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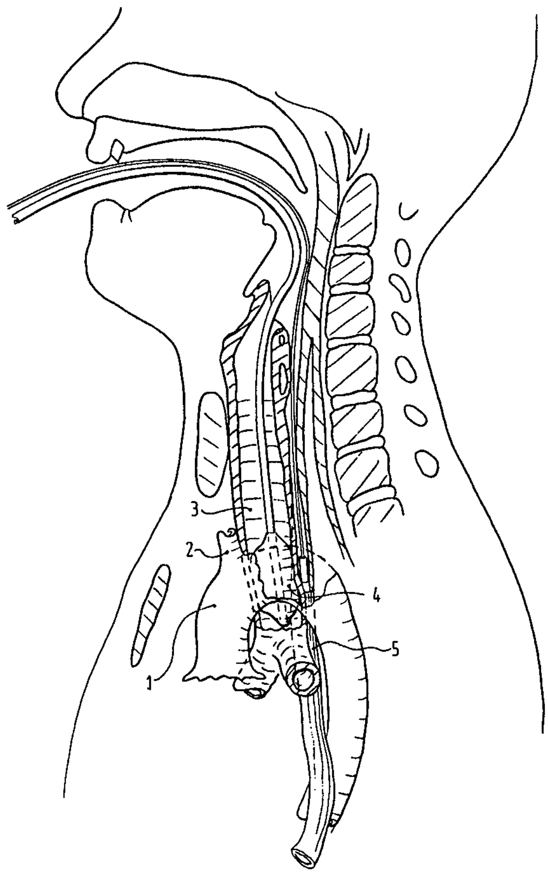
(54) Title: TRANSMISSION DEVICE FOR ULTRASONIC IMAGING SYSTEM

(57) Abstract

The invention relates to an ultrasonic imaging system (6) comprising in use two spacial separable devices: an ultrasound intra-esophageal endoscope device (7) for scanning a patient's organs (9), in particular for use in transesophageal echocardiography and an intratracheal transmission device (8) defining a transmission path for sound waves originating from the endoscope device. The invention further relates to a transmission device (8) specially adapted for use in association with an endoscope device (7) in an ultrasonic imaging system (6) comprising a flexible balloon member (13) connected to a supply line (10) for a sound wave transmission fluid medium.



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TRANSMISSION DEVICE FOR ULTRASONIC IMAGING SYSTEM

The invention relates to an ultrasonic imaging system comprising an ultrasound endoscope device for scanning a patient's organs, in particular for use in transesophageal echocardiography. Such a device specially adapted for transesophageal echographic scanning is for example disclosed in US-A-5,105,819.

Transesophageal echocardiography (TEE) has become a widely used imaging technique for evaluating cardiac structure, function, and valvular anatomy. Transesophageal echocardiography has also provided a new perspective on the thoracic aorta, and there is growing evidence that the technique contributes valuable and sometimes unique information about aortic structure and patholology.

Two-dimensional (2D) transesophageal echocardiography (TEE) and 2D intravascular ultrasound (IVUS) imaging face their greatest limitation in visualizing aortic disease in patients. Recently introduced multi-plane transesophageal probes have improved visualization of the proximal and transverse aorta. Three-dimensional (3D) image reconstruction, TEE and IVUS can even improve further visualization but still provide only limited spatial appreciation in aortic disease because 3D imaging of the thoracic aorta requires a broader spatial visualization of the mediastinum than provided by both techniques. Another approach called 3D lighthouse transesophageal echocardiography (LTEE) uses a thin intravascular ultrasound catheter, which provides a full circumferential (360 degree) image, but is invasive and cannot be used during cardiac surgery with cardio-pulmonary bypass.

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Also these three methods (3D, IVUS and LTEE) need special ultrasound equipment, which is not standard available.

The available evidence strongly supports the use of TEE in aortic dissection and atherosclerosis and suggests potential utility in additional diseases of the aorta such as aneurysm, ulceration, trauma, and congenital or inherited malformations.

The features of ultrasonic imaging systems cause main problems in visualization of certain organs in particular of the upper mediastinum, including the ascending aorta.

To understand these problems, it is important to know the physical limitations of ultrasound. Ultrasound consists of sound waves. The signal is determined by:

1. Frequency, f is determined by the generator.
2. Velocity, v is determined by the medium.
3. Wavelength, λ is the distance between two cycles of sound waves.

