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(54) Title: A METHOD AND SYSTEM FOR ULTRASONIC IMAGING OF AN ORGAN IN A PATIENT'S BODY THROUGH A PART OF THE PATIENT'S RESPIRATORY TRACT

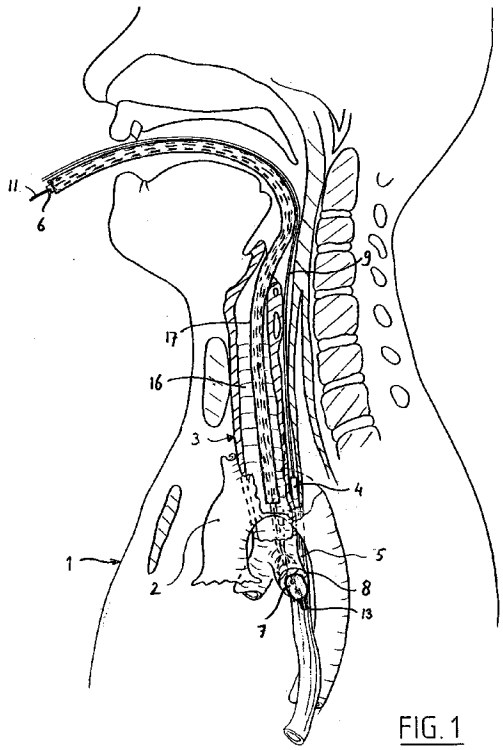


FIG. 1

(57) Abstract: The invention relates to a system for ultrasonic imaging of an organ in a patient's body through a part of the patient's respiratory tract, comprising an ultrasonic imaging device (4) to be arranged in or on the patient's body, a flexible catheter (6) carrying at least one inflatable member (7) to be arranged in the respiratory tract, means (10,11) for positioning the inflatable member at a predetermined location in the respiratory tract, and means for filling the inflatable member with an ultrasonic transmission fluid through the flexible catheter. The inflatable member can be positioned in the respiratory tract by manipulating guide means (10,11) that are attached to or integrated with the flexible catheter.

A METHOD AND SYSTEM FOR ULTRASONIC IMAGING OF AN ORGAN IN A PATIENT'S BODY THROUGH A PART OF THE PATIENT'S RESPIRATORY TRACT

The invention relates to a method for ultrasonic imaging of an organ in a patient's body through a part of the patient's respiratory tract, comprising the steps of:

- arranging an ultrasonic imaging device in or on the patient's body,
- introducing a flexible catheter carrying at least one inflatable member into the respiratory tract,
- positioning the inflatable member at a predetermined location in the respiratory tract,
- filling the inflatable member with an ultrasonic transmission fluid through the flexible catheter, and
- transmitting ultrasonic waves from the imaging device through the transmission fluid in the inflatable member to the organ to be imaged.

Such a method is known from WO 00/53098. This prior art document relates to an ultrasonic imaging method that is known as transesophageal echocardiography (TEE). TEE has become a widely used imaging technique for evaluating cardiac structure, function, and valvular anatomy. TEE 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 pathology.

TEE involves introducing an echo probe into the patient's esophagus and transmitting ultrasound waves across the thorax in the direction of the heart and aorta. However, visualization of the ascending aorta by internal TEE is limited by an air structure, i.e. the trachea and main left and right bronchi. This is due to an important physical

limitation of ultrasound: absorption of ultrasound waves. This absorption is dependent of the medium and expressed in terms of 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 in practice ultrasound waves will not travel through bone or air.

Unfortunately, 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.

In order to solve this problem, WO 00/53098 proposes the use of a balloon that may be arranged in the trachea or in one of the bronchi and that may be filled with an ultrasonic transmission fluid, e.g. water or a saline solution in minor concentrations. Obviously, this can only be done during operative surgery, when the patient is mechanically ventilated or on cardiopulmonary bypass, since in order to be effective the balloon has to completely fill and block the trachea or bronchus.

A problem which arises when trying to introduce the balloon in the left bronchus, which is the position of choice when visualizing the aorta ascendens, is that the flexible catheter carrying the balloon is hard to manipulate. Therefore, positioning the distal end of this flexible catheter in front of the left bronchus, so that the balloon may be lowered into that bronchus, is often a matter of trial and error. Since this positioning has to be performed during operative surgery, when timing is often critical, there is a clear need for an improved imaging method.

In accordance with the invention, this is achieved in a method for ultrasonic imaging as described above, wherein the inflatable member is positioned in the respiratory tract by manipulating guide means that are attached to or integrated with the flexible catheter. By providing the flexible catheter with dedicated guide means, its movement through the respiratory tract may be precisely controlled.

In a preferred variant of the method, the guide means are passive and comprise at least one stylet. Stylets are widely available and the skilled person is familiar with their operation.

The stylet may have a distal end which extends beyond the inflatable member and a proximal end which protrudes outside the patient's body, so that the inflatable member may be positioned in the respiratory tract by manipulating this proximal end.

In order to prevent the stylet from obstructing part of the area to be imaged from view, the stylet is preferably at least partially retracted before the ultrasonic waves are transmitted from the imaging device.

In that case, it is advantageous when the proximal end of the stylet protrudes from the catheter through a valve member, so that the stylet may be retracted after the inflatable member has been filled with the transmission fluid, without the risk of fluid leaking from the system.

In a preferred variant of the method of the invention the stylet is made from a resilient material and is preformed to conform substantially to the intended path of the catheter through the respiratory tract for positioning the inflatable member before being attached to or integrated with the flexible catheter. In this way the flexible catheter assumes the shape of the stylet. If the stylet and catheter are

partially guided through an endotracheal ventilation tube they will return to their slightly curved preformed shape when leaving that tube, after which the distal end of the catheter carrying the inflatable member may be easily directed to the left bronchus by manipulating the stylet.

In another variant of the method, on the other hand, the stylet is made from a deformable material and conforms substantially to the respiratory tract when the flexible catheter and inflatable member are introduced therein. In this way, the stylet and catheter will conform to the endotracheal tube through which they pass. After leaving the tube the material of the stylet will maintain the curved shape into which it was forced by the tube, so that the distal end of the catheter can again easily be guided to its predetermined position.

In yet another variant, the stylet is made from a resilient material and is substantially straight, so that after passing curved parts of the respiratory tract during introduction of the flexible catheter and inflatable member therein at least the distal end of the stylet and the catheter will run straight. In this way the distal end will be eccentric with respect to the endotracheal tube, which is somewhat curved. This again facilitates positioning of the distal end of the catheter and ultimately of the inflatable member.

