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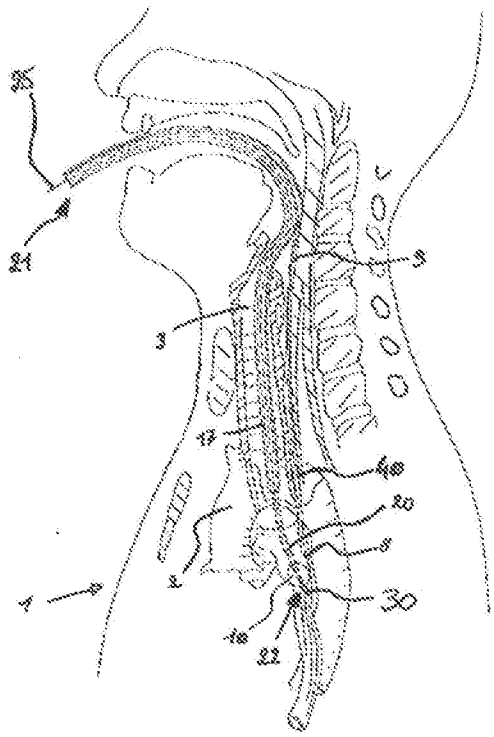
(54) **IMPROVED SYSTEM WITH AN INFLATABLE MEMBER AND IMAGING DEVICE FOR BEING ARRANGED IN THE PATIENT'S RESPIRATORY TRACT**

(57) A system with an inflatable member (10) configured for being arranged in part of the patient's respiratory tract, comprising a catheter (20) carrying an inflatable member (10) to be arranged in the respiratory tract, said catheter being provided with a fluid line (25) for filling the inflatable member (10) with a fluid; said catheter having a first end (21) intended for being located outside of the patient's body and a second end (22) intended for being located in the patient's respiratory tract; an imaging device (30) attached to or integrated with the second end (22) of the catheter.



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IMPROVED SYSTEM WITH AN INFLATABLE MEMBER AND IMAGING DEVICE FOR BEING ARRANGED IN THE PATIENT'S RESPIRATORY TRACT

TECHNICAL FIELD

The field of the invention relates to systems with an inflatable member configured for being arranged in part of the patient's respiratory tract, and in particular to systems for ultrasonic imaging.

BACKGROUND

WO 00/53098 relates to an ultrasonic imaging method that is known as transesophageal echocardiography, now referred to as TEE. This method 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.

In order to solve this problem, WO 00/53098 proposes the use of an inflatable member 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. This technique 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 has to completely fill and block the trachea or bronchus.

SUMMARY

A first problem which arises when trying to introduce the inflatable member in the left bronchus, which is the position of choice when visualizing the aorta ascendens, is that the flexible catheter carrying the inflatable member is hard to manipulate. The positioning of the distal end of the 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. Secondly, during the arrangement of the inflatable member in the patient's respiratory tract, contact between the TEE device and the trachea wall occurs which potentially causes tissue damage. Since this positioning has to be performed during operative surgery, when timing is often critical, there is a need for an improvement.

The object of embodiments of the invention is to provide a system with an inflatable member configured for being arranged in part of the patient's respiratory tract which can be positioned more easily and which reduces the chance of tissue damage.

According to a first aspect of the invention there is provided a system with an inflatable member configured for being arranged in part of the patient's respiratory tract. The system comprises a catheter and an imaging device, preferably a visible light imaging device. The catheter carries an inflatable member to be arranged in the respiratory tract. The catheter is provided with a fluid line for filling the inflatable member with a fluid. The catheter has a first end intended for being located outside of the patient's body and a second end intended for being located in the patient's respiratory tract. The imaging device is attached to or integrated with the second end of the catheter.

Embodiments of the invention are based inter alia on the insight that by attaching or integrating an imaging device to the second end, the positioning of the inflatable member is done more effectively. Indeed, the operator acquires more feedback, namely the images captured by the imaging device during the procedure, and the catheter is easier to manipulate. This results in a lower chance of tissue damage.

Preferably the imaging device comprises a light source which comprises a plurality of light emitting diodes arranged along a periphery of the second end of the catheter, preferably at least three light emitting diodes equally distributed along the periphery of the second end of the catheter.

According to an exemplary embodiment the imaging device is configured and arranged for positioning the second end of the catheter in for example the patient's the respiratory tract or the patient's left main bronchus. In other words, the second end with the imaging device may be

shaped such that the second end forms a stylet which functions as a guide when inserting the inflatable member.

According to an exemplary embodiment the system comprises an ultrasonic imaging device. Preferably this ultrasonic imaging device is configured to be arranged into the patient's esophagus and is configured to transmit ultrasound waves, across the thorax, through the inflatable member and to receive reflected ultrasound waves. This system allows the evaluation of an organ in a patient's body by ultrasound.

According to an exemplary embodiment the imaging device is configured to transmit the data gathered to a device outside the patient's body so it is accessible to an operator, for example a surgeon or an assistant during a medical procedure. This transmission is done in a wired or wireless manner. In a preferred embodiment with wired transmission, a wire is arranged inside the catheter but the skilled person understands that other arrangements are possible, for example in the wall of the catheter.

According to an exemplary embodiment the imaging device comprises a cylindrical housing aligned with a longitudinal axis of the catheter. Preferably, the cylindrical housing is arranged at least partially in the second end of the catheter, more preferably substantially entirely in the second end of the catheter. Preferably, the housing comprises a metal such as stainless steel or a plastic such as polyvinylchloride. These materials are more rigid than the flexible catheter. Since the housing is cylindrical and arranged at least partially in the second end of said catheter, the second end is given a stylet shape which can easily be inserted and can fulfil the role of guiding the catheter. The flexible catheter is easier to manipulate with the presence of the housing. Preferably, the housing has a diameter between 0.01 mm and 9 mm, more preferably 0.5 mm and 5 mm, more preferably 1 mm and 3 mm. Preferably, a length of the housing is smaller than 10 mm, more preferably smaller than 7 mm. The housing may be adhesively fixed to the second end of the catheter. In this way, the housing and the catheter cooperate to allow the inflatable member to be in an improved manner positioned.

According to an exemplary embodiment the imaging device further comprises an image sensor, preferably an active pixel sensor such as a complementary metal oxide semiconductor (CMOS) sensor. Alternatively, the image sensor may be a charge-coupled device (CCD). Preferably, the image sensor is surrounded by the plurality of light emitting diodes, more preferably in a way so that they are equally distributed. Optionally, optical fibers may be used to provide light next to the image sensor. In this manner, the quality of the obtained image data can be improved.

