



- (51) International Patent Classification:
A61B 5/022 (2006.01)
- (21) International Application Number:
PCT/EP2013/000386
- (22) International Filing Date:
8 February 2013 (08.02.2013)
- (25) Filing Language: English
- (26) Publication Language: English
- (71) Applicant: UP-MED GMBH [DE/DE]; Neumarkter
Straße 41, 81673 München (DE).
- (72) Inventors: PFEIFFER, Ulrich; Metzstrasse 34a, 81667
München (DE). KISBAN, Sebastian; Heimeranstrasse 63,
80339 München (DE). THOMAMÜLLER, Tobias; Aib-
linger Straße 2, 83052 Bruckmühl (DE). UHLITZ, Anna-
Luisa; Hilblestrasse 4, 80636 München (DE).
- (74) Agent: LAMBSDORFF & LANGE; Dingolfinger Str. 6,
81673 München (DE).

DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

— with international search report (Art. 21(3))

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,

(54) Title: BLOOD PRESSURE MEASURING SYSTEM COMPRISING A KINKING-PROOF SHELL

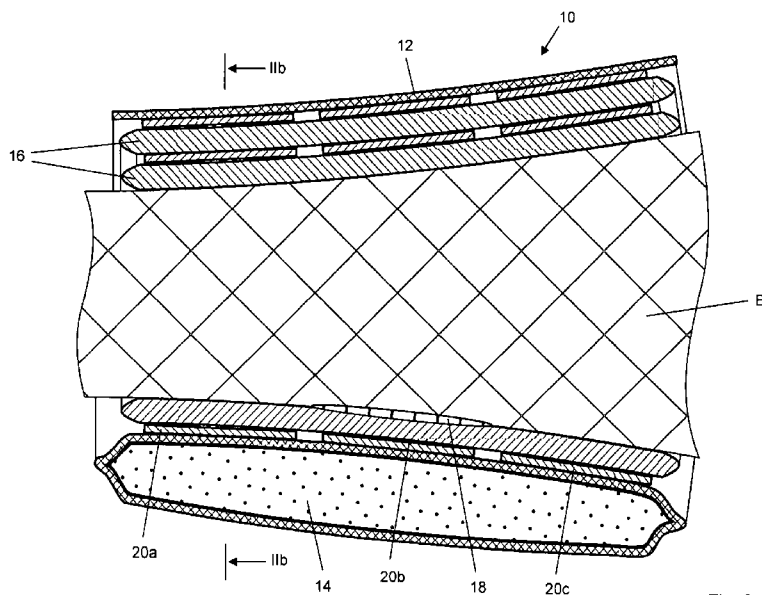


Fig. 3

(57) Abstract: The present invention refers to a blood pressure measuring system (10) configured to surround a patient's body part (E), comprising pressurization means (12, 14) for applying pressure to the body part (E), and comprising a kinking-proof shell (20a, 20b, 20c), wherein the kinking-proof shell (20a, 20b, 20c) is arranged so as to be located between the pressurization means (12, 14) and the body part (E), when the blood pressure measuring system (10) surrounds the body part (E).



Applicant:
UP-MED GmbH

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Blood pressure measuring system comprising a kinking-proof shell

The invention refers to a blood pressure measuring system configured to surround a
10 patient's body part, usually an extremity, comprising pressurization means for
applying pressure to the body part, and comprising a kinking-proof shell.

Such blood pressure measuring systems are generally known in the art. For example
the company OMRON offers such a system, named "Comfort Cuff" (PZN 2886114).
15 The "Comfort Cuff" product is adapted to be positioned around a patient's upper
arm. In order to apply pressure to the patient's upper arm for non-invasively
measuring the patient's arterial blood pressure, the "Comfort Cuff" comprises a
pressure cuff that can be inflated by supplying air to a fluid bag of the pressure cuff.
A pressure sensor measures the pressure in the fluid bag via a hose line. It is assumed
20 that the pressure in the fluid bag substantially corresponds to the pressure of the
body tissue at an outer surface of the patient's upper arm. Furthermore, the "Comfort
Cuff" comprises a relatively rigid (and thus kinking-proof) outer shell of substantially
cylindrical shape, exteriorly surrounding the pressure cuff with the fluid bag. The
outer shell makes it more comfortable to apply the "Comfort Cuff" to the patient's
25 upper arm, because it is not necessary to wrap the pressure cuff around the arm.
Moreover, the required filling volume of the fluid bag can be reduced compared to
blood pressure measuring systems without such a shell. Furthermore, the process of
positioning the system around the patient's upper arm and of measuring the patient's
blood pressure also becomes better reproducible with such a shell.

