die elastische Oberfläche am Außenende Verbindung mit dem Sensor (90) aufnimmt. 35
15. Gerät nach Anspruch 14, bei dem der Sensor (90) einen Beschleunigungsmesser umfasst, der die Beschleunigung der elastischen Oberfläche erfasst. 40
16. Gerät nach Anspruch 14, bei dem der Sensor (90) einen Druckwandler besitzt, der Druckänderungen an der elastischen Oberfläche erfasst. 45
17. Gerät nach Anspruch 14, das einen akustischen Sensor (94) umfasst, der mit dem Röhrenelement verbunden ist, um die akustische Energie zu erfassen, die durch die Seitenwände des Röhrenelements übertragen wird. 50
18. Gerät nach Anspruch 10, bei dem die Befestigungsstruktur einen beweglichen Träger besitzt, der dazu dient, das Außenende des Röhrenelements zur Bewegung des Röhrenelements zu halten, um die elastische Oberfläche am Innenende gegen den Carina-Bereich (52) zu drücken. 55
19. Gerät nach Anspruch 2, bei dem das zweite Ende der Röhre (4) so ausgeführt ist, dass es mit einer Ventilatereinheit verbunden werden kann.
20. Gerät nach Anspruch 1, bei dem der Sensor (40) ein Beschleunigungsmesser ist, der so angeordnet ist, dass er die Beschleunigung und die Geschwindigkeit der Röhre erfasst.
21. Gerät nach Anspruch 4, bei dem der starre Anker einen klappbaren Flansch (30) umfasst, der zwischen einer anliegenden Position an der Röhre und einer radial ausgefahrenen Position zwischen der Röhre (4) und der Trachea schwenkbar ist.
22. Gerät nach Anspruch 21, bei dem der klappbare Flansch (30) eine aufblasbare Blase (34) besitzt, die zwischen der Röhre (4) und dem Flansch (30) dermaßen positioniert ist, dass das Aufblasen der Blase (34) den Flansch (30) in die ausgefahrene Position versetzt, und das Auslassen der Blase (34) den Flansch (30) in die anliegende Position versetzt.
23. Gerät nach einem der vorangehenden Ansprüche, bei dem die Signalverarbeitungseinheit (45) Folgendes umfasst:
einen Verstärker zum Verstärken des Signals vom Beschleunigungsmesser;
einen Digitalisierer zum Digitalisieren des verstärkten Signals;
eine Signalanalyseeinheit zum Analysieren des verstärkten Signals und Generieren des für die Herzfunktion kennzeichnenden Wellensignals; und
ein Display zur Anzeige des Wellensignals.
24. Gerät nach Anspruch 2, umfassend ein Halteelement, das am zweiten Ende der Röhre (4) festgemacht werden kann, um zur Erhaltung der Position der Röhre (4) in einer Person beizutragen.
25. Gerät nach Anspruch 24, bei dem das Halteelement einen Riemen umfasst, der angrenzend an das zweite Ende an der Röhre (4) festgemacht und um den Hals der Person gelegt werden kann.
26. Gerät nach Anspruch 1, bei dem die Sonde eine

Röhre (4) ist, die in den Mund einer Person dermaßen eingeführt werden kann, dass sich ein erstes Ende in die Trachea erstreckt und ein zweites Ende aus dem Mund heraus ragt.

Revendications

1. Dispositif pour évaluer la fonction cardiaque chez un sujet comprenant :

une sonde (4) qui peut être insérée et soutenue dans la trachée pour transmettre un mouvement de la trachée en réponse à une fonction cardiaque au travers de la sonde (4) ;
un capteur (40) pour détecter le mouvement transmis de la trachée et générer un signal indicateur du mouvement de la trachée ; et
une unité de traitement du signal (45) pour recevoir le signal provenant du capteur (40) et générer un signal de forme d'onde caractéristique de la fonction cardiaque.

2. Dispositif selon la revendication 1, dans lequel la sonde est un tube creux (4) ayant un passage interne pour délivrer de l'air au sujet et de sorte que le mouvement du tube creux (4) serve à transmettre le mouvement de la trachée.

3. Dispositif selon la revendication 2, comprenant un support flexible (14, 16) qui peut s'étendre depuis le tube pour s'engager dans la trachée et suspendre le tube (4) dans la trachée pour le mouvement du tube (4) le long de l'axe longitudinal du tube (4).

4. Dispositif selon la revendication 2, comprenant un ancrage rigide qui peut s'étendre (30) depuis le tube (4) pour s'engager dans la trachée et transmettre un mouvement de la trachée en réponse à une fonction cardiaque au tube.

5. Dispositif selon la revendication 3, dans lequel le support flexible comprend au moins deux ballonnets espacés gonflables (14, 16) s'étendant autour du tube (4), chaque ballonnet (14, 16) étant gonflable à partir d'une position dégonflée contre le tube (4) vers une position gonflée avec la trachée ou la région de la bouche du sujet.

6. Dispositif selon la revendication 1, comprenant un tube endotrachéal pour abriter la sonde.

7. Dispositif selon la revendication 6, dans lequel la sonde (4) comprend un élément tubulaire (8) ayant une extrémité interne adaptée pour dépasser du tube endotrachéal (50) et s'engager contre la région de la carina (52) au niveau de laquelle la trachée bifurque dans les poumons et une extrémité exter-

ne supportée dans une structure de montage pour positionner l'extrémité interne contre la région de la carina (52).