According to an exemplary embodiment the imaging device comprises a lens arranged in front of the image sensor and protrudes out of the second end of the catheter. Preferably, the lens is adhesively fixed to the image sensor and/or the housing and/or the catheter. In this way the lens forms a protection layer between the image sensor and particles that could potentially interfere with the working of the image sensor. Preferably, the image sensor has a field of view between 90 and 180 degrees oriented away from the second end of the catheter.

According to an exemplary embodiment the system comprises a fluid line. In some embodiments, the catheter forms the fluid line. The fluid line may be formed centrally in the catheter or in the wall of the catheter. In other embodiments the fluid line is a separate line arranged inside or outside the catheter. The fluid line brings a fluid, preferably an ultrasonic fluid from an outside fluid source towards the inflatable member. In this way, air volumes that interfere with ultrasonic imaging are limited.

According to an exemplary embodiment the system comprises at least one electrical wire arranged in the catheter and configured for connecting the imaging device with a device outside the patient's body, typically a computer with a display screen on which the image data is displayed. In other embodiments, the imaging device may be configured to communicate with a device outside the patient's body without the use of a wire. In such cases the power to operate the imaging device may come from an internal energy storage means.

According to an exemplary embodiment the system comprises a catheter which is made from a flexible material, preferably a polymer material. These materials could be polyvinylchloride, silicone or synthetic latex. In this way the material makes the catheter flexible and pliable which allows trauma-free catheterization. The catheter may be coated with for example a polytetrafluorethylene. In this way, the catheter is better protected against acids, solvents and corrosion. On top of that, the adhesion coefficient is lower which also allows a trauma-free catheterization.

According to an exemplary embodiment the inflatable member in non-expanded state has a volume between 20 ml and 60 ml, preferable between 30 ml and 50 ml. The material of said inflatable member is a thermoplastic elastomer, preferably a thermoplastic polyurethane elastomer.

According to yet another exemplary embodiment the system further comprises a pressure monitoring and control member to be arranged outside the patient's body. This member is in fluid communication with the inflatable member and is configured to receive fluid from the inflatable member during operation when the pressure inside the inflatable member increases above a

predetermined threshold. The control member returns the received fluid when the pressure decreases below said threshold. This pressure monitoring and control member is an elastically expandable balloon made from a material which is configured to expand elastically when the pressure in the balloon increases above the threshold pressure. When the pressure decreases below the threshold, the monitoring and control member contracts. In this way high pressure which can potentially result in tissue damage is avoided while enough pressure to limit air volumes is still maintained.

BRIEF DESCRIPTION OF FIGURES

The accompanying drawings are used to illustrate presently preferred non-limiting exemplary embodiments of systems of the present invention. The above and other advantages of the features and objects of the invention will become more apparent and the invention will be better understood from the following detailed description when read in conjunction with the accompanying drawings, in which:

Figure 1 illustrates a partial sectional view of a patient's upper body showing an exemplary embodiment of a system with an inflatable member arranged in a patient's body.

Figure 2 is a schematic view of another exemplary embodiment of a system of the invention, including an imaging device, showing an inflatable member, a pressure and control member and a device outside the patient body configured and arranged to receive the data from the imaging device.

Figure 3 is an enlarged view of the second end of the catheter from figure 2 showing a more detailed schematic view of the imaging device and the inflatable member.

Figure 4A to 4C are cross sections of different exemplary embodiments of the secondary end of the catheter showing an imaging device.

Figure 5 is a perspective view of an exemplary embodiment of an imaging device showing the housing, multiple electrical wires, a light source and an image sensor.

Figure 6A to 6D show exemplary embodiments of the imaging device with various possibilities for the positioning of the lens.

Figure 7 is a schematic view of an exemplary embodiment of another system of the invention, showing the inflatable member filled with transmission fluid.

Figure 8 is a detailed, enlarged view of the encircled area VIII in figure 7.

Figure 9 is a view similar to the view of figure 8 showing yet another exemplary embodiment of a system of the invention.

DESCRIPTION OF EMBODIMENTS

For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal" and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume various alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

It is to be understood that the invention may assume various alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention.

In a preferred exemplary embodiment illustrated in figure 1 the system comprises an ultrasonic imaging device 40, which enables the 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. The ultrasonic imaging device 40, for instance an echo probe, is arranged in or on the patient's body 1. In the shown embodiment, the echo probe 40, which is carried on a flexible catheter 9, is introduced into the patient's oesophagus 5. Another flexible catheter 20 carrying an inflatable member 10 is introduced into the respiratory tract 3. The inflatable member 10 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. The flexible catheter 20 carrying the inflatable member 10 will be guided through the patient's trachea 3 by first introducing an endotracheal tube 17 into the trachea 3. This tube 17 is somewhat stiffer than the catheter 20 and therefore easier to control. The catheter 20 is then inserted in the endotracheal tube 17. After

leaving the endotracheal tube 17 the second end 22 of the catheter 20 and the inflatable member 10 are guided into the left bronchus 8.

The catheter 20 has a first end 21 intended for being located outside of the patient's body and a second end 22 intended for being located in the patient's respiratory tract. The system further comprises an imaging device 30 attached to or integrated with the second end 22 of the catheter 20. Typically the imaging device 30 comprises an image sensor and a light source, for example one or more light emitting diodes. The imaging device 30 is shaped such that the second end of the catheter 22 functions as a guide for the positioning of the inflatable member. The imaging device 30 is configured or connected to transmit image data to a device (not shown) outside the patient's body where the image data is displayed to a user. The presence of the imaging device 30 adds stiffness to the second end 22 of the flexible catheter 20, improving directional control and predictability of the movement, thereby allowing the inflatable member 10 to be swiftly and accurately positioned in the respiratory tract 3.

The catheter 20 may be made from a flexible material, preferably a polymer material, more preferably polyvinylchloride, silicone, synthetic latex. The inflatable member 10, in the non-expanded state, may have a volume between 20 ml and 60 ml, preferable between 30 ml and 50 ml. The material of the inflatable member may be a thermoplastic elastomer, preferably a thermoplastic polyurethane elastomer.

Figure 2 shows a second exemplary embodiment of a system. The system comprises at least one inflatable member 10 carried by a flexible catheter 20. For instance in the actual practice of ultrasonic imaging, the flexible catheter 20 carrying the inflatable member 10 will be guided through the patient's trachea into the right position, e.g. patient's left main bronchus. In this embodiment, the catheter comprises an imaging device 30 which is arranged at the second end 22 of the catheter 20. Positioning of the catheter 20 and the inflatable member 10 is done by manipulating the second end of the catheter 20. Figure 2 further shows a computer device 50 which is connected in a wired or wireless manner to the imaging device 30. This computer device 50 receives image data from the imaging device 30 and displays it to an operator. The imaging device 30 may have any one of the features of embodiments disclosed above and below.