Absorption of sound waves is dependent of the medium. This is reflected as the half power distance: The distance in which half of the ultrasound energy will be absorbed. For water this is 360 cm, bone 0,2 cm and for air 0,06 cm. This means that nor bone nor air will not let through ultrasound waves in practice.

Consequently, the prior art does not achieve good imaging results, if air or bone are between the ultrasound source and the area which are to be investigated.

In providing a solution to this problem the invention is directed towards a ultrasonic imaging system as specified in claim 1.

Providing a separate transmission device at a distance of the ultrasound endoscope thus providing a transmission path suitable for sound waves originating from the endoscope device. Visualization will be surprisingly enhanced using a device according to the invention.

In a preferred embodiment of the invention the transmission device comprises a flexible housing for receiving a sound wave transmission fluid medium. As an example of such a sound wave transmission fluid water or a salt solution in minor concentrations is preferred.

A further preferred embodiment provides a transmission device which is formed by a distensible balloon member connected to a supply line to permit fluid entry in said balloon member.

According to another aspect of the invention a transmission device is provided which is specially adapted for use in association with an endoscope device in an ultrasonic imaging system comprising a flexible balloon member connected to a supply line for a sound wave transmission fluid medium.

Further the present invention is also directed towards the use of an ultrasonic imaging system according to claims 8 and 9 and to a method for ultrasonic scanning a patient's organs according to claims 10-12.

Embodiments of the present invention are described below by way of example only. In a preferred embodiment of the invention the ultrasonic imaging system according to the invention is directed to the use in transesophageal echocardiography. It will become apparent that not only a specialized doctor could use the ultrasonic imaging system according to the invention, but also a skilled technician.

Echocardiography was first used solely by cardiologist by the transthoracic approach in the awake patient. Visualization is sometimes difficult by the bone (sternum) and air (lung) structures between the echo probe and the heart. The development of the transesophageal echocardiography, this problem is largely avoided. The disadvantage is more patient discomfort in the awake situation. Now only small parts of the cardiac structures and surrounding tissues are still difficult or impossible to image by this way. Since TEE is an excellent way of monitoring cardiac function, other specialities, like cardiac anaesthesiologists started to use this technique. It is even so that nowadays cardiac anaesthesiologists are trained to use TEE in the perioperative period of cardiac surgery without the interference of the cardiologist. The advantage is that during surgery the patient is asleep, so discomfort is not a problem. During cardiac surgery, a patient is paralysed, intubated in the trachea and mechanically ventilated. If the patient is on cardiopulmonary bypass, the ventilation is stopped since there is no blood flowing through the lungs and oxygenation is provided by the heart lung machine. Placing the echoprobe into the trachea is technically possible but limits the echo investigation to the upper part of the mediastinum and does not evaluate the heart like with TEE, which is a standard technique perioperative.

Visualization by external transthoracic echocardiography is limited by the bone structures between the echoprobe and the ascending aorta. During heart surgery with a split sternum this problem is overcome by epi-aortic scanning. However only a part of the aorta is visualized, needs to be done by the surgeon during surgery and needs an additional echoprobe besides the TEE probe. Visualization by internal transesophageal echocardiography of the ascending aorta is limited by an air structure, i.e. the trachea and main left and right bronchii. By the anatomical location of the Aorta ascendens and the upper part of the main vascular side branches, it is difficult to view this area by TEE because the view is obstructed by the trachea. The trachea is located between the esophagus and the vascular tree, so all echoes are reflected by the trachea, which is filled with air.

A possible solution is to fill the trachea with a medium not containing air, but with a medium which will absorb ultrasound signal less, like water. In the normal patient, this is not possible, but in the anesthetized patient or a patient on extracorporeal bypass it is possible to stop ventilation for a certain period of time. Oxygenation can be maintained by preoxygenation to a safe period of 4 minutes. If the patient is on extra-corporeal circulation, this time-period is at least one hour. Filling the lungs completely with water is not possible, but introducing a transmission device into the trachea, like a balloon which can be filled and emptied from outside the patient, would allow ultrasound to travel through the tracheal structure without absorption. This would allow visualization of structures in front of the trachea.