It is also conceivable that a relatively short stylet is used, which is arranged between the inflatable member and a distal end of the catheter, in which case the inflatable member may be positioned in the respiratory tract by manipulating a proximal end of the flexible catheter. By using only such a short stylet, which will not obstruct the view through the inflatable member, there is no need to retract the stylet before imaging. Consequently, there is no

risk of any fluid leaking from the system, so that the valve member may be dispensed with. This short stylet may also be either straight or preformed in a suitable shape.

In yet another variant of the method of the invention the guide means are active and comprise at least one pull wire having a distal end that is eccentrically connected to the flexible catheter and a proximal end connected to a pulling member arranged outside the patient's body, and the inflatable member is positioned in the respiratory tract by manipulating the pulling member. The use of such a pull wire allows a very precise positioning of the distal end of the catheter carrying the inflatable member.

Although the wire could in principle run along the outside of the catheter, it is preferable to arrange the wire in the catheter, in which case its proximal end may protrude from the catheter through a valve member. In this way the system may be filled with fluid and vented with the wire in place, without the risk of leaking.

The guide means may include a plurality of pull wires that are spaced at least in peripheral direction of the catheter, each said pull wire being connected to a respective pulling member, so that the inflatable member may be positioned in the respiratory tract by selectively manipulating the various pulling members. In this way the catheter may be controlled in different directions.

The invention further relates to a system for ultrasonic imaging of an organ in a patient's body through a part of the patient's respiratory tract with which the above method may be performed. A prior art imaging system of this type, which is also disclosed in WO 00/53098, comprises:

- an ultrasonic imaging device arranged in or on the patient's body,

- a flexible catheter carrying at least one inflatable member to be arranged in the respiratory tract,

- means for positioning the inflatable member at a predetermined location in the respiratory tract, and

- means for filling the inflatable member with an ultrasonic transmission fluid through the flexible catheter.

The ultrasonic imaging system of the present invention is distinguished from this prior art system in that the positioning means comprise guide means that are attached to or integrated with the flexible catheter. These guide means allow the inflatable member carried by catheter to be swiftly and easily guided to its predetermined position.

In a first preferred embodiment of the ultrasonic imaging system of the invention the guide means may be passive and comprise at least one stylet. As stated above, the stylet may advantageously be arranged in the catheter and may have a distal end which extends beyond the inflatable member and a proximal end which protrudes from the catheter.

In a further development of this embodiment, the catheter may have a main lumen for filling the inflatable member with the ultrasonic transmission fluid, the stylet being arranged in this main lumen. In this way no structural modification of the catheter is required.

Alternatively, the catheter may have a main lumen for filling the inflatable member with the ultrasonic transmission fluid and an additional lumen for accommodating the stylet. This additional lumen avoids any interference between the introduction and withdrawal of the stylet on one hand and filling or emptying the catheter on the other.

In these embodiments the stylet may be slidably arranged in the catheter and its proximal end may protrude from the catheter through a valve member to prevent leakage, as explained above.

In yet another embodiment of the ultrasonic imaging system the catheter may have a main lumen for filling the inflatable member with the ultrasonic transmission fluid and the stylet may be fixedly arranged in a peripheral wall surrounding the main lumen. In this case a very thin stylet is used, which does not adversely affect the ultrasonic imaging in any substantial way.

Rather than a long stylet extending over the entire length of the catheter, the ultrasonic imaging system may include a short stylet, which may be arranged between the inflatable member and a distal end of the catheter. Since this stylet does not extend across the inflatable member, it will not interfere with the imaging. This short stylet may also be arranged either in the main lumen, in an additional lumen or in the peripheral wall of the catheter.

In this embodiment the distal end of the catheter preferably includes a tip that is shaped to facilitate positioning in the patient's left main bronchus and the stylet is adhesively fixed to the catheter tip. In this way the stylet and tip cooperate to allow the inflatable member to be optimally positioned.

In yet another embodiment of the ultrasonic imaging system of the invention the guide means are active and comprise at least one wire having a distal end that is eccentrically connected to the flexible catheter and a proximal end connected to a pulling member arranged outside the patient's body. Such a wire provides excellent guidance of the catheter with minimum obstruction of the image.

In order to provide optimum control the distal end of the pull wire is preferably connected to the flexible catheter near a distal end thereof.

When the catheter has a main lumen for filling the inflatable member with the ultrasonic transmission fluid and

the pull wire is arranged in the main lumen the system may be used with a minimum of structural modifications to the catheter.

In an alternative embodiment of the ultrasonic imaging system the catheter, which has a main lumen for filling the inflatable member with the ultrasonic transmission fluid, may have an additional lumen for accommodating the pull wire. In this way interference between the pull wire and the transmission fluid is minimized.

In order to prevent fluid leakage, the proximal end of the or each pull wire preferably protrudes from the catheter through a valve member.

In yet another embodiment of the system the catheter has a main lumen for filling the inflatable member with the ultrasonic transmission fluid and the pull wire is fixedly arranged in a peripheral wall surrounding the main lumen, so that no valve member is required.

When the ultrasonic imaging system comprises a plurality of pull wires having their distal ends eccentrically connected to the flexible catheter, the pull wires being spaced at least in peripheral direction of the catheter, the catheter may be controlled in different directions.

Finally, the invention relates to an assembly of a flexible catheter carrying at least one inflatable member positioning means for use in the ultrasonic imaging system as described above.

The invention will now be illustrated by way of some exemplary embodiments, reference being made to the annexed drawings, in which corresponding parts are identified by reference numerals increased by 100, and in which:

Fig. 1 is a partly sectional view of a patient's upper body showing the ultrasonic imaging system of the invention during visualization of an organ,

Fig. 2 is an overview of a first embodiment of the ultrasonic imaging system of the invention, including a full length stylet, showing the inflatable member filled with transmission fluid,

Fig. 3 is a detailed, enlarged scale view of the encircled area III in Fig. 2,

Fig. 4 is a schematic view on an exaggerated scale of the distal end of the flexible catheter according to the first embodiment of the invention,

Fig. 5 is a view corresponding with Fig. 4, but showing a second embodiment,

Fig. 6 is a view corresponding with Figs. 4 and 5 and showing a third embodiment,

Figs. 7A to 7C are cross-sectional views of the catheter, showing the various possibilities for accommodating the full length stylet,

Fig. 8 is a detailed, enlarged scale view of the distal end of the catheter in a fourth embodiment of the invention, including a short stylet,

Fig. 9 is an overview of a fifth embodiment of the ultrasonic imaging system of the invention, including a pull wire,

Fig. 10 is a detailed, enlarged scale view of the encircled area X in Fig. 9,

Fig. 11 is a detailed, enlarged scale view of the distal end of the catheter in the fifth embodiment, and

Figs. 12A and 12B are cross-sectional views of the catheter, showing the various possibilities for accommodating the pull wire.