The system further comprises a pressure monitoring and control member 60 to be arranged outside the patient's body, said pressure monitoring member being in fluid communication with the inflatable member 10 and being configured to receive, during operation, fluid from the inflatable member 10 when the pressure increases above a predetermined threshold pressure and to return

said received fluid when the pressure decreases below said predetermined threshold pressure. The pressure monitoring and control member 60 may be an elastically expandable balloon made from a material which is configured to expand elastically when the pressure in the balloon increases above a predetermined threshold pressure and to contract when the pressure decreases below said predetermined threshold pressure.

After the inflatable member 10 has been positioned at the right position in the respiratory tract, it is filled with a fluid, e.g. water or a saline solution in minor concentrations, through the flexible catheter 20. The inflatable member 10, in the non-expanded state, has a volume between 30 ml and 70 ml, preferably between 40 ml and 60 ml. The fluid is injected into the catheter 20 by means of a syringe (not shown), which is connected to a fill connector 28 at the proximal end of a fill line 29.

The distal end of this fill line 29 in turn is connected to a proximal end of the catheter 20 through a connector 27. The degree of filling of the inflatable member 10 may be visually determined by monitoring the elastically expandable balloon 60, which is arranged at the end of a pilot line. This pilot line is also connected to the catheter 20 through the connector 27. In case of an increasing pressure within the inflatable member 10 exceeding the threshold level, e.g. during the movement of echo probe in the oesophagus 5 or the movement breathing tube in the respiratory tract, the pressure may cause a reflux of the fluid from the inflatable member 10 to the elastically expandable balloon 60. Such reflux may lead to an expansion of the elastically expandable balloon 60, thereby limiting the pressure increase within the inflatable member to a safety level. The predetermined threshold pressure of the system lies in a range between 30 and 90 mm Hg, such threshold pressure ensures a safe pressure within the inflatable member leading to no or less damage to the trachea wall.

Figure 3 shows in detail the arrangement of the imaging device 30 in the catheter 20. The imaging device is arranged at least partially in the second end 22 of the catheter. Optionally, the imaging device 30 extends partially into the zone of the inflatable member, but preferably over only a small distance (e.g. a distance which is less than 1 cm), such that the ultrasonic imaging is not disturbed.

Figures 4A-4C show three possible embodiments of an imaging device 30 arranged in the second end 22 of a catheter 20. The imaging device 30 is inserted in the second end 22 of the flexible catheter 20. In the embodiment of figure 4A, the imaging device 30 is inserted entirely in the second end 22, and the flexible catheter 20 protrudes over the imaging device 30 in the longitudinal directional. In the embodiment of figure 4B, the attachment or integration is such that an end portion of the imaging device 30 is aligned with an end portion of the flexible catheter 20.

Figure 4C shows an exemplary embodiment where the imaging device 30 protrudes out of the second end of the catheter 22 in the longitudinal direction.

Figure 5 shows in detail an exemplary embodiment of an imaging device. The imaging device 30 comprises a cylindrical housing 31 which is made from a material more rigid than the flexible catheter. This material could be a metal such as stainless steel and/or a plastic such as polyvinylchloride. The cylindrical housing 31 is intended to be aligned with a longitudinal axis of the catheter, as is also clear from figure 3 discussed above. Preferably, the housing 31 has a diameter between 0.01 mm and 9 mm, more preferably 0.5 mm and 5 mm, even more preferably 1 mm and 3 mm, and/or wherein a length of the housing is smaller than 10 mm, preferably smaller than 7 mm. Optionally, the housing 31 extends over a short distance in the inflatable member 10, as is also visible from figure 2 discussed above.

The imaging device 30 further comprises an image sensor 33 and at least one light source 32. The imaging device 30 may be coupled to an external power source (not shown) and may output image data through one or more electrical wires 35. Although wired solutions for both the power supply and the transferring of image data are preferred, it may also be envisaged to use a battery and/or a wireless transmission means in the imaging device 30.

The image sensor 33 is arranged in the housing 31 and may be for example an active pixel sensor such as a CMOS sensor. The light source 32 comprises a plurality of light emitting diodes arranged around the image sensor 33. The image sensor 33 may have a field of view between 90 and 180 degrees, preferably between 100 and 150 degrees.

Figures 6A to 6D show exemplary embodiments of an imaging device 30 comprising a centrally positioned image sensor 33, at least one light source 32, and a lens 34 arranged in front of the image sensor 33. More in particular, figures 6A-6D show various possibilities to arrange the lens 34 at the second end of the catheter 22. In addition to its optical function, the lens 34 is used as a protection layer for the image sensor 33 and in a preferred embodiment, the stiffness and shape of the lens help to position the second end of the flexible catheter 22.

In figure 6A the lens 34 is arranged in front of the image sensor 33 and has a diameter which is smaller than the diameter of the housing 31. The diameter of the lens 34 could be bigger, smaller or equal to the diameter of the housing 31.

In figure 6B, the image sensor is surrounded by light sources 32 and the lens 34 is arranged in front

of the image sensor 33 and the light sources 32 and has a diameter which is equal to the diameter of the housing 31. A skilled person knows different curvatures are possible, an exemplary embodiment of a lens 34 with a different curvature is shown in figure 6C. In another exemplary embodiment shown in figure 6D, the lens 34 is arranged in front of the image sensor 33 and has a diameter larger than the housing 31.

Figure 7 illustrates another exemplary embodiment of a system comprising at least one inflatable member 10 carried by a flexible catheter 20 provided with an imaging device 30 that may have any one of the features of embodiments disclosed above. Further the system comprises a fill line 29 connected to a trident connector 70 which forms the connection between the fill line 29, a pilot line 26 leading to a pilot balloon 24, and the flexible catheter 20. Figure 8 shows an enlarged view of section VIII in figure 7.

After the inflatable member 10 has been positioned, it is filled with an ultrasonic transmission fluid through the flexible catheter 20. The fluid is injected into the catheter 20 by means of a syringe (not shown) which is connected to a fill connector 20 at the end of a fill line 21 (see figure 8) . This fill line 21 in turn is connected to a proximal end of the catheter 20 through the trident connector 70. The degree of filling of the inflatable member 10 may be visually determined by monitoring the pilot balloon 24, which is arranged at the end of a pilot line 26. This pilot line 26 is also connected to the catheter 10 through the trident connector 70.

When the degree of inflation of the pilot balloon 24 indicates that the inflatable member 10 has been filled to such an extent that it completely covers the entire cross-sectional area of the left bronchus, so that no air is present between the echo probe and the organ to be imaged, the echo probe may be activated. Ultrasonic waves are then transmitted from the echo probe through the transmission fluid F in the inflatable member 10 to the ascending aorta. Reflections from the aorta are received at the echo probe and transmitted through a line running through the catheter 10 to a processing and display apparatus. Due to the presence of the inflatable member 10 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 with virtually no absorption. Consequently, very good ultrasound images of the aorta may be obtained.