- 5 8. Dispositif selon la revendication 7, dans lequel l'élément tubulaire (8) a des parois latérales sensiblement rigides (76) définissant un intérieur étanche rempli d'un fluide communiquant avec les extrémités interne et externe (72, 74).

- 10 9. Dispositif selon la revendication 8, dans lequel les parois latérales de l'élément tubulaire (8) comprennent une région pliable (80) pour s'adapter à la courbe de la trachée.

- 15 10. Dispositif selon la revendication 8, dans lequel les extrémités interne et externe (72, 74) comprennent des surfaces élastiques qui communiquent via l'intérieur étanche de sorte que le mouvement de la surface élastique à l'extrémité interne, dû au mouvement de la région de la carina (52), soit transmis par le fluide vers la surface élastique au niveau de l'extrémité externe.

- 25 11. Dispositif selon la revendication 10, dans lequel l'extrémité interne (72) comprend des doigts de repérage dégonflables (86) mobiles entre une position dégonflée alignée avec les parois latérales de l'élément tubulaire pour faciliter une insertion au travers du tube endotrachéal et une position étendue pour saisir la région de la carina (52) pour maintenir la surface élastique à l'extrémité interne en prise sur la région de la carina.

- 30 12. Dispositif selon la revendication 11, dans lequel les doigts dégonflables (86) sont déplacés entre les positions dégonflées et étendues par retrait de fluide depuis l'intérieur de l'élément tubulaire ou par injection de fluide dans celui-ci, respectivement.

- 35 13. Dispositif selon la revendication 11, comprenant une seringue communiquant avec l'intérieur de l'élément tubulaire pour retirer ou injecter du fluide.

- 40 14. Dispositif selon la revendication 10, dans lequel la surface élastique à l'extrémité externe vient en prise avec le capteur (90).

- 45 15. Dispositif selon la revendication 14, dans lequel le capteur (90) comprend un accéléromètre qui détecte l'accélération de la surface élastique.

- 50 16. Dispositif selon la revendication 14, dans lequel le capteur (90) comprend un capteur de pression qui détecte les changements de pression sur la surface élastique.

- 55 17. Dispositif selon la revendication 14, comprenant un

capteur acoustique (94) associé à l'élément tubulaire pour détecter l'énergie acoustique transmise par les parois latérales de l'élément tubulaire.

18. Dispositif selon la revendication 10, dans lequel la structure de montage comprend un plateau mobile pour soutenir l'extrémité externe de l'élément tubulaire pour que le mouvement de l'élément tubulaire dévie de la surface élastique au niveau de l'extrémité interne contre la région de la carina (52). 5 10

19. Dispositif selon la revendication 2, dans lequel la seconde extrémité du tube (4) est adaptée pour être reliée à une unité de ventilateur. 15

20. Dispositif selon la revendication 1, dans lequel le capteur (40) est un accéléromètre positionné pour capter l'accélération et la vitesse du tube.

21. Dispositif selon la revendication 4, dans lequel l'ancrage rigide comprend un rebord articulé (30) pivotable entre une position repliée contre le tube et une position étendue radialement s'étendant entre le tube (4) et la trachée. 20 25

22. Dispositif selon la revendication 21, dans lequel le rebord articulé (30) comprend une vessie gonflable (34) positionnée entre le tube (4) et le rebord (30) de sorte que le gonflement de la vessie (34) déplace le rebord (30) vers la position étendue et que le dégonflement de la vessie (34) déplace le rebord (30) vers la position repliée. 30

23. Dispositif selon l'une des revendications précédentes, dans lequel l'unité de traitement du signal (45) comprend : 35

un amplificateur pour amplifier le signal provenant de l'accéléromètre ;
un numériseur pour numériser le signal amplifié ; 40
une unité d'analyse du signal pour analyser le signal amplifié et générer le signal de forme d'onde caractéristique de la fonction cardiaque ; et 45
un affichage pour montrer le signal de forme d'onde.

24. Dispositif selon la revendication 2, comprenant un élément de fixation attachable à la seconde extrémité du tube (4) pour aider à maintenir la position du tube (4) dans un sujet. 50

25. Dispositif selon la revendication 24, dans lequel l'élément de fixation comprend une lanière que l'on peut attacher au tube (4), adjacente à la seconde extrémité et qui peut s'étendre autour du cou du sujet. 55

26. Dispositif selon la revendication 1, dans lequel la sonde est un tube (4) et est insérable dans la bouche d'un sujet de sorte qu'une première extrémité s'étende dans la trachée et une seconde extrémité dépasse de la bouche.