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The blood pressure measuring system described above has a problem that wrinkles (or kinks) may be formed at a compression acting surface of the fluid bag when measuring the blood pressure. If wrinkles are formed at the compression acting surface of the fluid bag, part of the patient's tissue at the measuring site may be trapped in the valley portions of the wrinkles, which may cause slight subcutaneous bleeding at the measuring site. Furthermore, wrinkles negatively influence the amplitude, form and reproducibility of the measured signal.

To avoid subcutaneous bleeding at the measuring site, i.e. at the skin of the patient's upper arm, when using a blood pressure measuring system as described above, US 2010/0137725 A1 proposes to accommodate a cushion material between the compression acting surface of the fluid bag and the measuring site. To ensure that, instead of the skin, the cushion material is trapped in the valley portions of the wrinkles, the cushion material has to be of a relatively high compressibility.

However, accommodating a cushion material between the compression acting surface of the fluid bag and the measuring site does not avoid the negative influence of the wrinkles (or kinks) as to the amplitude, form and reproducibility of the measured signal. To the contrary, part of the arterial pressure is absorbed and attenuated by the cushion material, thus, negatively influencing the measurement accuracy. As one countermeasure for preventing lowering in the measurement accuracy by pressure propagation loss, US 2010/0137725 A1 proposes to apply an empirical approach, i.e. to calculate for example the diastolic pressure value based on the measured maximum pressure value multiplied by an empirically determined factor. However, such empirically approaches are *per se* of poor preciseness, leading to unsatisfying results.

It is therefore an object of the present invention to improve blood pressure measuring systems of the above type so as to avoid subcutaneous bleeding at the measuring site, while at the same time improving the measurement accuracy.

This object is achieved by the features of independent claim 1. Preferred features of the inventive system are described in the dependent claims. In particular, the object

is achieved by a blood pressure measuring system configured to surround a patient's body part, comprising pressurization means for applying pressure to the body part, and comprising a kinking-proof shell, wherein the kinking-proof shell is arranged so as to be located between the pressurization means and the body part, when the
5 blood pressure measuring system surrounds the body part.

In contrast to the known blood pressure measuring systems described above, the blood pressure measuring system according to the present invention does not have the kinking-proof shell radially outside of the fluid bag (the fluid bag serving as the
10 pressurization means to apply pressure to the patient's body part) but the kinking-proof shell is located (or sandwiched) between the pressurization means (e.g. comprising a pressure cuff with a fluid bag) and the body part, when the blood pressure measuring system surrounds the body part for measuring the patient's blood pressure. Therefore, the kinking-proof shell – that is relatively stiff – avoids or at least
15 significantly reduces the creation of wrinkles or kinks at the compression acting surface of the fluid bag. Consequently, the measurement accuracy can be improved, since no wrinkles negatively influence the amplitude, form and reproducibility of the measured signal. In particular, if a pressure sensor unit is located at least partially between the kinking-proof shell and the body part, a high accuracy of the signals
20 measured by the pressure sensor unit can be achieved. With such a configuration of the pressure sensor unit, the kinking-proof shell does not absorb or attenuate the arterial pressure signal.

By arranging the kinking-proof shell according to the present invention, the
25 pressurization means, e.g. a pressure cuff with the fluid bag, maintains in its substantially ring-shaped form (without any wrinkles) when pressure is applied to the body part. Substantially the same is true for a flexible element having a stiffening element for stiffening the flexible element, if such a flexible element is accommodated between the kinking-proof shell and patient's body part, as will be
30 described in more detail below. When pressure is applied to the body part by the pressurization means, overlapping portions of the kinking-proof shell move or slide relatively to each other, thereby reducing the diameter of the kinking-proof shell.