The imaging device 30 may be coupled to an external power source (not shown) through one or more electrical wires 35, and the images captured by the imaging device 30 may be output through one or more external wires 35. There are various possibilities for accommodating the one or more wires 35 in the catheter 20. In a first variant, which is structurally simple, the catheter 20 has a

main lumen for filling the inflatable member 10 with the ultrasonic transmission fluid and the one or more wires 35 is arranged in the main lumen. Alternatively, the catheter 20 may have a main lumen for the ultrasonic transmission fluid and an additional lumen for accommodating the one or more wires 35. In this way the one or more wires 35 does not interfere with the fluid supply function of the catheter 20. To allow the passage of the one or more wires to a device 50 outside the catheter 20, the trident connector 70 comprises a centre prong 71 and a cap 72 carrying a valve member 73.

Figure 9 shows another exemplary embodiment of an alternative arrangement of the one or more electrical wires 35. This embodiment is similar to the embodiment of figures 7 and 8 with this difference that the one or more wires 35 are arranged eccentrically to the flexible catheter 20. Such an embodiment has the advantage that no special sealing is needed to bring the one or more wires 35 out of the catheter 20 as in the embodiment of figures 7 and 8. On the other hand a sealed passage may be provided at the second end to connect the one or more wires 35 to the imaging device 30.

Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

Conclusies

1. Een systeem met een opblaasbaar element (10) ingericht om in een deel van de luchtpijp van de patiënt te worden aangebracht, omvattende:

   een katheter (20) die een opblaasbaar element (10) draagt, bedoeld om in de luchtpijp te worden aangebracht, welke katheter is voorzien van een vloeistoflijn (25) om het opblaasbaar element te vullen met een vloeistof; de katheter heeft een eerste einde (21) bedoeld om buiten het lichaam van de patiënt gesitueerd te zijn en een tweede einde (22) bedoeld om in de luchtweg van de patiënt gesitueerd te zijn;

   een beeldvormingsinrichting (30) bevestigd aan of geïntegreerd met het tweede einde (22) van de katheter.

2. Een systeem volgens de voorgaande conclusie, waarbij de beeldvormingsinrichting (30) een lichtbron (32) omvat.

3. Het systeem volgens conclusies 1 en 2, waarbij de lichtbron (32) een meervoud aan lichtgevende diodes omvat, welke langs de omtrek van het tweede einde van de katheter (22) zijn aangebracht, bij voorkeur ten minste drie lichtgevende diodes die gelijk verdeeld zijn langs de omtrek van het tweede einde van de katheter (22).

4. Het systeem volgens één der voorgaande conclusies, waarbij de beeldvormingsinrichting (30) ingericht en aangebracht is zodanig dat het tweede einde van de katheter (22) als gids functioneert om het opblaasbaar element te positioneren.

5. Het systeem volgens één der voorgaande conclusies, verder omvattende een ultrasone beeldvormingsinrichting (40) die is ingericht om ultrasoon golven doorheen het opblaasbaar element (10) te zenden en om gereflecteerde ultrasoon golven te ontvangen.

6. Het systeem volgens één der voorgaande conclusies, waarbij de beeldvormingsinrichting (30) ingericht of geconnecteerd is om beeldgegevens over te brengen naar een apparaat (50) buiten het lichaam van de patiënt.

7. Het systeem volgens één der voorgaande conclusies, waarbij de beeldvormingsinrichting een cilindrische behuizing (31) omvat, gealigneerd met een lengteas van de katheter.

8. Het systeem volgens de voorgaande conclusie, waarbij de cilindrische behuizing (31) gedeeltelijk in het tweede einde (22) van de katheter is aangebracht, bij voorkeur in zijn geheel in het tweede einde van de katheter.

9. Het systeem volgens conclusie 7 of 8, waarbij de behuizing (31) een diameter heeft tussen 0.01 mm en 9 mm, bij voorkeur 0.5 mm en 5 mm, nog meer bij voorkeur 1 mm en 3 mm, en/of waarbij een lengte van de behuizing kleiner is dan 10 mm, bij voorkeur kleiner dan 7 mm.

10. Het systeem volgens de voorgaande conclusie, waarbij de beeldvormingsinrichting (30) een actieve pixelsensor (33) omvat, bij voorkeur een CMOS sensor.

11. Het systeem volgens conclusie 3 of 10, waarbij het meervoud aan lichtgevende diodes rond de actieve pixelsensor (33) is aangebracht.

12. Het systeem volgens één der voorgaande conclusies, waarbij de beeldvormingsinrichting (30) een lens (34) omvat, welke is aangebracht vóór de actieve pixel sensor (33) en voorbij het tweede deel (22) uitsteekt.

13. Het systeem volgens één der voorgaande conclusies, waarbij de beeldvormingsinrichting (32) een gezichtsveld tussen de 90 en 180 graden heeft, bij voorkeur tussen 100 en 150 graden.

14. Het systeem volgens één der voorgaande conclusies, waarbij de katheter (20) de vloeistoflijn (25) omvat.

15. Het systeem volgens één der voorgaande conclusies, verder omvattende ten minste één elektrische draad (35), welke bij voorkeur in de katheter is aangebracht, en is ingericht om de beeldvormingsinrichting te verbinden met een apparaat (50) buiten het lichaam van de patiënt.

16. Het systeem volgens één der voorgaande conclusies, waarbij de katheter uit een flexibel materiaal is vervaardigd, bij voorkeur een polymeermateriaal, nog meer bij voorkeur polyvinylchloride, silicone, synthetische latex.

17. Het systeem volgens één der voorgaande conclusies, waarbij het opblaasbaar element (10), in de niet-geëxpandeerde toestand, een volume heeft tussen 20 ml en 60 ml, bij voorkeur tussen 30 ml en 50 ml.

18. Het systeem volgens één der voorgaande conclusies, waarbij het materiaal van het opblaasbaar element een thermoplastisch elastomeer is, bij voorkeur een thermoplastisch polyurethaan elastomeer.

19. Het systeem volgens één der voorgaande conclusies, verder omvattende:

- een druktoezicht en -controle element (60) om buiten het lichaam van de patiënt te worden aangebracht, waarbij het druktoezicht en -controle element in vloeistofverbinding staat met het opblaasbaar element en is ingericht om, in operationele toestanddrijf, vloeistof te ontvangen van het opblaasbaar element (10) wanneer de druk boven een voorafbepaalde drempeldruk stijgt en om de ontvangen vloeistof terug te geven wanneer de druk daalt onder de voorafbepaalde drempeldruk;
- waarin het druktoezicht en -controle element een elastisch expandeerbare ballon is, welke vervaardigd is uit een materiaal dat is ingericht om elastisch te expanderen wanneer de druk in de ballon boven een vooraf bepaalde drempeldruk stijgt en om samen te trekken wanneer de druk daalt onder de vooraf bepaalde drempeldruk.