After the patient is intubated there is an easy access route to the distal trachea. The average diameter is 1,7 cm, the average distance to occlude is maximum 10 cm. An inflatable balloon connected to a small extension tube with distally multiple holes allows easy insertion in the trachea. If the material is easily distensible, it will line up against the tracheal wall and might even fill up the right and/or left main bronchi. The trachea wall is not fully round and is vulnerable, so the material of the balloon must be flexible and there must be a possibility to monitor the pressure inside the device to prevent barotrauma of the trachea by overdistension of the balloon. This can be accomplished by a safety valve or pressure monitor at the end of the flexible extension tube. This extension line must be thin with a diameter of approximately 2-3 mm, stiff to allow easy insertion by the tracheal tube without chinking.

By the side holes in the tube water can be inserted in the balloon, so the balloon will distend and occlude the trachea. Air in the trachea will not obstruct TEE view and an view of the upper mediastinum will be obtained. After the TEE examination the water can be aspirated by suction on the tube and if empty, it is easily removed from the ventilation tube or directly out of the trachea.

Examples of clinical applications of the transmission device of the invention.

1. Aortic atherosclerosis.

In cardiac surgery, it is important to obtain information regarding the ascending aorta. Atherosclerosis of the cannulation site is an important source of emboli. It is just this area which is difficult to scan until now. By introducing the transmission device after induction of anesthesia with tracheal intubation, a first sceening of this area can be performed, also in non-cardiac situations. Surgical strategy can be altered if atherosclerosis is a fact, e.g. femoral artery cannulation, beating heart surgery without CPB, aortic arch replacement, et al.

2. Aortic dissection

Aortic dissection and its diagnosis are major clinical problem. Dissections can start at all sides of the aortic root. However the clinical treatment is dependent on the location and the extension of the rupture of the aortic wall. A rupture in the ascending or transverse aorta is treated by surgery, a dissection in the descending aorta by medication treatment. Also the extension of a dissection in the main branches of the aorta can be evaluated. This way of evaluation would allow a fast diagnosis, in contrast to Computer tomography or angiography, thus reducing time loss before surgery.

3. Carotid disease

In patients at risk for having atherosclerosis, a evaluation can be made during all forms of anesthesia, in order to evaluate carotid disease. Flow measurements can be made by doppler ultrasound.

4. Cardiac output monitoring.

The aortic arch will be viewed by crossectional view. To use the echodoppler feature of ultrasound, the moving object must be viewed within an angle of 30 degrees. By measuring the anatomical diameter and by measuring the blood flow, cardiac output can be calculated.

Without this device this can be performed by viewing the aortic valve by looking at this valve from the deep transgastric direction. This view is sometimes difficult to obtain, like by example during beating heart coronary artery bypass grafting.

5. Monitoring of flow and intravascular lines during CPB

The aortic CPB line will be inserted in the ascending aorta. Appropriate flow can be visualized.

During a Heartport procedure an intra-aortic balloon must be placed just above the aortic valve but below the truncus brachiocephalicus. The flow of all sections can be easily monitored now.

Intra aortic balloon counterpulsation is a device which is used a an assist device in cardiac failure. Flow patterns can be measured to optimize timing of balloon inflation and deflation in order to optimize the effectivity of this device.

6. Monitoring of embolism during surgery

7.Pulmonary embolism

The visualization of the left and right pulmonary artery is partially obstructed by the main bronchii. The blocker might allow this view.

The invention will hereunder be further elucidated with reference to the drawing wherein:

figure 1 is a schematic view of the anatomical location of the aorta, the trachea and the esophagus in relation to the system according to the invention;

figure 2 is a schematic view of an ultrasonic imaging system according to the invention; and

figure 3 is a perspective view of a preferred embodiment of a transmission device according to the invention.

As explained in the description visualization of the aorta ascendens 1 and the upper part of the main vascular side branches 2 is difficult to view because an obstruction of the trachea 3 disturbs the ultrasound waves originating from a echoprobe 4 in the esophagus 5. When a patient is intubated with a transmission device according to the invention, which normally consists of a distensible balloon connected to a supply line for a sound wave transmission fluid medium, a suitable sound wave path is formed for the sound waves originating from an ultrasound endoscope positioned in the esophagus 5. An optimal visualization of these parts of the aorta is thus obtained by a combined use of an endoscope device and a transmission device forming an ultrasonic imaging system according to the invention.

