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(54) Title: DETECTION OF FLUID RETENTION IN A PATIENT

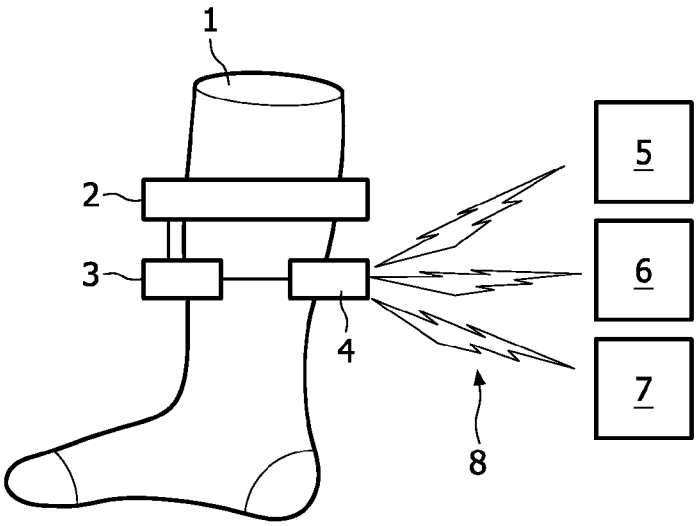

FIG. 1

(57) Abstract: The invention concerns a system for detection of fluid retention in a patient, comprising a garment 1 provided with a circumference measuring sensor 2 and adapted to be worn around a patient's limb, like an ankle, and an analyzer 3 for analyzing circumference data acquired by the circumference measuring sensor 2. Variations in circumference of the limb can be measured in different ways, e.g. based on a resistive or an inductive principle. This way, a reliable and easy to use possibility for detection of fluid retention in a patient is provided.

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Detection of fluid retention in a patient

FIELD OF THE INVENTION

The invention relates generally to the field of cardiovascular disease management and, in particular, to a system for detection of fluid retention in a patient, especially for treating patients with heart failure.

BACKGROUND OF THE INVENTION

Heart failure (HF) is a principal complication of virtually all forms of heart disease, e.g. coronary artery disease and heart attack. With heart failure, blood moves through the heart and body at a slower rate, and pressure in the heart increases. As a result, the heart cannot pump enough oxygen and nutrients to meet the body's needs. The kidneys often respond by causing the body to retain fluid, i.e. water, and sodium. If fluid builds up in the arms, legs, ankles, feet, lungs or other organs, the body becomes congested.

HF is a progressive condition characterized by frequent hospital admissions and ultimately high mortality rates. The prevalence of HF increases dramatically with age, occurring in 1 to 2 percent of persons aged 50 to 59 and up to 10 percent of individuals older than the age of 75. With the overall aging population, it is expected that the number of chronic cardiovascular disease patients - especially for congestive heart failure and atrial fibrillation - will increase in the coming years and, thus, the costs of disease management will increase, too. Further, HF is the most frequent cause of hospitalization among patients over 65.

Heart failure may affect the left, right, or both sides of the heart. If the left half of the heart fails (left ventricular failure), fluid builds up in the lungs due to congestion of the veins of the lungs. In case of right ventricular failure, general body vein pressure will increase and fluid will accumulate in the body, especially the tissues of the legs and abdominal organs. Often, left heart failure leads to right heart failure causing biventricular failure.

The current treatment of heart failure, and cardiovascular diseases in general, entails following a treatment program involving, sometimes complex, mixtures of medication, exercise and diet. The treatment focuses on treating the symptoms and signs of

HF and preventing the progression of disease. Patients with HF are educated to undertake various non-pharmacological measures to improve symptoms and prognosis. Such measures include moderate physical activity, weight reduction, sodium and fluid restriction.

The life expectancy and quality of life of HF patients has improved by more than 60 % due to the introduction of new pharmacological and device therapies. A key factor in order to alleviate symptoms and prolong the survival has been the extension of the range of medications from diuretics and cardiac glycosides to include angiotensin converting enzyme inhibitors (ACEI), beta-blockers, angiotensin receptor blockers (ARB), aldosterone receptor antagonists in the main treatment line. Despite major advances in the prevention and treatment of HF, patients have an impaired quality of life and a shortened life expectation.