Fig. 1

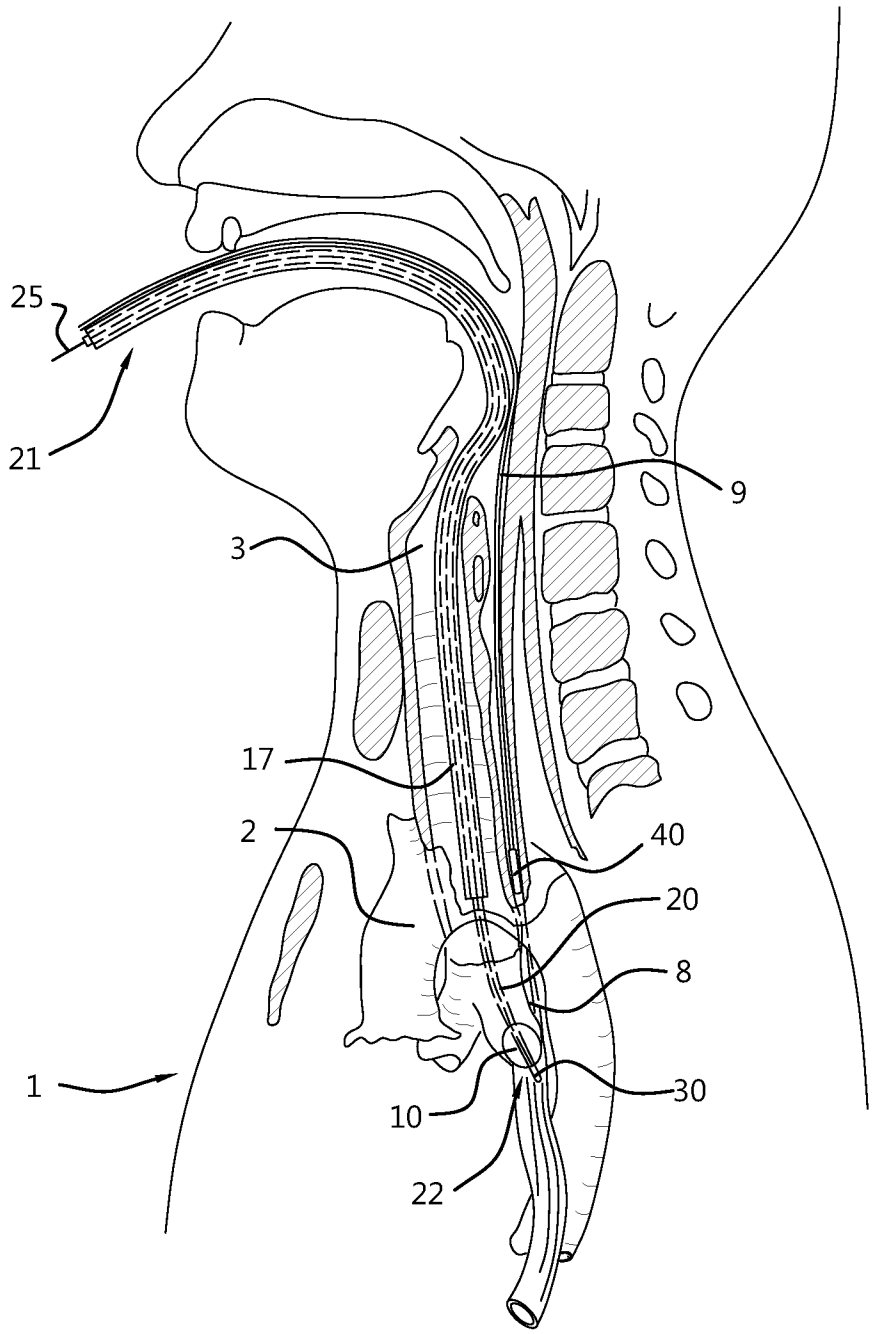


Fig. 2

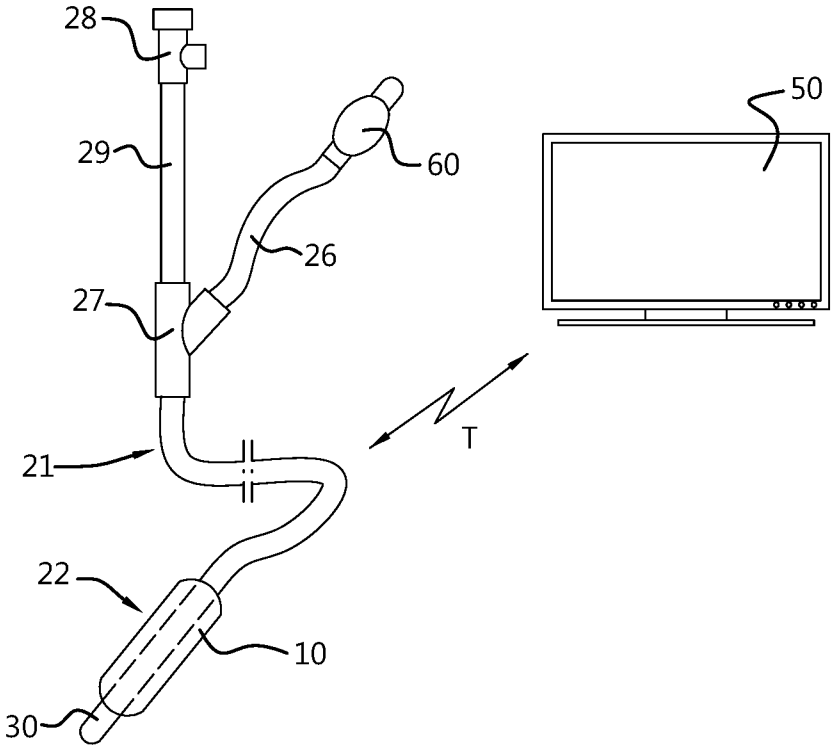


Fig. 3

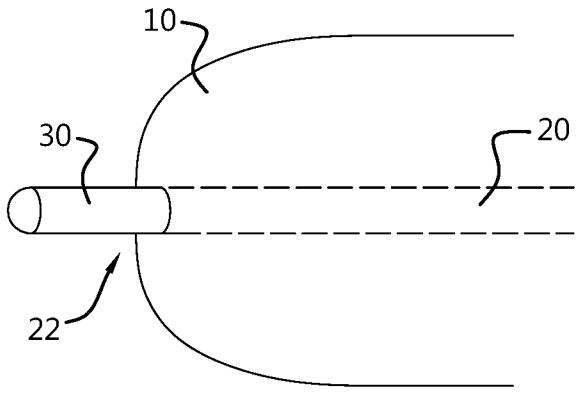


Fig. 4A

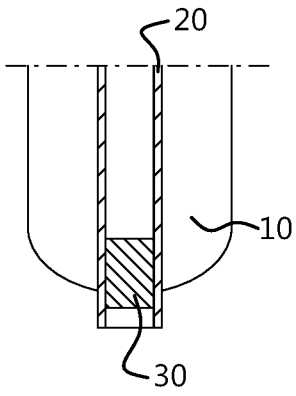


Fig. 4B

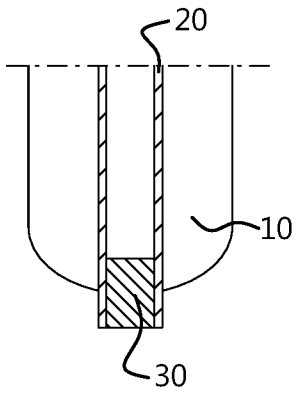