Figure 2 shows very schematically an ultrasonic imaging system 6 comprising an ultrasound endoscope 7 and a separate transmission device 8. When viewed with a target organ 9 ultrasound waves originating from the ultrasound endoscope 7 will have a suitable transmission path and where no such path is provided, for example in cavities with air, a separate tranmission device 8 is introduced in order to replace the air with a sound wave transmission fluid medium, such as water or a salt solution.

A separate transmission device 8 generally consists of a flexible, distensible balloon member 13 which is connected to a supply line 10 which supply line 10 is at its distal end provided with pump and pressure control means 11 and is further connected to a container 12 which is provided with the sound wave transmission fluid. The supply line 10 is provided with perforations 14 at the proximal end in the volume of the flexible balloon member 13. These perforations 14 permit filling and emptying the balloon 13 over the entire volume and no air inclusion will occur.

CLAIMS

1. Ultrasonic imaging system comprising in use two spacial separable devices: an ultrasound intra-esophageal endoscope device for scanning a patient's organs, in particular for use in transesophageal echocardiography and an intratracheal transmission device defining a transmission path for sound waves originating from the endoscope device.

2. Ultrasonic imaging system according to claim 1, wherein the transmission device comprises a flexible housing for receiving a sound wave transmission fluid medium.

3. Ultrasonic imaging system according to claim 1 or 2, wherein the transmission device is formed by a distensible balloon member connected to a supply line to permit fluid entry in said balloon member.

4. Ultrasonic imaging system according to claim 3, wherein the supply line is provided with side perforations in order to fill and empty the balloon over its entire length.

5. Ultrasonic imaging system according to any of the previous claims 1-4, wherein pressure control means are provided for controlling the pressure inside the transmission device.

6. Ultrasonic imaging system according to any of the previous claims 1-5, further comprising positioning means for determining the position of the transmission device.

7. Transmission device specially adapted for use in association with an endoscope device in an ultrasonic imaging system as claimed in any of the claims 1-6, comprising a flexible balloon member connected to a supply line for a sound wave transmission fluid medium.

8. Use of an ultrasonic imaging system according any of the previous claims in transesophageal echocardiography.

9. Use according to claim 8, for scanning upper mediastinum including the ascending aorta.

10. Method for ultrasonic scanning a patient's organs in particular in transesophageal echocardiography **characterized by** positioning a transmission device for sound waves into the transmission path for sound waves being emitted from an endoscope.

11. Method according to claim 9, wherein the transmission device is filled with a sound wave transmission fluid medium thereby displacing a volume of air.