A method for ultrasonic imaging of an organ in a patient's body 1, in particular the heart or the aorta 2, through a part of the patient's respiratory tract 3, comprises the following steps.

First an ultrasonic imaging device 4, for instance an echo probe, is arranged in or on the patient's body 1. In the shown embodiment, the echo probe 4, which is carried on a flexible catheter 9, is introduced into the patient's esophagus 5 (fig. 1). Then another flexible catheter 6 carrying an inflatable member 7 is introduced into the respiratory tract 3. The inflatable member 7 is positioned at a predetermined location in the respiratory tract 3. When the organ to be imaged is the ascending aorta 2, the predetermined position will be in the top part of the left bronchus 8.

In actual practice, the flexible catheter 6 carrying the inflatable member 7 will be guided through the patient's trachea 16 by first introducing an endotracheal tube 17 into the trachea 16. This tube 17 is somewhat stiffer than the catheter 6 and therefore easier to control. The catheter 6 is then inserted in the endotracheal tube 17. After leaving the endotracheal tube 17 the distal end 13 of the catheter 6 and the inflatable member 7 are guided into the left bronchus 8.

After the inflatable member 7 has been positioned, it is filled with an ultrasonic transmission fluid F through the flexible catheter 6. The fluid F is injected into the catheter 6 by means of a syringe (not shown), which is connected to a fill connector 20 at the end of a fill line 21 (fig. 2). This fill line 21 in turn is connected to a proximal end 22 of the catheter 6 through a trident connector 23 (fig. 3). The degree of filling of the inflatable member 7 may be visually determined by monitoring a pilot balloon 24, which is arranged at the end of a pilot line 25. This pilot

line 25 is also connected to the catheter 6 through the trident connector 23.

When the degree of inflation of the pilot balloon 24 indicates that the inflatable member 7 has been filled to such an extent that it completely covers the entire cross-sectional area of the left bronchus 8, so that no air is present between the echo probe 4 and the organ 2 to be imaged, the echo probe 4 is activated. Ultrasonic waves are then transmitted from the echo probe 4 through the transmission fluid F in the inflatable member 7 to the ascending aorta 2. Reflections from the aorta 2 are received at the echo probe 4 and transmitted through a line running through the catheter 9 to a processing and display apparatus, which does not form part of the present invention and is not shown here.

Due to the presence of the inflatable member 7 that is filled with the transmission fluid F, e.g. water or a saline solution in minor concentrations, the ultrasonic waves can travel pass the respiratory tract 3 with virtually no absorption. Consequently, very good ultrasound images of the aorta 2 may be obtained. Obviously, this can only be done during operative surgery, when the patient is mechanically ventilated or on cardiopulmonary bypass, since in order to be effective the inflatable member 7 has to completely fill and block the left bronchus 8.

In order to properly visualize the aorta it is important that the inflatable member 7 be positioned in precisely the right location. In accordance with the present invention the inflatable member 7 is positioned in the respiratory tract by manipulating guide means 10 that are attached to or integrated with the flexible catheter 6.

In a first embodiment these guide means 10 are passive and include a stylet 11 that extends over the entire

length of the flexible catheter 6. A distal end 12 of the stylet 11 extends beyond the inflatable member 7 to a distal end 13 of the catheter 6. A proximal end 14 of the stylet 11 protrudes from the proximal end 22 of the catheter 6 outside the patient's body 1 and extends into the center prong of the trident connector 23. This center prong is closed by a cap 15 carrying a valve member 26, the function of which will be described below. This arrangement allows the inflatable member 7 to be swiftly and accurately positioned in the respiratory tract 3, since the presence of the stylet 11 adds stiffness to the flexible catheter 6, thus improving directional control and predictability of the movement.

There are various possibilities for accommodating the full length stylet 11 in the catheter 6. In a first variant, which is structurally simple, the catheter 6 has a main lumen 27 for filling the inflatable member 7 with the ultrasonic transmission fluid F and the stylet 11 is arranged in the main lumen 27 (fig. 7A). Alternatively, the catheter 6 may have a main lumen 27 for the ultrasonic transmission fluid F and an additional lumen 28 for accommodating the stylet 11 (fig. 7B). In this way the stylet 11 does not interfere with the fluid supply function of the catheter 6.

In order to prevent the full length stylet 11 from obstructing part of the area to be imaged from view, it has to be at least partially retracted before the ultrasonic waves are transmitted from the imaging device 4. To that end the stylet 11 may be slidably arranged in either the main lumen 27 or the additional lumen 28. Although for proper imaging it would be sufficient to withdraw the stylet 11 only so far that its distal end 12 is on the proximal side of the inflatable member 7, in actual practice the stylet 11 will be completely withdrawn from the catheter 6, since it has served its purpose when the inflatable member 7 has been properly

positioned. To allow the stylet 11 to be retracted after the inflatable member 7 has been filled with the transmission fluid F, without the risk of fluid F leaking from the system, the proximal end 14 of the stylet 11 protrudes from the catheter 6 through a valve member 26. In the illustrated embodiment this valve member 26 is a one-way valve that is arranged in the center prong of the trident connector 23.

Alternatively, the stylet 11 may be fixedly arranged in a peripheral wall 29 surrounding the main lumen 27 of the catheter 6 (fig. 7C). In this case a very thin stylet 11A is used, which does not adversely affect the ultrasonic imaging in any substantial way, and which therefore does not have to be retracted. This thin stylet 11A may be fixedly arranged in the catheter wall 29.

There are various possibilities for the stylet 11 and the catheter 6 carrying the inflatable member 7 to be guided to the predetermined position in e.g. the left bronchus 8.

In the illustrated embodiment the stylet 11 is made from a resilient material and is substantially straight. Consequently, the stylet 11 will always try to assume its original straight shape. When the flexible catheter 6 and the stylet 11 are guided through the endotracheal tube 17, which itself follows the curvature of the trachea 16, they will have to follow the curvature of the tube 17 as well. However, after leaving the distal end 18 of the endotracheal tube 17 the stylet 11 will return to its straight shape due to its resiliency. The part of the stylet 11 and the catheter 6 protruding from the distal end 18 of the tube 17 will therefore enclose an angle with an imaginary extension of the centerline C_L of the tube 17. Consequently, rotating the proximal end 14 of the stylet 11 will lead to the distal end 12 describing a circular motion, which facilitates

positioning of the distal end 13 of the catheter 6 at the entrance of the left bronchus 8 (fig. 4).