Fig. 4C

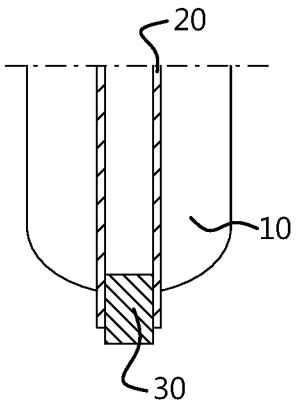


Fig. 5

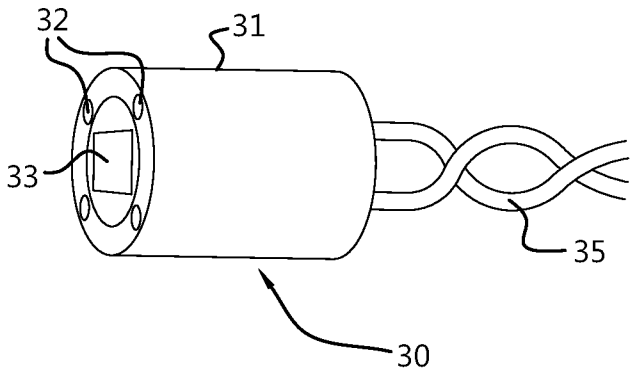


Fig. 6A

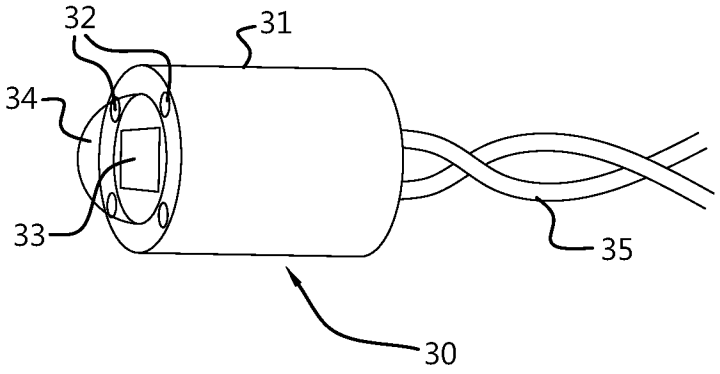


Fig. 6B

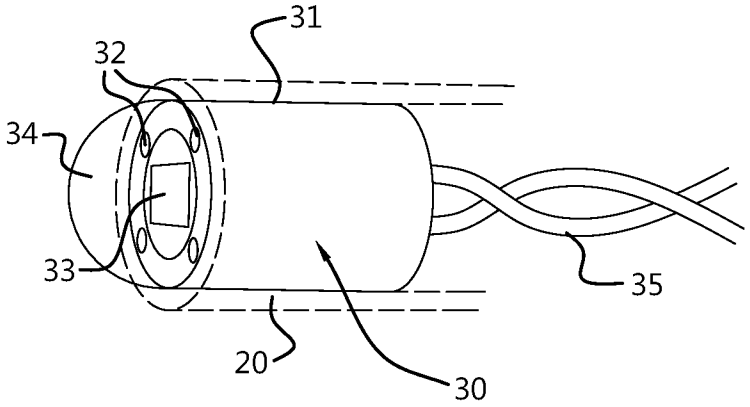


Fig. 6C