The kinking-proof shell according to the present invention preferably exhibits stiffness notably larger than the stiffness of the flexible wall of a fluid bag if the pressurization means comprise such a fluid bag. Preferably the stiffness of the kinking-proof shell is chosen so as to ensure that no buckling of the kinking-proof shell will occur when pressure is applied to the body part by the pressurization means for measuring the patient's blood pressure. At the same time, the kinking-proof shell should be flexible enough so as to allow the kinking-proof shell to reduce its inner diameter when pressure is applied to the fluid bag for measuring the patient's blood pressure.

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If a flexible element having a stiffening element is accommodated between the kinking-proof shell and patient's body part, the stiffness of the kinking-proof shell is preferably also larger than the stiffness of the flexible element, at least as long as the flexible element is not stiffened by the stiffening element.

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Similarly to the outer shell of the "Comfort Cuff" product, the kinking-proof shell accommodated according to the present invention can provide more comfort in view of the positioning of the blood pressure measuring system around the patient's body part, such as the patient's upper arm or wrist, compared to a conventional blood pressure cuff without a shell, because it is not necessary to wrap a pressure cuff around the arm. Moreover, the required filling volume of the fluid bag can be reduced compared to blood pressure measuring systems without a corresponding shell. Furthermore, the process of positioning the system around the patient's upper arm and of measuring the patient's blood pressure is better reproducible with the shell.

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The pressurization means may be implemented by a mechanical pressure cuff, in particular by a fluid-free pressure cuff, such as a pressure cuff comprising an actuator, e.g. a motor, and a cable pull. The cable of the cable pull may connect the two longitudinal ends of the pressure cuff and/or the cable may surround the body part. However, additionally or alternatively to a mechanical pressure cuff, the pressurization means may equally comprise a pressure cuff with a fluid bag, similar to the above described "Comfort Cuff" product.

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If the pressurization means comprise a pressure cuff with a fluid bag, another advantage of accommodating the kinking-proof shell according to the invention, i.e. accommodating the kinking-proof shell between the pressure cuff with the fluid bag and the body part, is that more pressure (e.g. the double amount of pressure) has to be applied to the fluid bag for achieving the same pressure at the patient's body part compared to a system of the prior art, because part of the applied pressure is not transmitted to the patient's body part due to the relatively rigid kinking-proof shell. Applying more pressure to the fluid bag means making the fluid bag – which acts as a gas spring – stiffer, thereby reducing attenuation of pressure oscillations stemming from the patient's heart beats. Thus, measurement accuracy can be further improved.

Notably, with the blood pressure measuring system according to the present invention, another relatively rigid shell may additionally be applied radially outside from the pressurization means, similar to the outer shell of the above described "Comfort Cuff" product. Such a configuration allows reducing the required filling volume of a fluid bag – if the pressurization means comprises a pressure cuff with a fluid bag – when the fluid bag is sandwiched between the radially outer rigid shell and the radially inner kinking-proof shell. Reducing the filling volume, in turn, allows for faster reaching the required pressure to be applied to the patient's body part.

Preferably, the kinking-proof shell is dimensioned so as to overlap when surrounding the body part. In other words, the kinking-proof shell preferably completely surrounds the patient's body part. Thus, kinks or wrinkles can be avoided – or at least significantly reduced – along the whole circumference of the blood pressure measuring system. For example, the patient's body part may correspond to a patient's upper arm or to a patient's wrist.

As kinks or wrinkles are avoided – or at least significantly reduced – due to the accommodation of the kinking-proof shell according to the present invention, overlapping portions of the blood pressure measuring system should be able to move or slide relatively to each other when its inner diameter is reduced due to the supply

of pressurized fluid, preferably air, to the fluid bag. Therefore, the blood pressure measuring system is preferably designed so that overlapping portions can easily slide relatively to each other. For example, surface portions of the blood pressure measuring system that are in direct sliding contact with each other may exhibit a relatively low friction coefficient, e.g. by choosing the materials and/or the surface structures correspondingly. The term "low friction coefficient" in the context of the present invention refers to a friction coefficient (of two flat surfaces) of less than 0.5, preferably of less than 0.3, more preferably of less than 0.2, and even more preferably of less than 0.1. Sliding may also be enhanced by providing the blood pressure measuring system with a substantially cylindrical or conic shape.