In an alternative embodiment the stylet 111 is made from a resilient material and is preformed to conform substantially to the intended path of the catheter 106 through the respiratory tract 3. Preforming the stylet 111 may advantageously be done before it is attached to or integrated with the flexible catheter 106. In this way the catheter 106 assumes the shape of the stylet 111. When the flexible catheter 106 and the stylet 111 are guided through the endotracheal tube 117, which has less curvature than the stylet 111, they will be straightened somewhat. However, after leaving the distal end 118 of the endotracheal tube 117 the stylet 111 will return to its curved shape due to its resiliency, again extending under an angle with respect to the extension of the centerline C_L of the tube 117. Therefore, also in this embodiment rotating the proximal end 114 of the stylet 111 will result in a circular motion of its distal end 112, thus allowing the distal end 113 of the catheter 106 to be positioned at the entrance of the left bronchus 8 (fig. 5).

In a third embodiment the stylet 211 is made from a deformable material. In this way, the stylet 211 will conform to the respiratory tract 3, or to the endotracheal tube 217, when the flexible catheter 206 including this stylet 211 passes through the trachea 16. After leaving the tube 217 the material of the stylet 211 will maintain the curved shape into which it was forced. Consequently, the distal end 213 of the catheter 206 will form a continuation of the curvature of the tube 217, so that it can again easily be guided to its predetermined position at the entrance of the left bronchus 8 (fig. 6) by manipulating the proximal end of the stylet 211.

In yet another embodiment, the ultrasonic imaging system may include a short stylet 311, which may be arranged between the inflatable member 307 and the distal end 313 of the catheter 306 (fig. 8), rather than a full length stylet. Since this short stylet 311 does not extend across the inflatable member 307, it will not interfere with the imaging and there is no need to retract it. The distal end 313 of the catheter 306 includes a tip 330 that is shaped to facilitate positioning in the patient's left main bronchus 8 and the stylet 311 is adhesively fixed to the catheter tip 330. In this way the stylet 311 and tip 330 cooperate to allow the inflatable member 307 to be optimally positioned.

Since the stylet 311 does not extend beyond the distal end of the inflatable member 307, this embodiment will not have any part extending outside the patient's body 1. Positioning of the catheter 306 and the inflatable member 307 is done by manipulating the proximal end of the catheter 306. And since this stylet 311 does not have to be retracted from the catheter 306, there is no need for a special valve means.

In another main embodiment of the ultrasonic imaging system of the invention the guide means 410 comprise a wire 431 rather than a stylet. A distal end 432 of the wire 431 is eccentrically connected to the flexible catheter 406 and a proximal end 433 of the wire 431 is connected to a pulling member 434 arranged outside the patient's body 1 (fig. 9). The wire 431, which is very thin, provides excellent guidance of the catheter 406 with minimum obstruction of the image. The inflatable member 407 is positioned in the respiratory tract 3 by manipulating the pulling member 434. By pulling on the wire 431, its effective length within the catheter 406 will decrease. Since the wire 431 is eccentrically attached to the catheter 406, shortening of the wire 431 will lead to the catheter 406 assuming a curved shape, at least in the

vicinity of the point where the wire 431 is attached. In the illustrated embodiment this attachment point is located near the distal end 413 of the catheter 406. This location allows optimum control of the catheter 406.

In this embodiment the inflatable member 407 is again filled by means of a syringe which may be connected to a fill connector 420 at the end of a fill line 421. This fill line 421 is again connected to the catheter 406 through a trident connector 423, in this case through the center prong thereof. Also connected to the trident connector 423 is a pilot line 425 carrying a pilot balloon 424. Finally, the proximal end of the wire 431 is guided through the third prong of the trident connector 423. In order to prevent fluid leakage, the proximal end 433 of the pull wire 431 protrudes from this third prong through a valve member, in particular a one-way valve 426 (fig. 10).

There are various possibilities for accommodating the pull wire 431 in the catheter 406. The pull wire 431 may be accommodated in the main lumen 427 of the catheter 406 (fig. 11). This has the advantage of that the use of the guide means 410 entails a minimum of structural modifications. Alternatively, the catheter 406 may have an additional lumen 428 for accommodating the pull wire 431, besides the main lumen 427 for filling the inflatable member 407 with the ultrasonic transmission fluid F (fig. 12A). In this way interference between the pull wire 431 and the transmission fluid F is again minimized.

Instead of just a single pull wire, the ultrasonic imaging system may comprise a plurality of pull wires 431A (fig. 12B), which are spaced in the peripheral direction of the catheter 406. This allows the catheter 406 to be controlled in different directions by manipulating the various pull wires 431. Additionally or alternatively, the

distal ends of the various wires 431A may also be spaced in lengthwise direction of the catheter 406 to further improve controllability of the catheter 406.

Thus, the invention provides a method and a system with which an inflatable member that is to be filled with an ultrasound transmission fluid may be swiftly and accurately brought into a predetermined position within the respiratory tract of a patient. This in turn allows certain parts of the circulatory system, in particular the heart or aorta, to be visualized through the respiratory tract, using an imaging device that is arranged in the patient's esophagus, thus providing valuable information during operative surgery.

Although the invention has been described by means of a number of examples, it will be clear to the skilled person that many variations or modifications may be envisaged within the scope of the appended claims.

Claims

1. A method for ultrasonic imaging of an organ in a patient's body through a part of the patient's respiratory tract, comprising the steps of:

- arranging an ultrasonic imaging device in or on the patient's body,
- introducing a flexible catheter carrying at least one inflatable member into the respiratory tract,
- positioning the inflatable member at a predetermined location in the respiratory tract,
- filling the inflatable member with an ultrasonic transmission fluid through the flexible catheter, and
- transmitting ultrasonic waves from the imaging device through the transmission fluid in the inflatable member to the organ to be imaged,

wherein the inflatable member is positioned in the respiratory tract by manipulating guide means that are attached to or integrated with the flexible catheter.

2. The method of claim 1, wherein the guide means are passive and comprise at least one stylet.

3. The method of claim 2, wherein the stylet has a distal end which extends beyond the inflatable member and a proximal end which protrudes outside the patient's body.

4. The method of claim 3, wherein the stylet is at least partially retracted before the ultrasonic waves are transmitted from the imaging device.

5. The method of claim 4, wherein the proximal end of the stylet protrudes from the catheter through a valve member, and wherein the stylet is retracted after the inflatable member has been filled with the transmission fluid.

6. The method of any of claims 2 to 5, wherein the stylet is made from a resilient material and is preformed to conform substantially to the intended path of the catheter through the respiratory tract for positioning the inflatable member before being attached to or integrated with the flexible catheter.

7. The method of any of claims 2 to 5, wherein the stylet is made from a deformable material and conforms substantially to the respiratory tract when the flexible catheter and inflatable member are introduced therein.