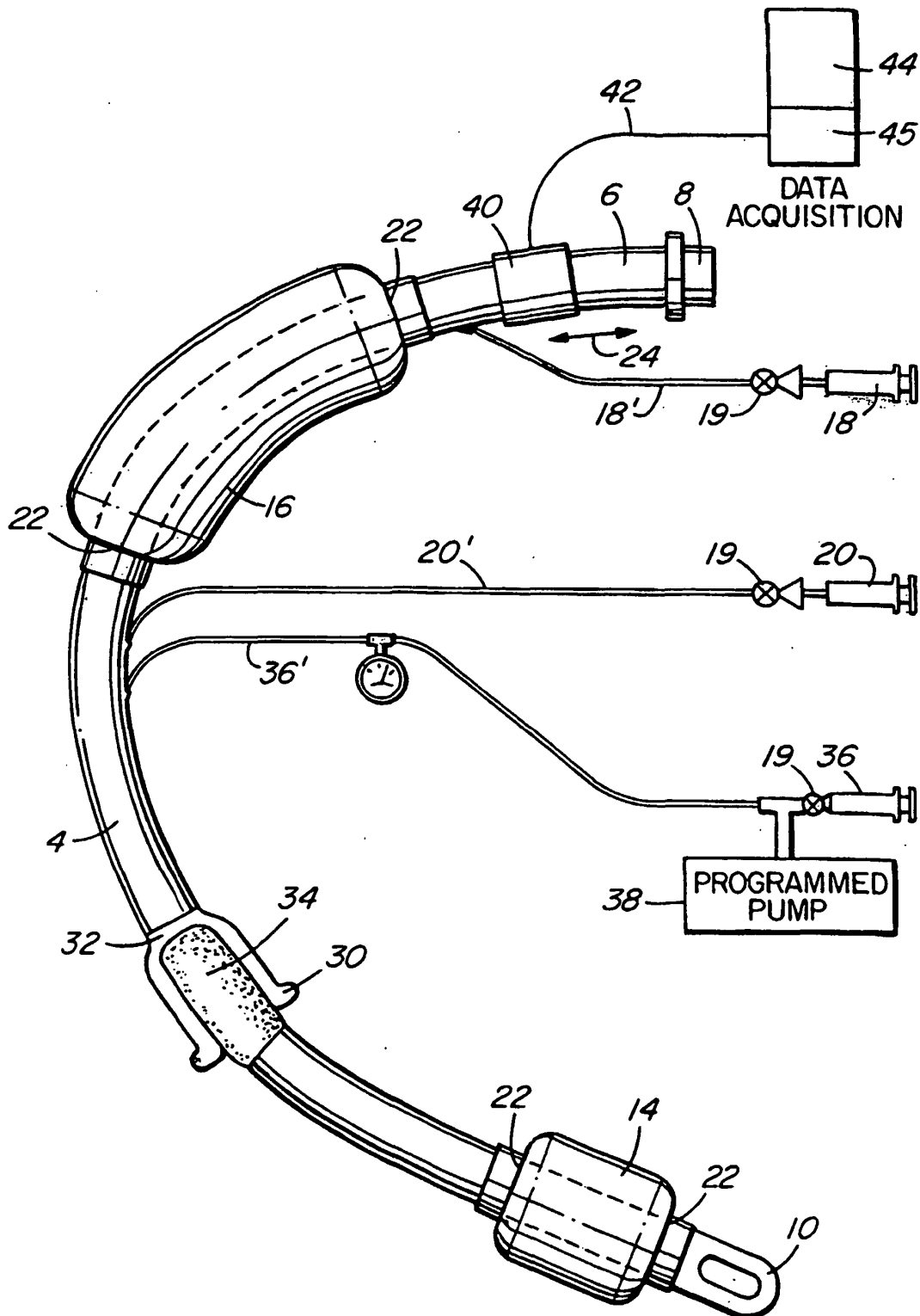


FIG. 1

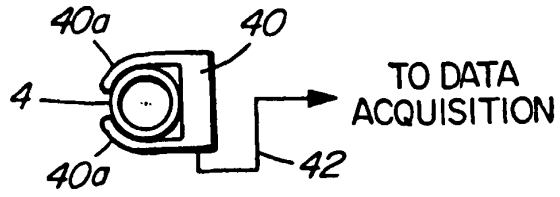


FIG. 1a

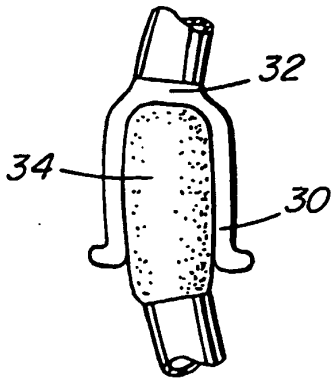