Monitoring weight to detect abnormal fluid accumulation as an indication for potential complications is part of the current treatment. However, the use of a scale is a burden on the patients, and the measurement has not proven to be accurate enough to predict fluid congestion. A build up of water in the legs results in swelling in the legs, which can be seen as an increase in the circumference around the ankle.

Peripheral edemas are also common in many other conditions: renal or hepatic insufficiency, diabetes, overweight, pregnancy, elderly population and people with limited mobility. In all these cases it is desirable to monitor the fluid accumulation in the limbs of these patients.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a reliable and easy to use possibility for detection of fluid retention in a patient.

This object is achieved by a system for detection of fluid retention in a patient, comprising:

a garment provided with a circumference measuring sensor and adapted to be worn around a patient's limb, and

an analyzer for analyzing circumference data acquired by the circumference measuring sensor.

In the context of the present invention, the term "garment" means any kind of wearable piece of clothing, bandage, tape or the like, like medical, therapeutical and/or compression stockings, hosiery etc. Further, the term "limb" means any extremity of the human body which is suitable for wearing a respective garment, e.g. calf, leg, arm, wrist etc. Furthermore, the garment may be reusable or disposable. Moreover, the analyzer may be a

passive or an active device. As an active device, the analyzer may comprise a current or voltage source for providing the circumference measuring sensor with electrical energy or for analyzing a property of the circumference measuring sensor that varies with circumference of the garment. Further, the terms "circumference", "circumference data" and "circumference variations" are related to the total circumference (360°) or only part of the total circumference (< 360°).

Heart failure patients and people with diseases where fluid build-up can occur in the legs are often elderly with limited technical expertise and little mental capacity to be able to carry out complex measurements to monitor their health status. Patients' capacity to assess their own health status may be limited:

They may see that the leg is more or less swelled than the day before, but be unable to quantitatively measure the phenomenon. Furthermore, extensive and complicated regular health status measurements can impinge greatly on the lives of the patient, resulting in a significant reduction in patient quality of life.

With respect to this, according to the invention, a system is proposed that gives reliable measurements of the circumference of a limb, e.g. an ankle, and - derived from this - the swelling level, e.g. in the leg. These measurements can be carried out without requiring any extra patient effort, while preferably wearing a garment that the patient would be wearing anyway.

Regular ankle circumference measurements enable a new and improved treatment, which can alert of a worsening of the patient's health state, enabling preventative action, and reducing the number of expensive and stressful hospitalizations and re-hospitalizations. Such measurements can easily be integrated into the patient's daily life, which is already disturbed by the often complicated medication and treatment regime.

Thus, according to the invention, a system is provided that comprises at least one circumference measuring sensor which is incorporated into a garment, like a sock. This can be for example a widely used medical sock, to measure the circumference of a limb, e.g. an ankle, and thus the fluid retention in the lower legs in an unobtrusive way. Preferably, the system can store the circumference values measured over several days, allowing significant changes in these values to be detected. Further, according to a preferred embodiment of the invention, the system can then warn of a dangerous change in the fluid level by alerting the patient, using a visual or audible signal, or the caregiver, e.g. using a wireless connection without the patient being actively involved. An accurate assessment of the limb

circumference, and thus the accumulated fluid helps physicians to optimize therapies for their patients.

The system according to the invention can be tuned specifically for the patient concerned, thus improving the accuracy of the warning system. Further, according to a preferred embodiment of the invention, the system can be combined with other measurement and therapy technologies integrated into the garment, such as thermal measurement used in treatment of phlebitis or venous stasis, or adaptive compression, used in the treatment of varicose veins or thrombophlebitis. The sensor endowed garment will be easy to wear and easy to wash.

In general, the garment can be made of different materials. However, according to a preferred embodiment of the invention, the garment comprises an elastic material. This makes the garment more comfortable to wear and supports circumference variations which directly relate to variations of the circumference of the limb.