8. The method of any of claims 2 to 5, wherein the stylet is made from a resilient material and is substantially straight, so that after passing curved parts of the respiratory tract during introduction of the flexible catheter and inflatable member therein at least the distal end of the stylet and the catheter will run straight.

9. The method of claim 2, wherein the stylet is arranged between the inflatable member and a distal end of the catheter, and wherein the inflatable member is positioned in the respiratory tract by manipulating a proximal end of the flexible catheter.

10. The method of claim 1, wherein the guide means are active and comprise at least one pull wire having a distal end that is eccentrically connected to the flexible catheter and a proximal end connected to a pulling member arranged outside the patient's body, and wherein the inflatable member is positioned in the respiratory tract by manipulating the pulling member.

11. The method of claim 10, wherein the wire is arranged in the catheter and its proximal end protrudes from the catheter through a valve member.

12. The method of claim 10 or 11, wherein the guide means comprise a plurality of pull wires that are spaced at

least in peripheral direction of the catheter, each said pull wire being connected to a respective pulling member, and wherein the inflatable member is positioned in the respiratory tract by selectively manipulating the various pulling members.

13. A system for ultrasonic imaging of an organ in a patient's body through a part of the patient's respiratory tract, comprising:

- an ultrasonic imaging device arranged in or on the patient's body,
- a flexible catheter carrying at least one inflatable member to be arranged in the respiratory tract,
- means for positioning the inflatable member at a predetermined location in the respiratory tract, and
- means for filling the inflatable member with an ultrasonic transmission fluid through the flexible catheter,

wherein the positioning means comprise guide means that are attached to or integrated with the flexible catheter.

14. The ultrasonic imaging system of claim 13, wherein the guide means are passive and comprise at least one stylet.

15. The ultrasonic imaging system of claim 14, wherein the stylet is arranged in the catheter and has a distal end which extends beyond the inflatable member and a proximal end which protrudes from the catheter.

16. The ultrasonic imaging system of claim 15, wherein the catheter has a main lumen for filling the inflatable member with the ultrasonic transmission fluid and wherein the stylet is arranged in the main lumen.

17. The ultrasonic imaging system of claim 15, wherein the catheter has a main lumen for filling the

inflatable member with the ultrasonic transmission fluid and an additional lumen for accommodating the stylet.

18. The ultrasonic imaging system of any of claims 15 to 17, wherein the stylet is slidably arranged in the catheter and its proximal end protrudes from the catheter through a valve member.

19. The ultrasonic imaging system of claim 15, wherein the catheter has a main lumen for filling the inflatable member with the ultrasonic transmission fluid and wherein the stylet is fixedly arranged in a peripheral wall surrounding the main lumen.

20. The ultrasonic imaging system of any of claims 15 to 19, wherein the stylet is made from a resilient material.

21. The ultrasonic imaging system of claim 20, wherein the stylet is preformed to conform substantially to the intended path of the catheter through the respiratory tract.

22. The ultrasonic imaging system of claim 20, wherein the stylet is substantially straight.

23. The ultrasonic imaging system of any of claims 15 to 19, wherein the stylet is made from a deformable material.

24. The ultrasonic imaging system of claim 14, wherein the stylet is arranged between the inflatable member and a distal end of the catheter.

25. The ultrasonic imaging system of claim 24, wherein the distal end of the catheter includes a tip that is shaped to facilitate positioning in the patient's left main bronchus and the stylet is adhesively fixed to the catheter tip.

26. The ultrasonic imaging system of claim 13, wherein the guide means are active and comprise at least one wire having a distal end that is eccentrically connected to

the flexible catheter and a proximal end connected to a pulling member arranged outside the patient's body.

27. The ultrasonic imaging system of claim 26, wherein the distal end of the pull wire is connected to the flexible catheter near a distal end thereof.

28. The ultrasonic imaging system of claim 26 or 27, wherein the catheter has a main lumen for filling the inflatable member with the ultrasonic transmission fluid and wherein the pull wire is arranged in the main lumen.

29. The ultrasonic imaging system of claim 26 or 27, wherein the catheter has a main lumen for filling the inflatable member with the ultrasonic transmission fluid and an additional lumen for accommodating the pull wire.

30. The ultrasonic imaging system of claim 28 or 29, wherein the proximal end of the pull wire protrudes from the catheter through a valve member.

31. The ultrasonic imaging system of claim 26 or 27, wherein the catheter has a main lumen for filling the inflatable member with the ultrasonic transmission fluid and wherein the pull wire is fixedly arranged in a peripheral wall surrounding the main lumen.

32. The ultrasonic imaging system of any of claims 26 to 31, further comprising a plurality of pull wires having their distal ends eccentrically connected to the flexible catheter, the guide wires being spaced at least in peripheral direction of the catheter.

33. An assembly of a flexible catheter carrying at least one inflatable member to be arranged in the respiratory tract of a patient and means for positioning the inflatable member at a predetermined location in the respiratory tract, wherein the positioning means comprise guide means that are attached to or integrated with the flexible catheter, for use in the ultrasonic imaging system of any of claims 13 to 32.