FIG. 2a

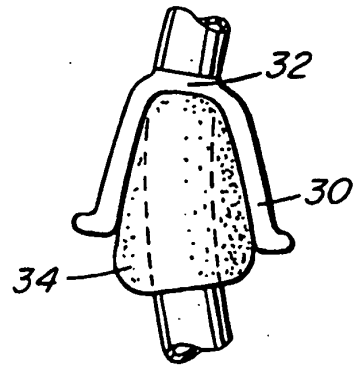


FIG. 2b

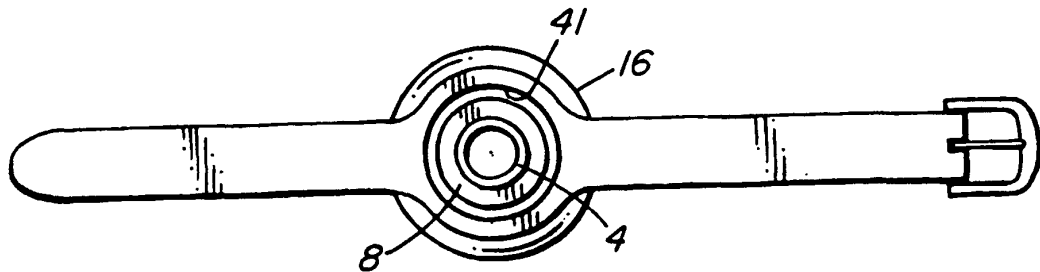
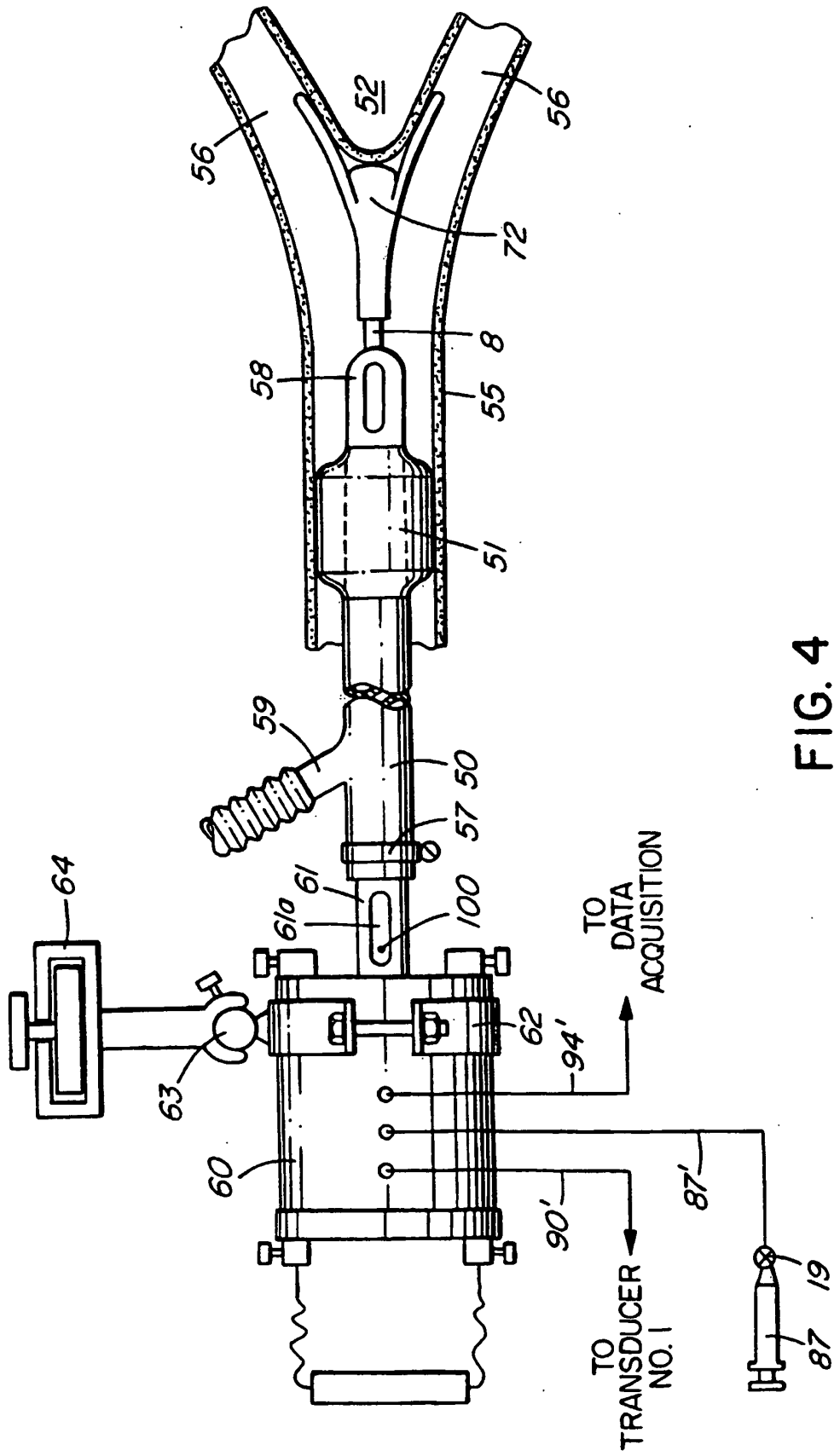