Preferably, the blood pressure measuring system further comprises a flexible element configured to at least partially surround the body part and having a stiffening element configured to stiffen the flexible element. Such a flexible element is described in detail in DE 10 2009 39257 A1. The content of DE 10 2009 39257 A1 is incorporated herein by reference. Due to the stiffening element, the flexible element is changeable from a non-stiffened state to a stiffened state. For example, the flexible element with the stiffening element may be formed by an air-tight pouch that includes essentially incompressible elements having a volume in vacuum configured to change less than 50%, preferably less than 25%, more preferably less than 10%, and even more preferably less than 1% in comparison to a volume at atmospheric pressure. The essentially incompressible elements are, for instance, plastic granules, rice, particles made of polystyrene or a similar plastic, shredded paper, paper pellets, sheets of paper, Styrofoam beads, sawdust, salt, any powder or similar elements. The essentially incompressible elements located in the air-tight pouch are preferably a mixture of different types of incompressible elements. As the incompressible elements, special preference is given to sheets of paper or of another material that are layered to form a stack. After placing the blood pressure measuring system with the flexible element in a non-stiffened state around a patient's body part, pressure may be applied to the body part by the pressurization means, e.g. pressure may be applied to a fluid bag. Then, air may be evacuated from the air-tight pouch of the flexible element, thereby stiffening the flexible element. The flexible element is preferably arranged (sandwiched) between the pressurization means and the

patient's body part, more preferably between the kinking-proof shell and the patient's body part. The stiffened flexible element, thus, avoids (or at least significantly reduces) pressure oscillations stemming from the patient's heart beats to be attenuated by the pressurization means which may comprise e.g. a fluid bag. A
5 pressure sensor unit – that is preferably located at least partially between the flexible element and the patient's body part – can therefore obtain signals of high measurement accuracy, when the flexible element is in its stiffened state during the measurement.

10 If the incompressible elements are essentially formed by sheets of paper or of another material that are layered to form a stack, each layer preferably comprises a plurality of subareas that are displaceable relatively to each other, wherein each subarea is preferably connected with at least one other subarea of the same layer. Preferably, the subareas are interconnected with each other by connection elements.
15 More preferably, the connection elements are integrally formed with the subareas. The connecting elements may be formed so as to function as hinges for the subareas interconnected by the connecting elements. That way, the flexible element is extremely flexible in its non-stiffened state and, thus, can easily adapt to the three-dimensional shape of the patient's body part. However, in its stiffened state, when a
20 vacuum is applied to the air-tight pouch, the stacked layers are pressed against each other, thereby forming a very stiff force-fitted compound.

If the blood pressure measuring system comprises a flexible element having the stiffening element, the kinking-proof shell is preferably sandwiched between the
25 pressurization means, e.g. a pressure cuff with the fluid bag, on the one hand and the flexible element having the stiffening element on the other hand. At their edge regions, the pressurization means and the flexible element having the stiffening element may be connected to each other, thereby securely enclosing the kinking-proof shell. For example, the pressurization means may be irreversibly connected to
30 the flexible element having the stiffening element, e.g. by heat welding or by adhesive bonding.

Furthermore, if the blood pressure measuring system comprises a flexible element having the stiffening element, the kinking-proof shell may be attached to an outer surface of the flexible element having the stiffening element. For example, the kinking-proof shell may be irreversibly attached to the flexible element having the stiffening element, e.g. by heat welding or by adhesive bonding. However, in a particularly preferred embodiment, the flexible element having the stiffening element comprises on its outer surface at least one sleeve, preferably made from a plastic material, which at least one sleeve is adapted for housing the kinking-proof shell. The kinking-proof shell is preferably housed in the at least one sleeve in such a way that it can move, e.g. slide, relatively to the flexible element having the stiffening element. With such a configuration, the flexible element having the stiffening element and the kinking-proof shell may better adapt to the shape of the patient's body part when pressure is applied by the pressurization means.