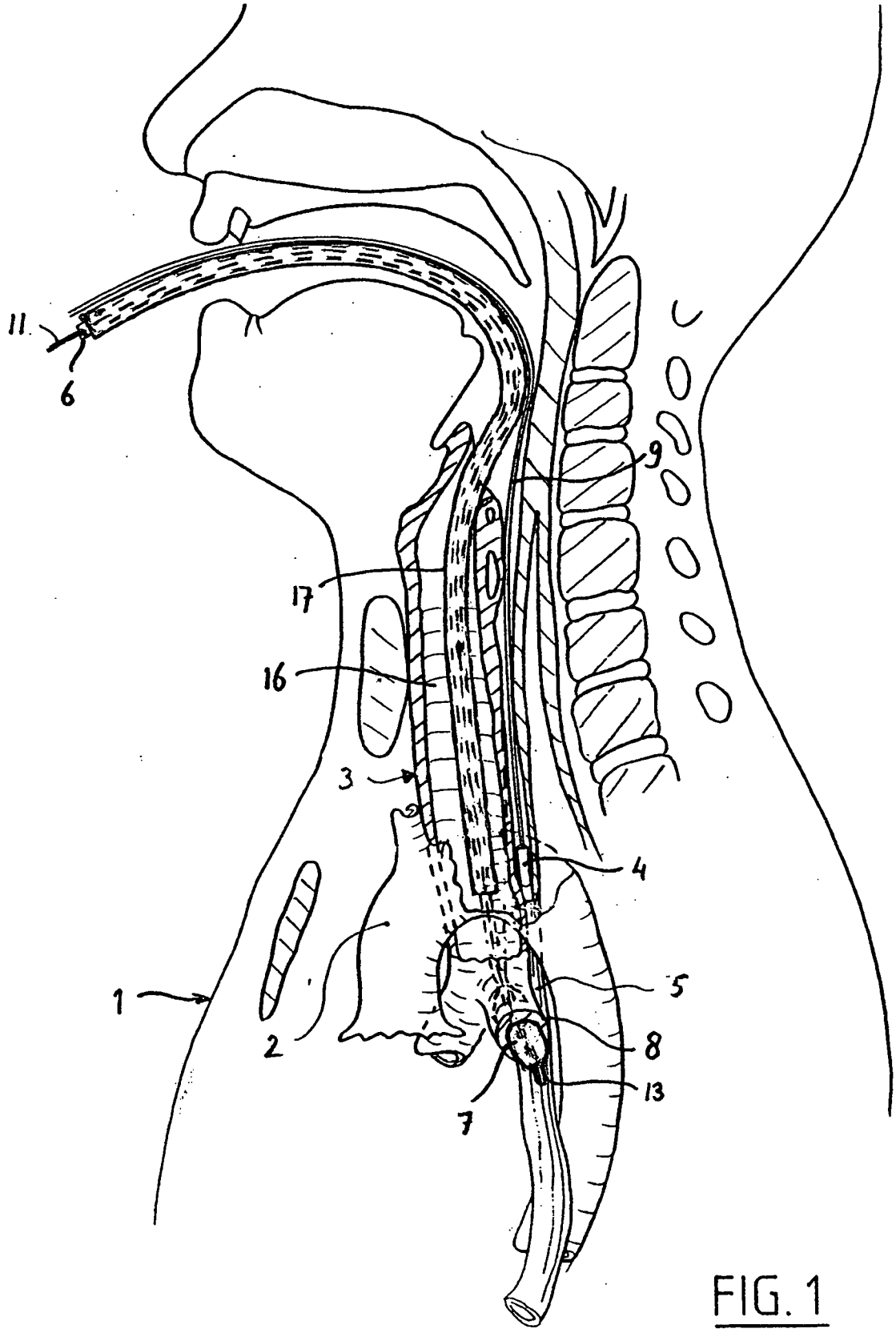


FIG. 1

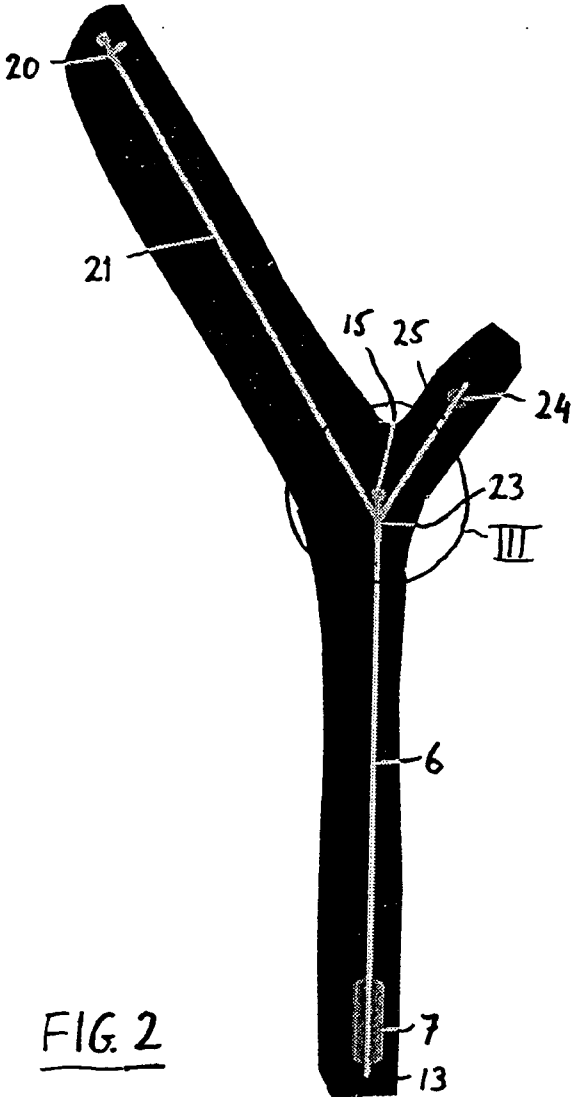


FIG. 2

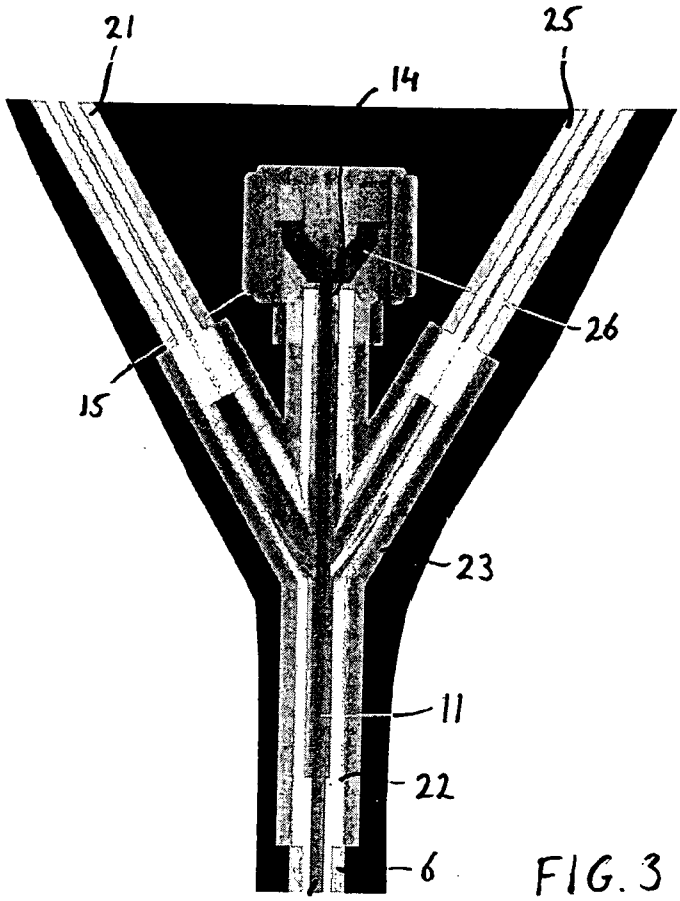


FIG. 3

FIG. 4

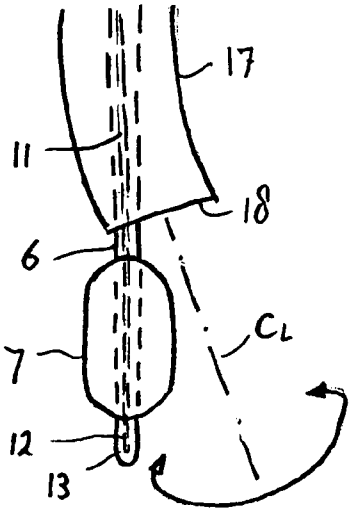
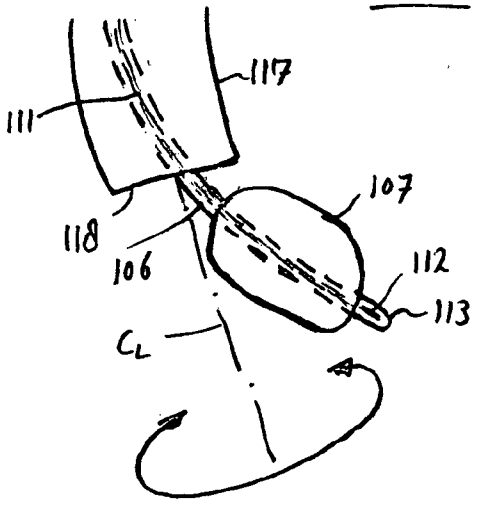