12. Method according to claim 11, wherein the air volume to be replaced is situated in the trachea.

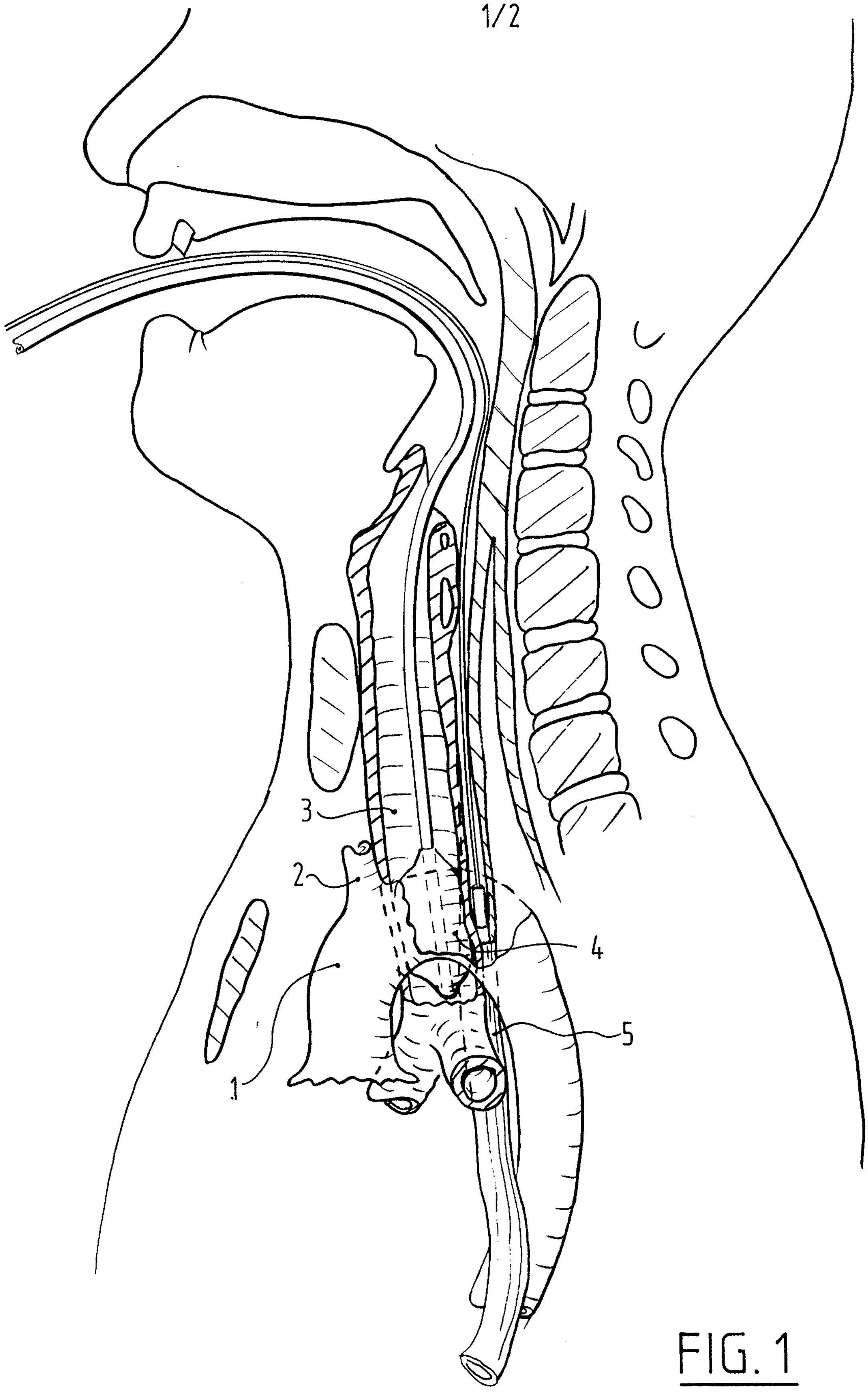

FIG. 1

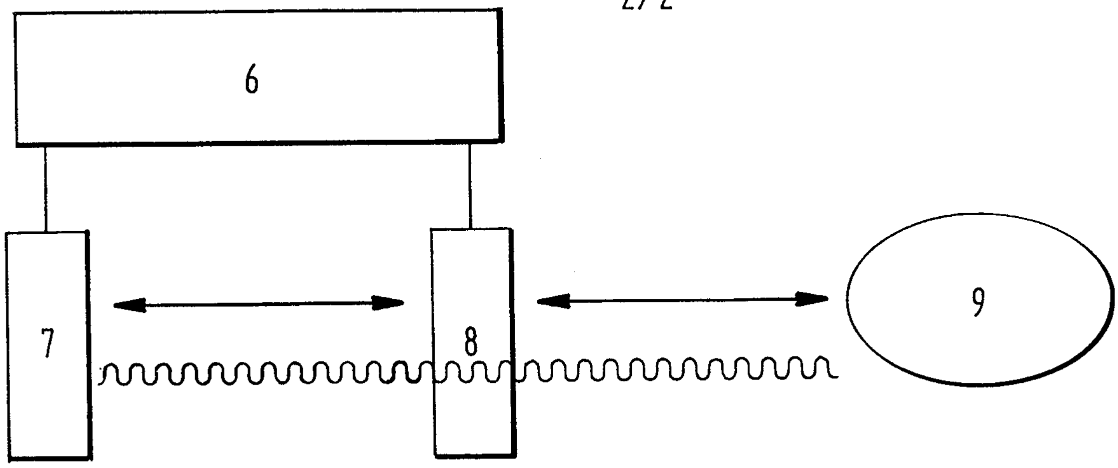

FIG. 2

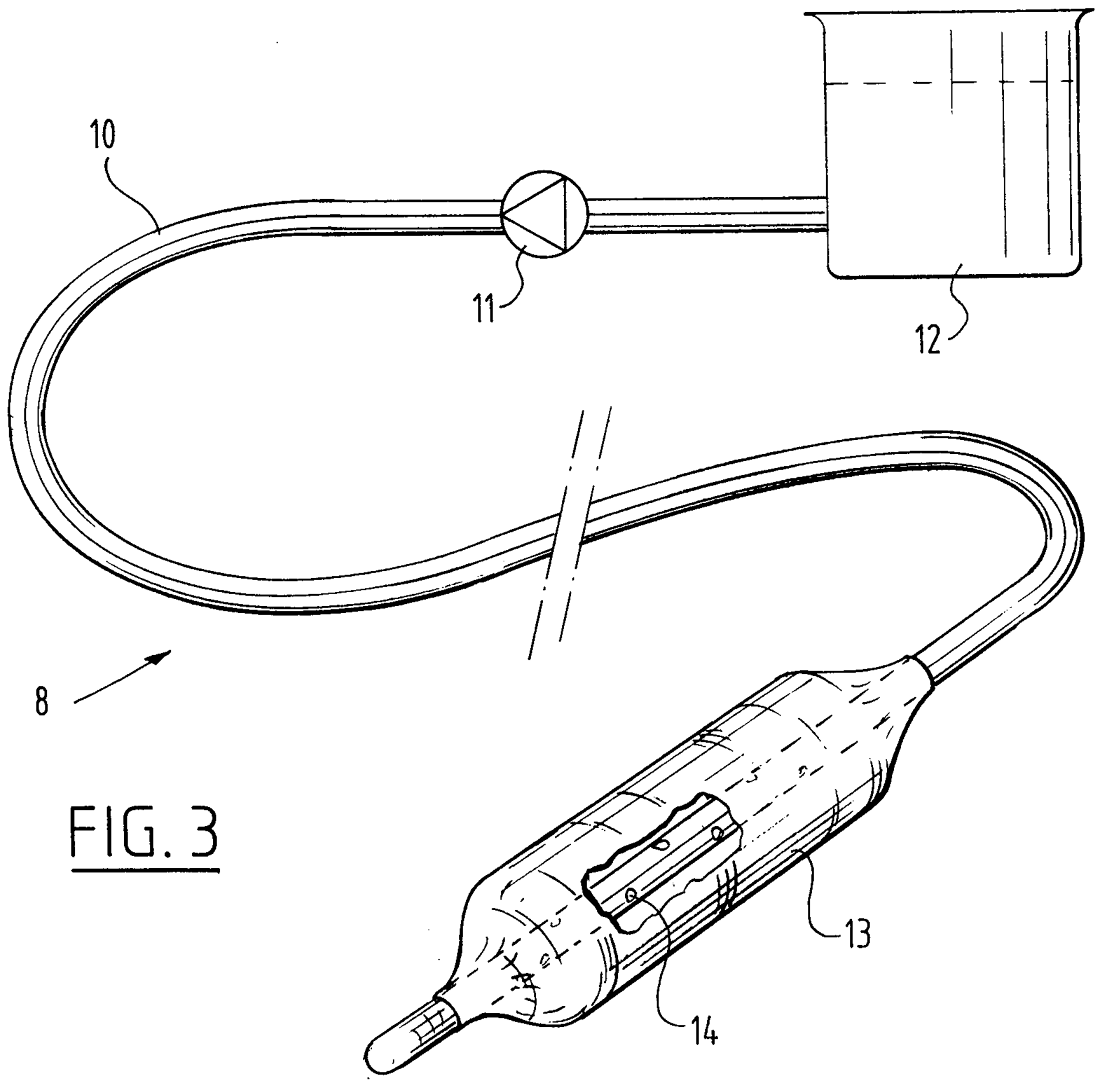

FIG. 3

INTERNATIONAL SEARCH REPORT

Intei ɔnal Application No
PCT/EP 00/02212

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B8/12 A61B5/03 A61B8/00

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)
IPC 7 A61B

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

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 190 046 A (LEONID SHTURMAN) 2 March 1993 (1993-03-02) column 1, line 11 - line 21 column 2, line 43 -column 4, line 22	1-3,5-7
A	WO 91 04708 A (HERBERT R. C. DRUE ET AL.) 18 April 1991 (1991-04-18) page 4, line 23 -page 6, line 21	1-3,5,7
A	US 4 349 033 A (ROBERT D. EDEN) 14 September 1982 (1982-09-14) column 2, line 28 - line 48 column 3, line 20 - line 23	1-5,7

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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