FIG. 3



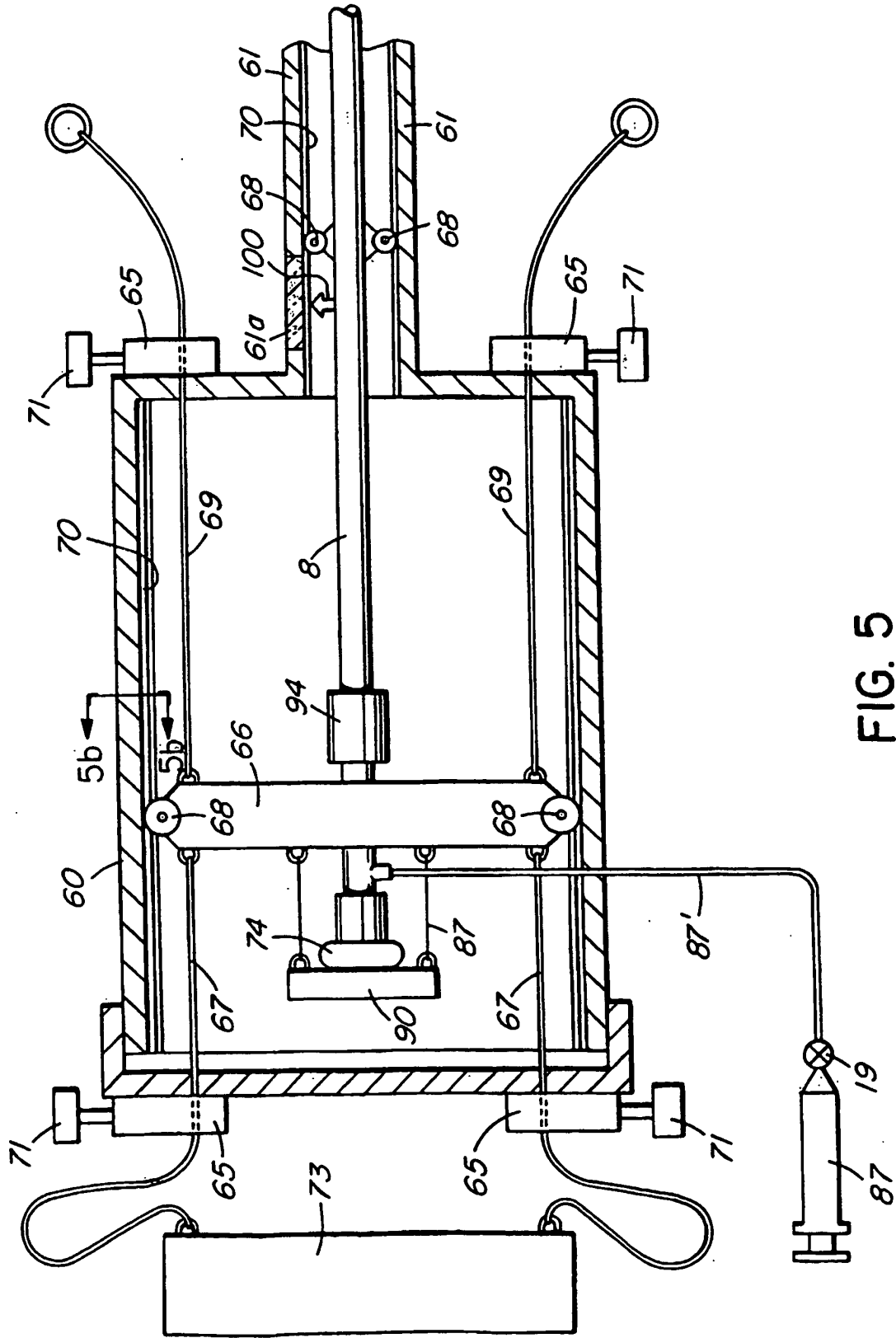


FIG. 5

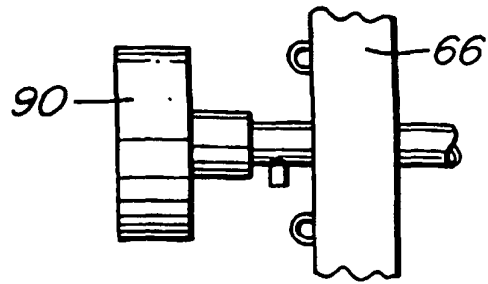


FIG. 5a

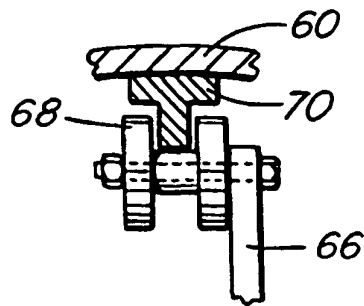


FIG. 5b

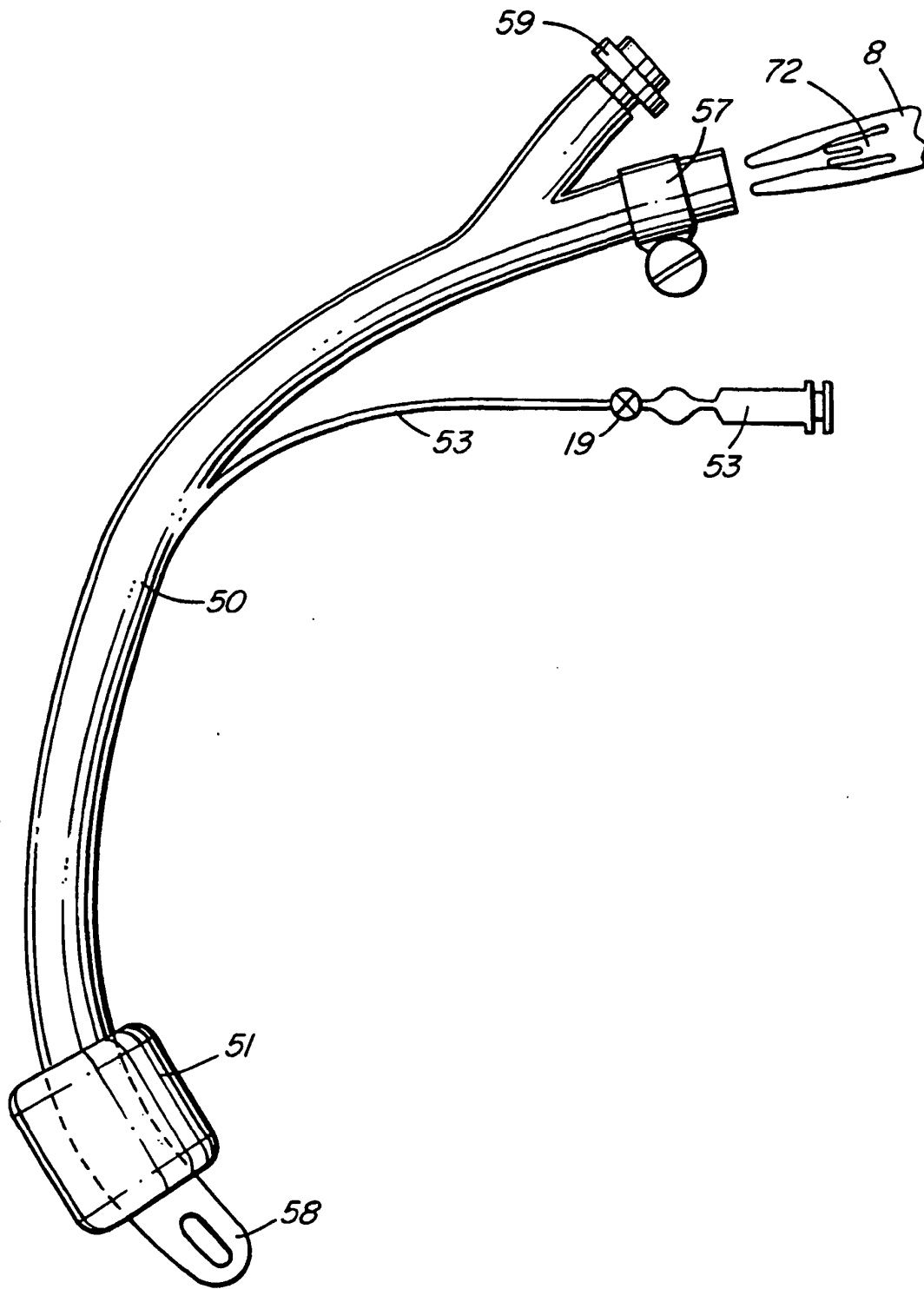


FIG. 6

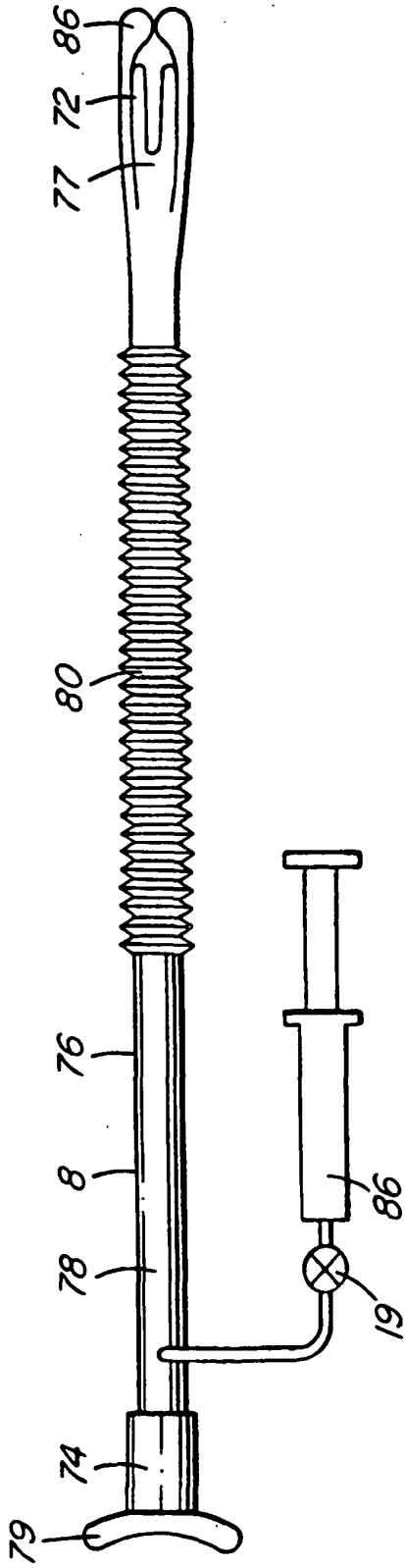