As already indicated above, according to a preferred embodiment of the invention, the garment is a sock to be worn on a patient's foot. Currently, therapeutic socks are available and are common items for bed-ridden people. However, these socks are only used to minimize the symptoms, and are not used for monitoring the patient's condition. The limb circumference measurements proposed according to this invention, to be preferably carried out in a sock, will give valuable health status information without being a burden for the patient.

Different techniques may be used for integrating a circumference measurement in the garment. As limb circumference may increase or decrease if the patient is walking or otherwise exercising the muscles, preferably this is to be taken into account when deriving the level of accumulation. According to a preferred embodiment of the invention, building an average value of the day and comparing this to a series of values rather than relying on a single measurement will consider this.

According to a preferred embodiment of the invention, the garment is provided with an electrical conductor having two electrical contacts. Preferably, as an electrical conductor an electric cable is used. Such an electrical conductor provides for different possibilities of measuring circumference variations.

According to one preferred embodiment, at least one contact is a sliding contact such that the length of the electrical conductor between the contacts varies according to circumference variations of the garment. Further, with respect to this, it is preferred that the analyzer is adapted for measuring the resistance of the electrical conductor between the

two contacts. This way, circumference variations of the limb can be measured by variations of the electrical resistance of the conductor.

Alternatively, according to another preferred embodiment, the ends of the electrical conductor are fixed to a respective electrical contact in a non-movable manner. Further, with respect to this, the electrical conductor is spirally wound. This provides for the possibility of detecting circumference variations of the limb based on the inductance of the electrical conductor. In other words, a coil is formed, the inductance value of which is proportional to the loop area of the coil. Accordingly, it is also preferred that the analyzer is adapted for measuring the inductance of the electrical conductor between the two electrical contacts. Furthermore, it is preferred that an elastic core is provided around which the electrical conductor is wound, which makes the design more robust and easy to apply.

According to still another embodiment of the invention, the garment is provided with a strain gauge for indicating variations in the circumference of the garment. For that, preferably multiple strain gauges are provided. Further, according to a preferred embodiment of the invention, the strain gauge is provided with an electrostatic shielding, preferably made of a metal foil, e.g. an aluminum foil.

Moreover, according to still an alternative embodiment of the invention, the garment is provided with an optical fiber. With respect to this, according to a preferred embodiment of the invention, the analyzer is adapted for detecting variations in the circumference of the garment based on an electromagnetic signal guided in the optical fiber. This means that according to this preferred embodiment, an emitted light or radio frequency signal can be transmitted inside a flexible optical fiber transversal to the limb. With a detector at the other end of the circumference, it is possible to estimate the length of the fiber based on the signal received, e.g. via phase detection, attenuation in amplitude, interference, distortions etc.

The circumference data can be dispatched in different ways. However, according to a preferred embodiment of the invention, the analyzer is adapted for wireless communication with an external unit. Accordingly, the circumference data can be sent, e.g. via a Bluetooth connection, to a patient mobile station and from there to a nurse or GP mobile station for further evaluation. For that, the system is preferably equipped with a battery, preferably with a rechargeable battery.

A preferred application of the invention is decompensation detection of right ventricular HF patients. The system is suitable for home or hospital application. Other target groups are patients suffering from renal or hepatic insufficiency, diabetes, overweight,

pregnancy, elderly population and people with limited mobility. The system can be included in a patient monitoring system, predicting either decompensation for HF patients or reporting fluid accumulation for the above diseases where peripheral edemas are common.

The system according to the invention can also be used for assessing the hydration level in elderly or sick people, covering also the problem of monitoring the adequate fluid intake in these populations. In this case, the term "fluid retention" applies to the degree of hydration of these patients.

The garments described above can be used for the present system according to the invention or any other system that requires measuring the circumference of a patient's limb. Accordingly, the invention also concerns a garment with a circumference measuring sensor and adapted to be worn around a patient's limb, wherein the circumference measuring sensor comprises an electrical conductor having two electrical contacts for electrically contacting the conductor. As described above in more detail, preferably, the measuring principle of the circumference measuring sensor is based on a resistive or an inductive principle. Alternatively, the circumference measuring sensor comprises at least one strain gauge and/or an optical fiber.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects of the invention will be apparent from and elucidated with reference to the embodiments described hereinafter.