FIG. 5



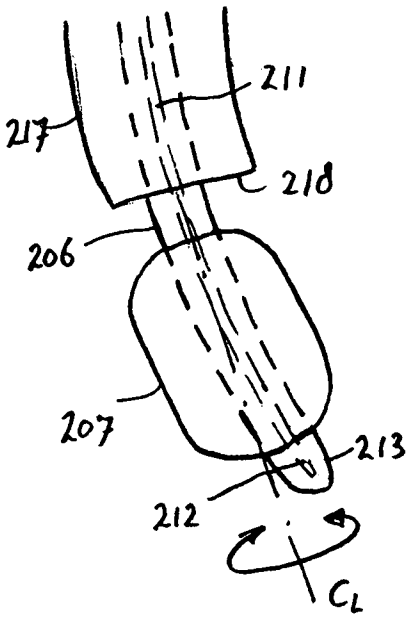


FIG. 6

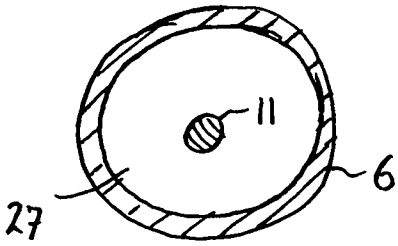


FIG. 7A

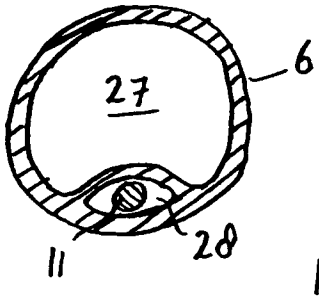


FIG. 7B

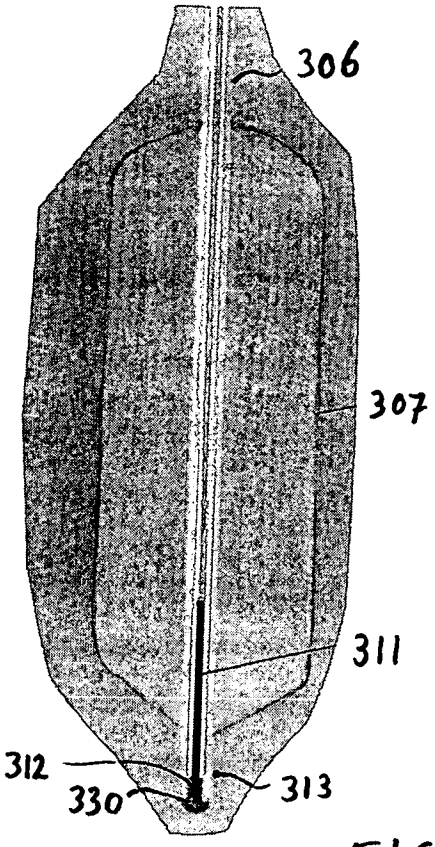


FIG. 8

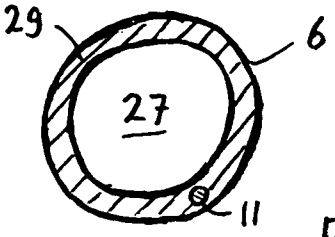


FIG. 7C

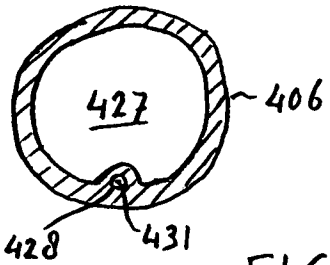


FIG. 12 A

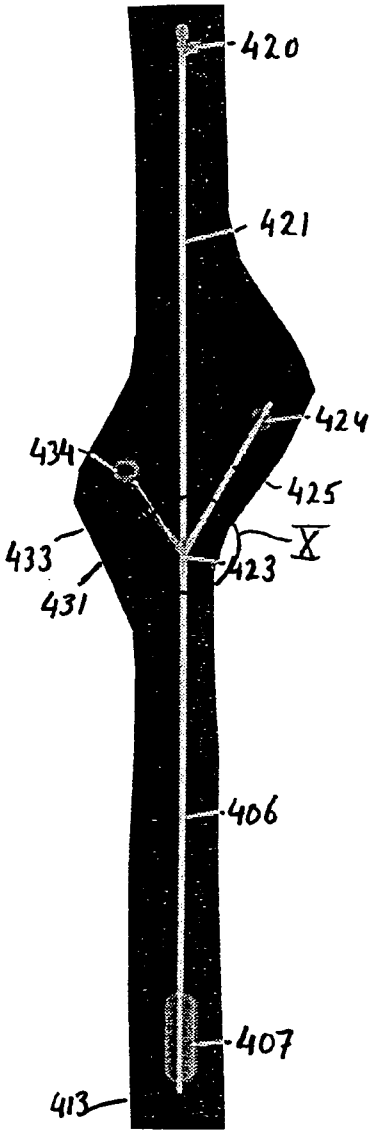


FIG. 9

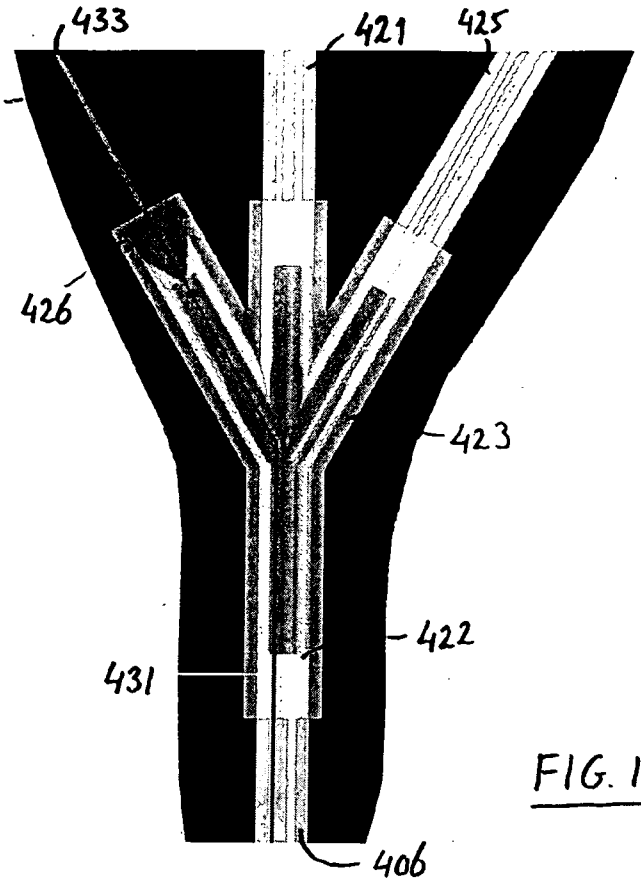


FIG. 10

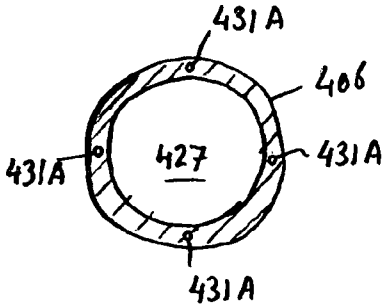


FIG. 12B

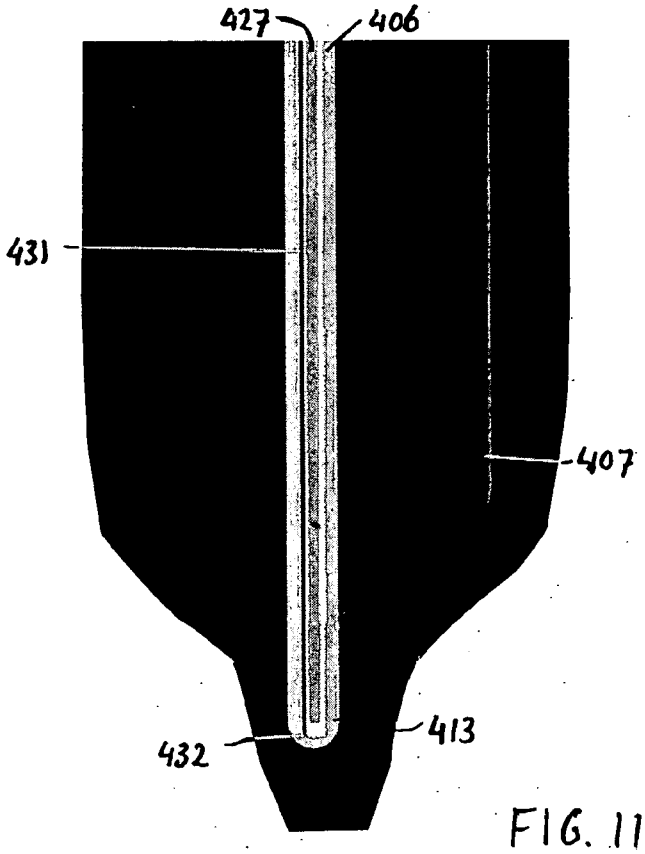


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/002209

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B8/12 A61M25/10 A61M25/09 A61M25/01

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

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 practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 190 046 A (SHTURMAN LEONID [US]) 2 March 1993 (1993-03-02) the whole document	13-19, 23-25,33
Y		20-22, 26-32
Y	US 2003/208119 A1 (CROWLEY ROBERT J [US]) 6 November 2003 (2003-11-06) paragraph [0151] figure 23	20-22, 26-32
A	WO 00/53098 A (NIERICH ARNO [BE]) 14 September 2000 (2000-09-14) cited in the application abstract figures 1,3	13-33

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

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 September 2008	01/10/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Willig, Hendrik

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2008/002209

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. [X] Claims Nos.: 1-12
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers 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 and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 1-12