FIG. 7a

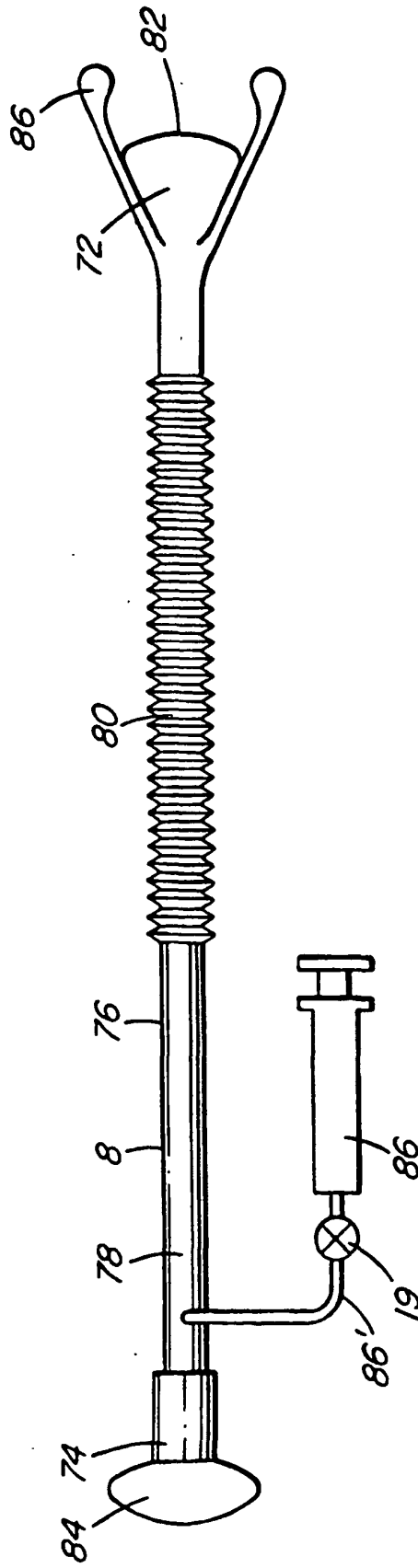


FIG. 7b

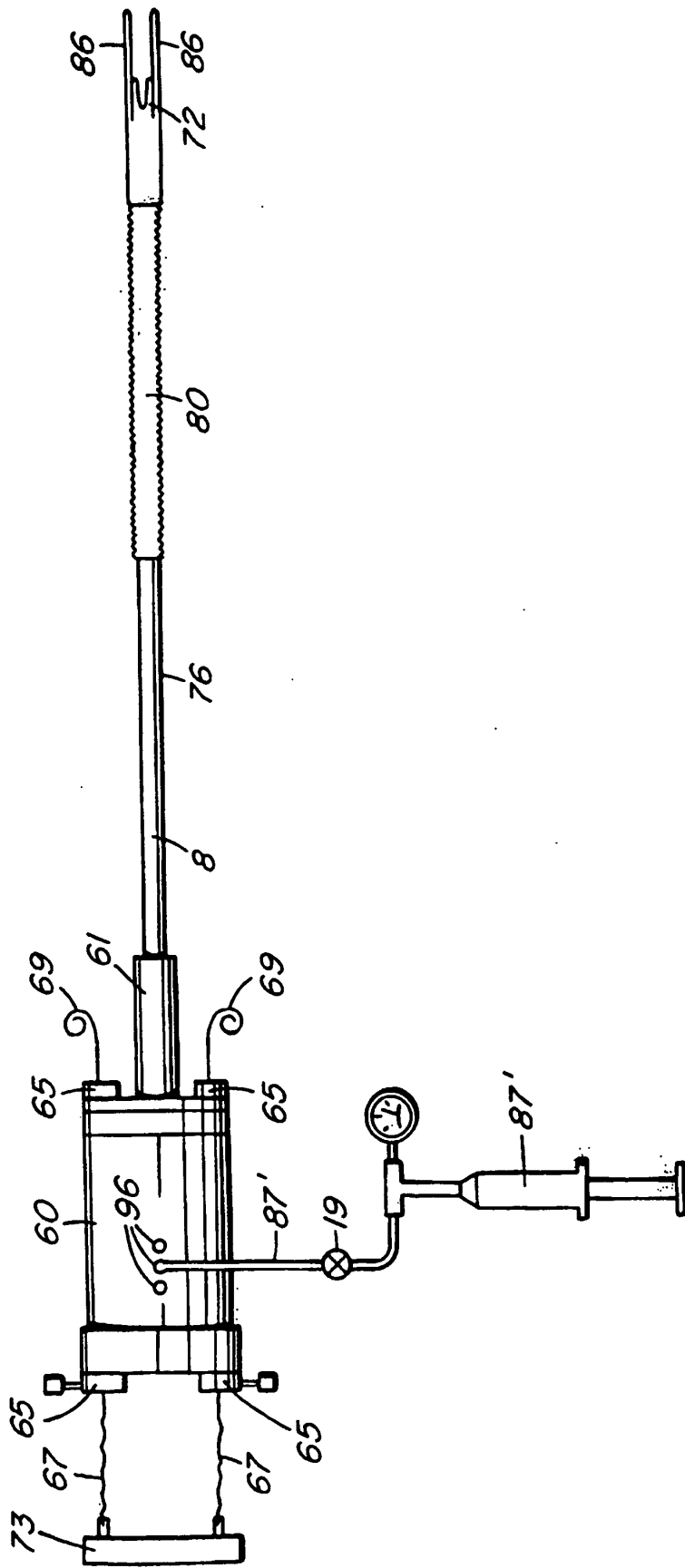


FIG. 8

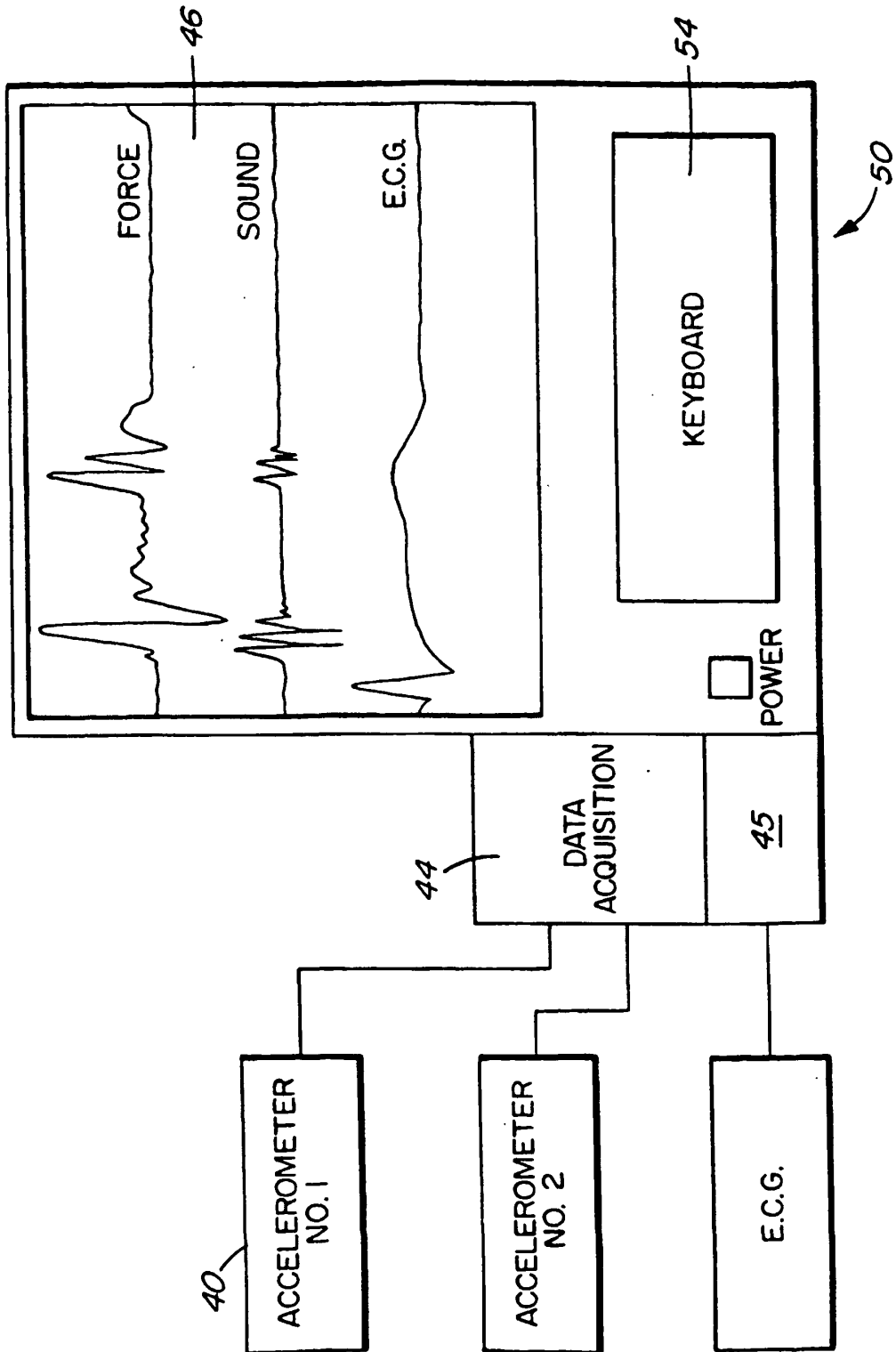


FIG. 9

专利名称(译)	通过监测气管运动来评估心脏功能的装置		
公开(公告)号	EP1361818B1	公开(公告)日	2005-11-09
申请号	EP2002710734	申请日	2002-02-05