In the drawings:

Fig. 1 shows a schematic depiction of a preferred embodiment of the invention,

Fig. 2 shows a schematic depiction of another preferred embodiment of the invention using a resistive principle,

Fig. 3 shows a schematic depiction of another preferred embodiment of the invention using an inductive principle,

Fig. 4 shows a schematic depiction of another preferred embodiment of the invention using strain gauges, and

Fig. 5 shows a schematic depiction of another preferred embodiment of the invention using an optical fiber.

DETAILED DESCRIPTION OF EMBODIMENTS

As can be seen from Fig. 1, according to a first preferred embodiment of the invention, the system for detection of fluid retention in a patient comprises a sock 1 provided with a circumference measuring sensor 2 and adapted to be worn around a patient's foot, an analyzer 3 for analyzing circumference data acquired by the circumference measuring sensor 2 and a wireless communication unit 4 for transmitting circumference data to an external unit like a patient mobile station 5, a nurse mobile station 6 and/or a doctor's office station 7 by a wireless connection 8. The circumference measuring sensor 2 and the analyzer 3 for analyzing circumference data acquired by the circumference measuring sensor 2 can be designed in different ways as set out in the following:

According to a preferred embodiment of the invention, a resistive flexible but not stretchable electrical cable 9 is positioned transversal to the ankle as can be seen from Fig. 2. This cable 9 is connected to a current source 10 by a fixed contact 11 and a sliding contact 12. By measuring the voltage between the two contacts 11, 12, with a voltmeter 13, it is possible to extract the value of the resistance of the cable 9 between the two contacts 11, 12, which is directly proportional to the length of the circumference of the ankle on which the sock 1 is worn. It is to be stressed that the change of circumference of the electrical cable 9 is independent of the change of circumference of the garment 1. The electrical cable 9 described is not stretchable but changes its circumference by the mechanism described. The garment 1 adjacent to the electrical cable 9 in the contrary is normally stretchable to a certain amount, as the garment 1 can be designed as common having common textile fibers. Garment 1 and electrical cable 9 being combined and changing circumference therefore means that garment 1 changes circumference by stretching the textiles comprised in the garment 1 whereas the electrical cable 9 changes circumference one end of the cable 9 sliding along the other end of the cable 9 or changing geometry, respectively. This is shown exemplary in Fig. 2 and Fig. 3, respectively.

According to another preferred embodiment of the invention, a circumference measurement via an elastic coil is used. For that, an electrical cable 14 is wound spirally around an elastic core 15, so that the cable 14 is stretchable in longitudinal direction. Thereby a coil is formed which is positioned transversally relative to the ankle, and the inductance value of which is proportional to the loop area S of the coil as shown in Fig. 3. The inductance of the coil can be expressed in terms of the geometry of the solenoid:

$$L = \mu_0 l \left(\frac{N}{l} \right)^2 S ,$$

where N is the number of loops, and l is the length, i.e. the circumference diameter.

An alternating current is injected into the cable 14 from an alternating current source 18.

By measuring the voltage between two fixed contacts 16, 17, with a voltmeter 19, the thickness of the ankle can be deduced.

According to a still further preferred embodiment of the invention, as can be seen from Fig. 4, strain gauges 20 integrated into the flexible material of a therapeutic sock 1 may yield a signal indicating changes in the circumference of the ankle. An electrostatic shielding 21, e.g. a shield of aluminum foil, suitably surrounds the strain gauges 20.

Finally, according to a still further preferred embodiment of the invention, as can be seen from Fig. 5, an emitted light or radio frequency signal is transmitted inside a flexible optical fiber 22 transversal to the ankle. With a sender 23 at the one end and a detector 24 at the other end of the fiber 22, it is possible to estimate the length of the fiber 22 based on the received signal, e.g. via phase detection, attenuation in amplitude, interference, distortions etc.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive; the invention is not limited to the disclosed embodiments. Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims. In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measured cannot be used to advantage. Any reference signs in the claims should not be construed as limiting the scope.