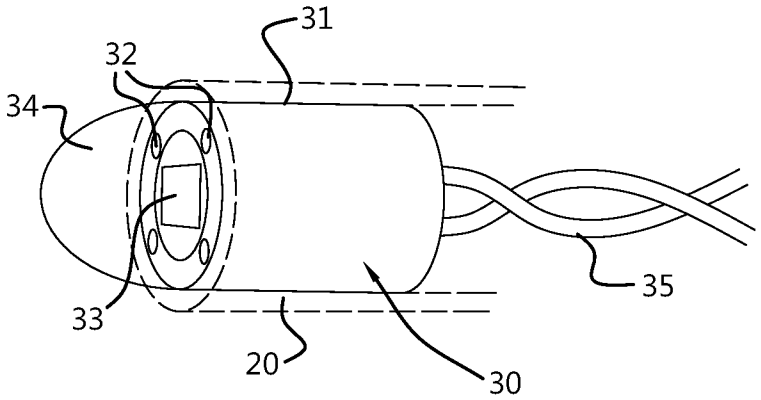


Fig. 6D

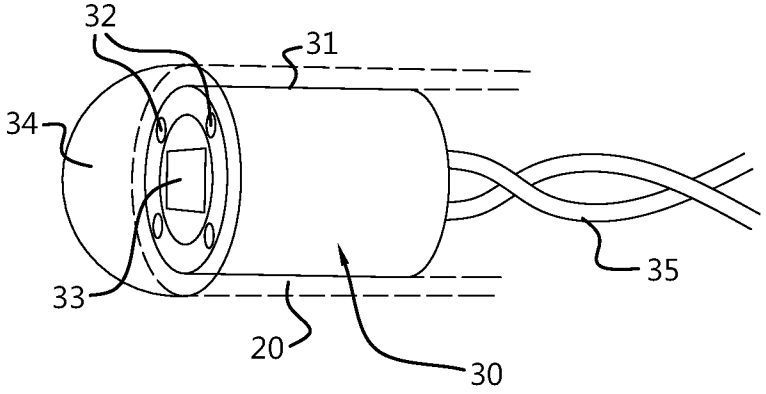


Fig. 7

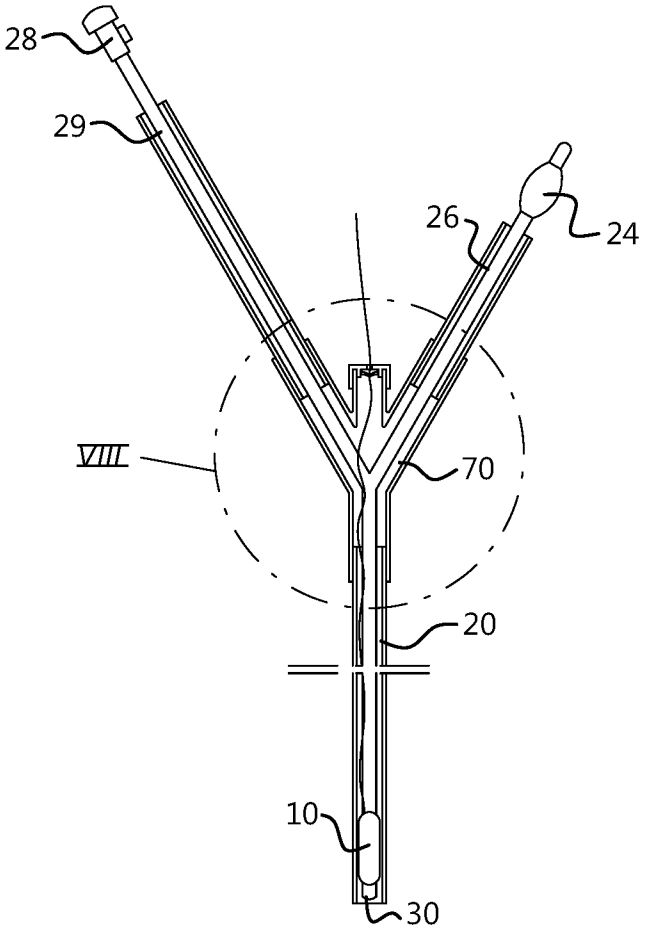


Fig. 8

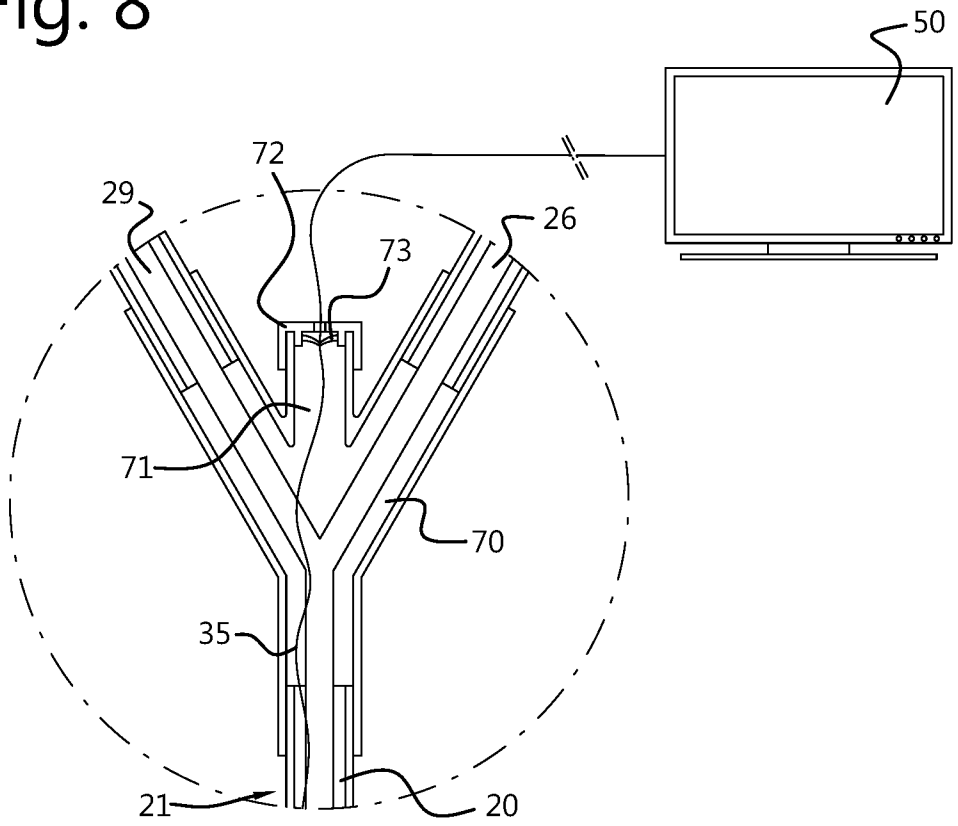
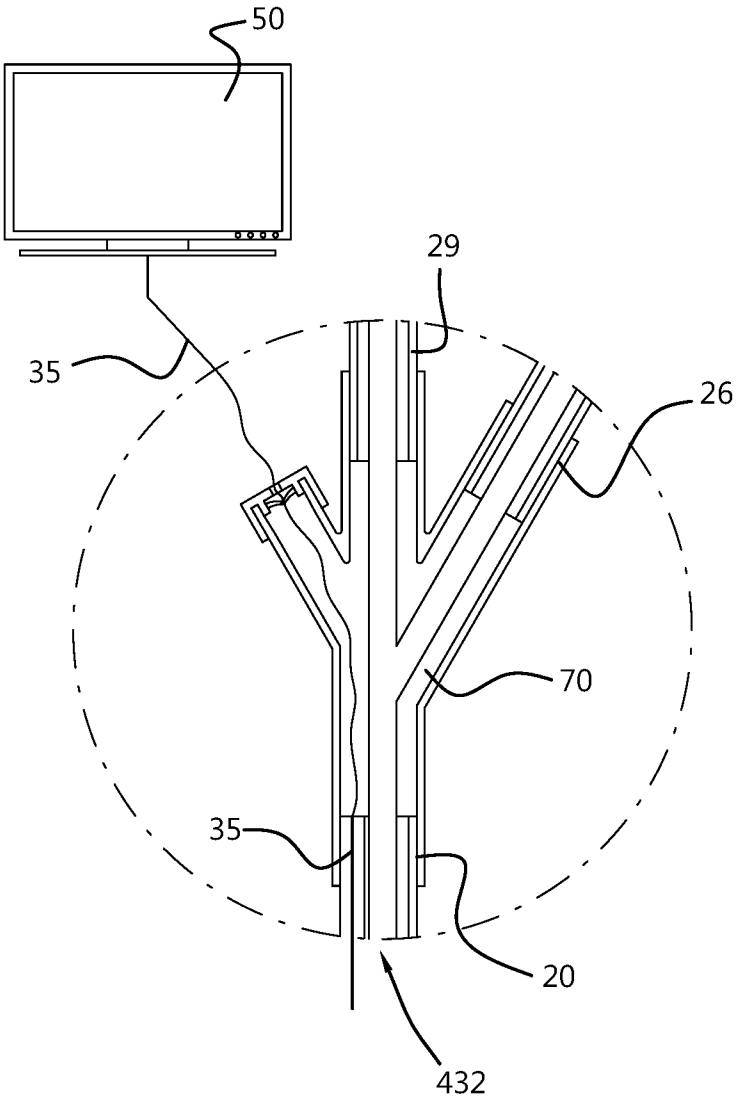