Claims 1-12 are related to a method of ultrasonically imaging of an organ in a patient's body. The method comprises the step of introducing a flexible catheter into the respiratory tract of the patient. This step represents a surgical intervention by means of which the method as a whole is considered to form a method for treatment of the human body by surgery in the sense of Rule 39.1(iv) PCT.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2008/002209

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5190046 A	02-03-1993	AU 3609293 A	29-11-1993
		WO 9321829 A1	11-11-1993
US 2003208119 A1	06-11-2003	NONE	
WO 0053098 A	14-09-2000	AT 327714 T	15-06-2006
		AU 772367 B2	22-04-2004
		AU 3810700 A	28-09-2000
		CA 2402419 A1	14-09-2000
		DE 60028349 T2	29-03-2007
		DK 1161181 T3	02-10-2006
		EP 1034743 A1	13-09-2000
		ES 2263462 T3	16-12-2006
		NZ 514741 A	28-11-2003
		US 2007038109 A1	15-02-2007

专利名称(译)	一种用于通过患者呼吸道的一部分对患者体内的器官进行超声成像的方法和系统		
公开(公告)号	EP2265182A1	公开(公告)日	2010-12-29
申请号	EP2008734676	申请日	2008-03-19
[标]申请(专利权)人(译)	CORDATEC		
申请(专利权)人(译)	CORDATEC NV		
当前申请(专利权)人(译)	STROKE2PREVENT BV		
[标]发明人	NIERICH ARNO		
发明人	NIERICH, ARNO		
IPC分类号	A61B8/12 A61M25/10 A61M25/09 A61M25/01 A61F2/958		
CPC分类号	A61B8/12 A61B8/445 A61M25/0147 A61M25/0152 A61M25/0662 A61M25/09 A61M25/10		
其他公开文献	EP2265182B1		
外部链接	Espacenet		

摘要(译)

本发明涉及一种用于通过患者呼吸道的一部分对患者体内器官进行超声成像的系统，包括将被布置在患者身体内或身体上的超声成像装置（4），携带的柔性导管（6）至少一个可充气构件（7）布置在呼吸道中，装置（10,11）用于将可充气构件定位在呼吸道中的预定位置，以及用于通过超声波传输流体填充可充气构件的装置柔性导管。可充气构件可通过操纵附接到柔性导管或与柔性导管集成的引导装置（10,11）而定位在呼吸道中。