CLAIMS:

1. A system for detection of fluid retention in a patient, comprising:

a garment (1) provided with a circumference measuring sensor (2) and adapted to be worn around a patient's limb, and

an analyzer (3) for analyzing circumference data acquired by the circumference measuring sensor (2) to conclude to a fluid retention on basis of the circumference data.

2. The system according to claim 1, wherein the garment (1) comprises an elastic material.

3. The system according to claim 1 or 2, wherein the garment (1) is a sock to be worn on a patient's foot.

4. The system according to any of claims 1 to 3, wherein the garment (1) is provided with an electrical conductor (9; 14), preferably an electrical cable, having two electrical contacts (11, 12; 16, 17) for electrically contacting the conductor (9; 14).

5. The system according to claim 4, wherein at least one contact (12) is a sliding contact such that the length of the electrical cable (9) between the contacts (11, 12) varies according to circumference variations of the garment (1).

6. The system according to claim 4 or 5, wherein the analyzer (2) is adapted for measuring the resistance of the electrical conductor (9) between the two contacts (11, 12).

7. The system according to claim 4, wherein the ends of the electrical conductor (14) are fixed to a respective electrical contact (16, 17) in a non-movable manner and wherein the electrical cable (14) is spirally wound.

8. The system according to claim 7, wherein the analyzer (2) is adapted for measuring the inductance of the electrical conductor (14) between the two electrical contacts (16, 17).

9. The system according to any of claims 1 to 3, wherein the garment (1) is provided with at least one strain gauge (20) for indicating variations in the circumference of the garment (1).

10. The system according to claim 9, wherein the strain gauge (20) is provided with an electrostatic shielding (21).

11. The system according to claim 1 to 3, wherein the analyzer (2) is adapted for detecting variations in the circumference of the garment (1) based on an electromagnetic signal guided in an optical fiber (22) provided in the garment (1).

12. The system according to any of claims 1 to 11, wherein the analyzer (2) is adapted for wireless communication with an external unit (6, 7, 8).

13. A garment with a circumference measuring sensor (2) and adapted to be worn around a patient's limb, wherein the circumference measuring sensor (2) comprises an electrical conductor (9; 14) having two electrical contacts (11, 12; 16, 17) for electrically contacting the conductor (9; 14).

14. The garment according to claim 13, wherein the measuring principle of the circumference measuring sensor (2) is based on a resistive or an inductive principle.

15. A garment with a circumference measuring sensor (2) and adapted to be worn around a patient's limb, wherein the circumference measuring sensor (2) comprises at least one strain gauge and/or an optical fiber.