[标]申请(专利权)人(译)	TEXON TECH		
申请(专利权)人(译)	TEXON TECHNOLOGIES LTD.		
当前申请(专利权)人(译)	TEXON TECHNOLOGIES LTD.		
[标]发明人	KOBLANSKI JOHN		
发明人	KOBLANSKI, JOHN		
IPC分类号	A61B5/00 A61B5/0205 A61B5/0402 A61B10/00 A61M16/04		
CPC分类号	A61B5/0205		
代理机构(译)	SPECHT , PETER		
优先权	09/791518 2001-02-22 US		
其他公开文献	EP1361818A1		
外部链接	Espacenet		

摘要(译)

评估受试者的心脏功能的方法和设备包括支撑气管中的探针以响应心脏功能传递气管的运动。传输的运动由产生波形信号的传感器检测。显示并评估波形信号以确定心脏功能。通过直接接合气管，本发明的装置和方法对气管的非常小的加速度，速度或位移敏感，以允许精确测量心脏功能。

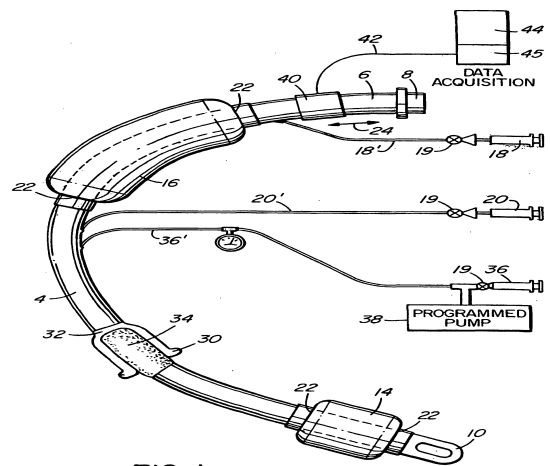


FIG. 1