Fig. 9



SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
	2H/P168975NL00
Nederlands aanvraag nr. **2024964**	Indieningsdatum **21-02-2020**
	Ingeroepen voorrangsdatum
Aanvrager (Naam) **Stroke2Prevent BV**	
Datum van het verzoek voor een onderzoek van internationaal type **04-07-2020**	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. **SN76478**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)

Volgens de internationale classificatie (IPC)

Zie onderzoeksrapport

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimumdocumentatie

Classificatiesysteem	Classificatiesymbolen
IPC	**Zie onderzoeksrapport**

Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

III. ☐ **GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES** (opmerkingen op aanvullingsblad)

IV. ☐ **GEBREK AAN EENHEID VAN UITVINDING** (opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2024964

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61B8/08 A61B8/12 A61B18/00
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte miminum documentatie (classificatie gevolgd door classificatiesymbolen)
A61B

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X	US 5 331 947 A (SHTURMAN LEONID [US]) 26 juli 1994 (1994-07-26)	1,2, 4-11, 13-17
Y	* samenvatting * * figuren 1-17 * * kolom 4, regel 4 - kolom 7, regel 52 *	3,12,18, 19

Y	WO 99/64099 A1 (CARDEON CORP [US]) 16 december 1999 (1999-12-16) * samenvatting * * figuren 1-19 * * bladzijde 6, regel 14 - bladzijde 31, regel 6 *	3,12,18

Y	US 2019/321001 A1 (NIERICH ARNO [NL]) 24 oktober 2019 (2019-10-24) * samenvatting * * figuren 1-9 * * alinea [0043] - alinea [0055] *	19

☐ Verdere documenten worden vermeld in het vervolg van vak C.

☒ Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid	Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type
21 oktober 2020	

Naam en adres van de instantie	De bevoegde ambtenaar
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Moehrs, Sascha

Formulier PCT/ISA/201 (tweede blad) (Januari 2004)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2024964

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
US 5331947	A 26-07-1994	AU 4106193 A	29-11-1993
		US 5331947 A	26-07-1994
		WO 9321816 A1	11-11-1993
WO 9964099	A1 16-12-1999	AU 762236 B2	19-06-2003
		CA 2334978 A1	16-12-1999
		EP 1091782 A1	18-04-2001
		WO 9964099 A1	16-12-1999
US 2019321001	A1 24-10-2019	CN 110461241 A	15-11-2019
		EP 3551080 A1	16-10-2019
		US 2019321001 A1	24-10-2019
		WO 2018106103 A1	14-06-2018

WRITTEN OPINION

File No.	Filing date *(day/month/year)*	Priority date *(day/month/year)*	Application No.
SN76478	21.02.2020		NL2024964

International Patent Classification (IPC)
INV. A61B8/08 A61B8/12 A61B18/00

Applicant
Stroke2Prevent BV

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the application
- ☐ Box No. VIII Certain observations on the application

	Examiner
	Moehrs, Sascha

Application number

WRITTEN OPINION

NL2024964

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	3, 9-13, 17-19
	No:	Claims	1, 2, 4-8, 14-16
Inventive step	Yes:	Claims	
	No:	Claims	1-19
Industrial applicability	Yes:	Claims	1-19
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION

Box No. VII Certain defects in the application

see separate sheet

Reference is made to the following documents:

D1	*US 5 331 947 A (SHTURMAN LEONID [US]) 26 juli 1994 (1994-07-26)*
D2	*WO 99/64099 A1 (CARDEON CORP [US]) 16 december 1999 (1999-12-16)*
D3	*US 2019/321001 A1 (NIERICH ARNO [NL]) 24 oktober 2019 (2019-10-24)*

Re Item V

1 The present application does not meet the criteria of patentability, because the subject-matter of independent apparatus claim 1 is not new.

1.1 Document *D1* discloses *(the references in parentheses applying to this document)*:

Een systeem *(the system according to figure 1)* met een opblaasbaar element *(figure 1: element 30)* ingericht om in een deel van de luchtpijp van de patiënt te worden aangebracht *(description, column 4, lines 4 - 24)*, omvattende:

een katheter *(figure 1: 20)* die een opblaasbaar element draagt *(figure 1: 30)*, bedoeld om in de luchtpijp te worden aangebracht *(description, column 4, lines 4 - 24)*, welke katheter *(20)* is voorzien van een vloeistoflijn *(the space 38 according to figure 5)* om het opblaasbaar element *(30)* te vullen met een vloeistof *(the fluid according to the description, column 4, lines 25 - 66)*;

de katheter *(20)* heeft een eerste einde *(figure 1: 28)* bedoeld om buiten het lichaam van de patiënt gesitueerd te zijn en een tweede einde *(figure 1: 36)* bedoeld om in de luchtweg van de patiënt gesitueerd te zijn *(see figure 1)*;

een beeldvormingsinrichting *(figure 1: 22)* bevestigd aan of geïntegreerd met het tweede einde *(36)* van de katheter *(20)*.

The subject-matter of independent apparatus claim 1 is therefore not new.

2 Dependent claims 2 - 19 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of patentability.

2.1 The subject-matter of dependent claims 2, 4 - 8, 14 - 16 is not new, see particularly

Claim 2
D1: see the light source according to the description, column 4, line 67 - column 5, line 22;

Claim 4
D1: see the guiding according to figure 1;

Claim 5
D1: see the ultrasound imaging according to figure 8;

Claims 6 and 15
D1: see the connection / wires according to the description, column 4, lines 25 - 40;

Claims 7 and 8
D1: see the alignment and housing according to figure 5;

Claim 14
D1: figure 5: 38;

Claim 16
D1: see the flexibility according to figure 1.

2.2 The subject-matter of dependent claims 3, 12, 18, 19 is not inventive. Document *D1* is considered as the closest prior art with respect to these claims and the person skilled in the art is aware of the additional features from the following documents:

Claim 3
D2: description, page 11, lines 18 - 29;

Claim 12

D2: description, page 11, lines 14 - 17;

Claim 18
D2: description, page 9, lines 26 - 29;

Claim 19
D3: description, paragraphs 0053, 0054.

2.3 The subject-matter of dependent claims 9 - 11, 13, 17 is also not inventive. It relates to obvious design options (size of certain elements, dimensions, type and placement of sensors) which come within the scope of the customary practice followed by persons skilled in the art.

Re Item VII

3 The relevant background art disclosed in *D1 - D3* is not mentioned in the description, nor are these documents identified therein.