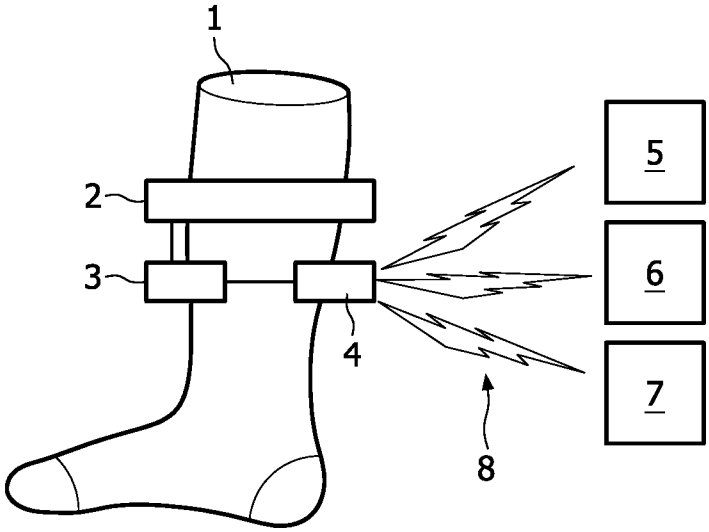

FIG. 1

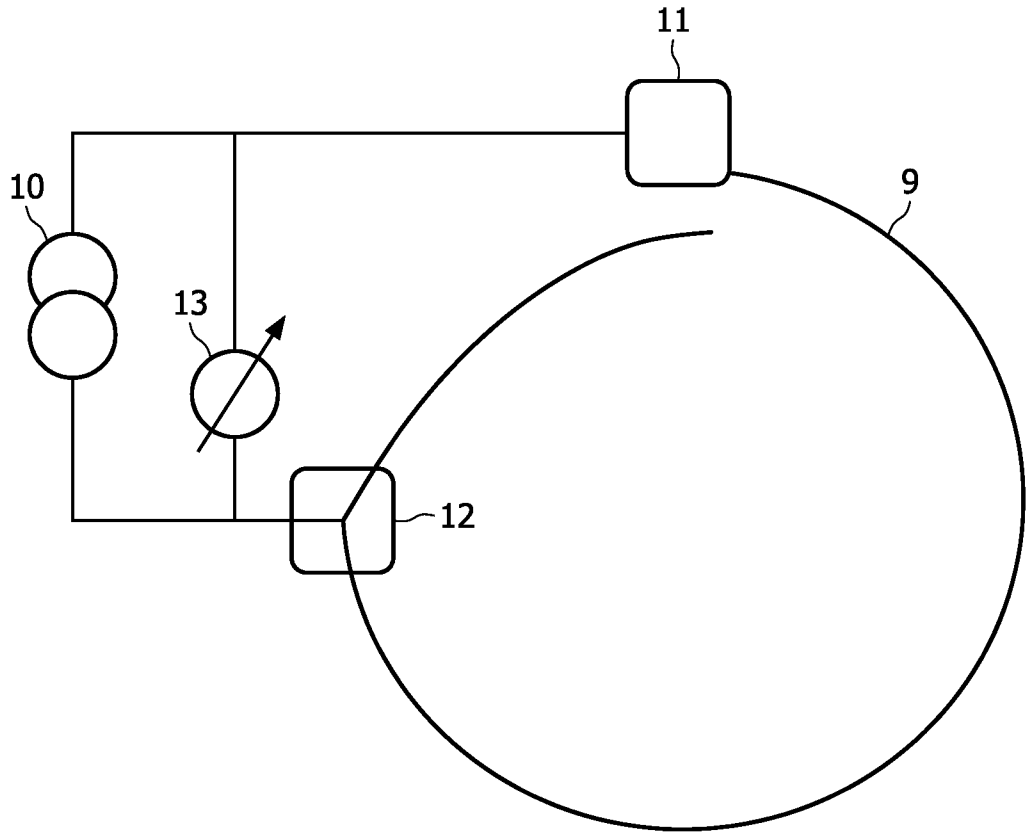

FIG. 2

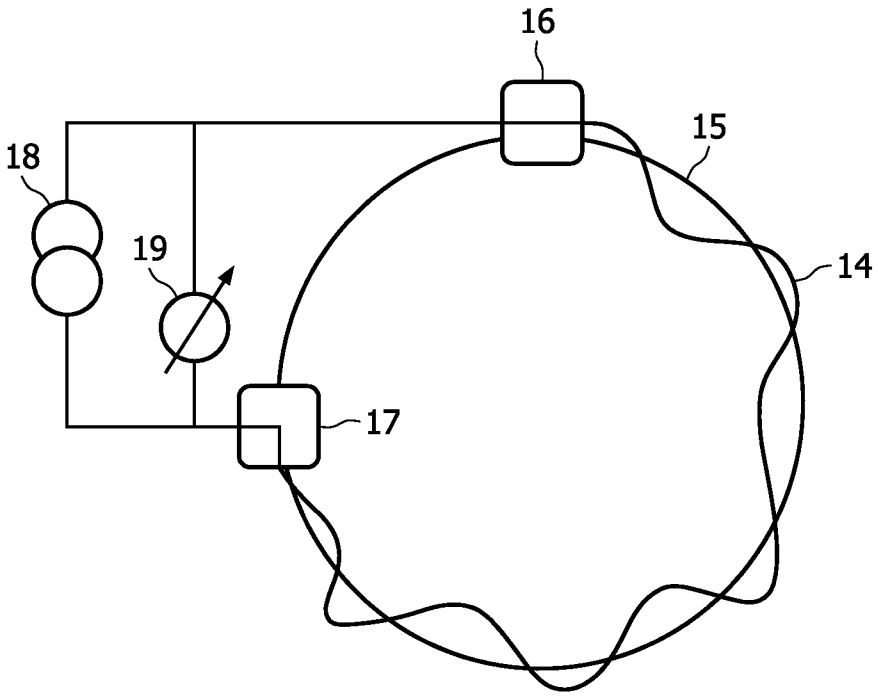

FIG. 3

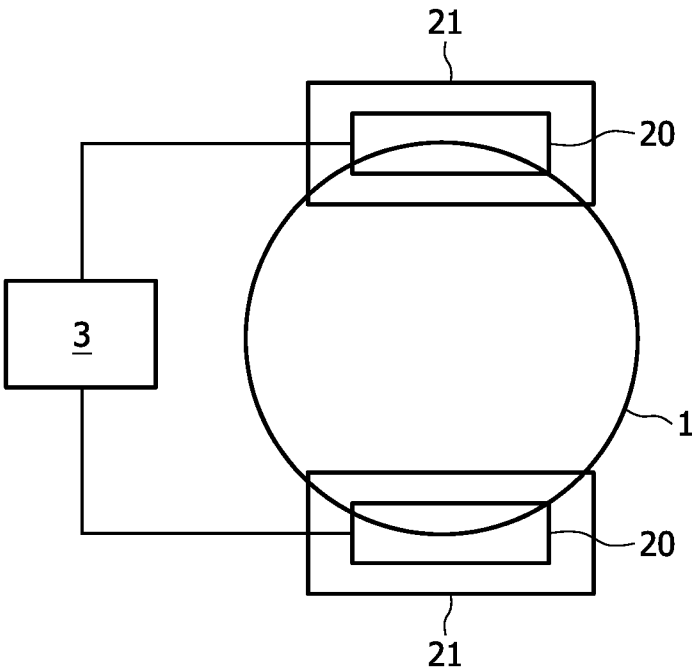

FIG. 4

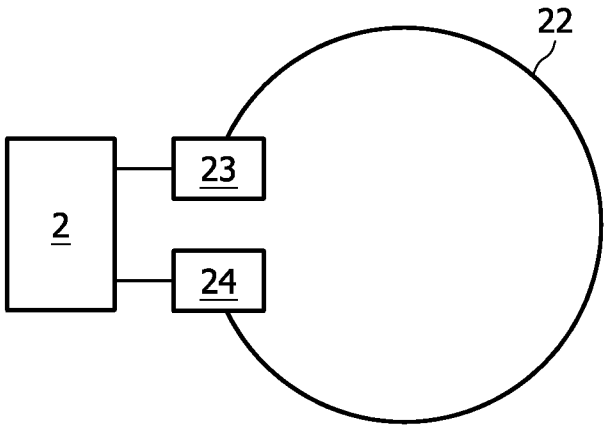

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2009/051411

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/107

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 497 787 A (NEMESDY GABOR [US] ET AL) 12 March 1996 (1996-03-12) abstract column 4, line 39 - column 7, line 5; figures 1-5	1-4,9, 10,13,15 5-8,11, 12,14
Y	US 3 853 118 A (SCHENDEL R) 10 December 1974 (1974-12-10) column 1, line 35 - column 2, line 35 figures 1-3	5-8,14
Y	WO 2007/097635 A (SANDHOLDT CARSTEN [NO]) 30 August 2007 (2007-08-30) abstract page 4, line 10 - page 6, line 33 figures 1,2,6,7	11,12

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[X] Further documents are listed in the continuation of Box C.

[X] 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)

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"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
28 July 2009	06/08/2009

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, Fax: (+31-70) 340-3016	Artikis, T

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2009/051411

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 891 059 A (ANDERSON JARED ARNOLD [US]) 6 April 1999 (1999-04-06) abstract column 2, line 53 - column 6, line 6 figures 1,2	1-15
A	US 5 915 386 A (LLOYD LESTER JOHN [US] ET AL) 29 June 1999 (1999-06-29) the whole document	1-15
A	US 4 383 533 A (LOVELACE ALAN M ADMINISTRATOR ET AL) 17 May 1983 (1983-05-17) abstract column 2, line 44 - column 6, line 40; figure 1	1-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2009/051411

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