Preferably, the kinking-proof shell is made from metal and/or plastic, in particular fiber-reinforced plastic. For example, the kinking-proof shell might be made from a thermoplastic material, preferably from a polyolefin, more preferably from polyethylene and/or polytetrafluorethylene. If the kinking-proof shell comprises fiber-reinforced plastic material, the fibers may be natural fibers, organic fibers or inorganic fibers. The material and the shape, in particular the thickness, of the kinking-proof shell should be chosen so that the kinking-proof shell, on the one hand, is stiff enough not to buckle when pressure is applied by the pressurization means, and that the kinking-proof shell, on the other hand, is flexible enough so as to allow a reduction of its inner diameter when pressure is applied by the pressurization means. Especially if the kinking-proof shell is substantially made from plastic material, experimental tests performed by the inventors have shown that the kinking-proof shell preferably exhibits a thickness of between about 0.25mm and about 6mm, more preferably between about 1mm and about 3mm, even more preferably between about 1.5mm and about 2.5mm. For example the kinking-proof shell may be made from polyethylene, having a thickness of about 2mm. The thickness of the kinking-proof shell may be reduced, preferably gradually, at the edge regions of the kinking-proof shell. Thus, the kinking-proof shell may have some

kind of ramp-shaped form at its edge regions so as to promote relative sliding of the overlapping portions of the blood pressure measuring system.

Experimental tests of the inventors have also shown that it is advantageous – in order to avoid kinks on the one hand and to allow a reduction of the inner diameter on the other hand – that the kinking-proof shell preferably exhibits a modulus of elasticity of more than 50MPa, more preferably of between about 100MPa and about 10GPa, even more preferably of between about 200MPa and about 1GPa.

10 The kinking-proof shell may exhibit a substantially cylindrical configuration, so that the blood pressure measuring system can be easily applied to the patient's body part, preferably the patient's upper arm, without having to wrap the system around that body part. Preferably, the kinking-proof shell, however, exhibits a rather conical configuration so as to better adapt to the shape of the body part.

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To have close contact with the patient's body part during blood pressure measurement is important for the blood pressure measuring system in order to obtain results of high quality. However, as the patient's body part, e.g. the patient's upper arm, may have a complex shape (i.e. not an ideal cylindrical or conical shape, but a rather concave and/or convex shape), it is advantageous that the kinking-proof shell comprises a plurality of individual shell elements. For example, the kinking-proof shell may comprise a plurality of strap-like shell elements (substantially arranged in parallel and preferably spaced apart from each other), each element being adapted for surrounding the patient's body part. If the blood pressure measuring system comprises a flexible element with a stiffening element, as described above, portions of the flexible element located substantially between two adjacent shell elements may function as hinges (as long as the flexible element is not stiffened), thereby allowing the kinking-proof shell to well adapt to the shape of the patient's body part. When the flexible element is then stiffened by the stiffening element, also the hinge-
25
30 portions are stiffened, thereby impeding relative movement of the individual shell elements.

If the kinking-proof shell comprises a plurality of individual shell elements, preferably at least two elements of the plurality of individual shell elements are arranged substantially parallel to each other, each extending in a circumferential direction of the body part when the blood pressure measuring system surrounds the body part. Such a configuration provides good flexibility of the system in a direction perpendicular to the circumferential direction of the patient's body part.

Additionally or alternatively, at least two elements of the plurality of individual shell elements may be arranged adjacent to each other in a circumferential direction of the body part when the blood pressure measuring system surrounds the body part. Such a configuration provides good flexibility of the system in the circumferential direction of the patient's body part. The at least two adjacent shell elements may be connected to each other by at least one flexible link. The at least one flexible link preferably restricts the maximal bending angle range between the adjacent shell elements. For example, the maximal bending angle range may be limited to 90°, preferably to 45° or even less. Furthermore, at least one link – preferably all links – may comprise a backing member which allows for angles between two adjacent shell elements smaller than a predetermined maximal angle (e.g. 180°) while at the same time inhibiting any bending angles greater than the predetermined maximal angle. This way, a shape different from circular, e.g. an elliptic shape, may be enabled and mechanical stress in the shell material is reduced, while kinking is still inhibited. In addition, the body part is not forced to take on a circular cross-section.

The blood pressure measuring system may further comprise a pressure sensor unit, wherein the pressure sensor unit is preferably arranged so as to be at least partially located between the kinking-proof shell and the body part, preferably next to the body part, when the blood pressure measuring system surrounds the body part. The pressure sensor unit may comprise a relatively small gel cushion or the like provided in direct contact with the patient's body part. The pressure sensor unit preferably further comprises a pressure transducer. The pressure transducer may be located in or on the gel cushion. Alternatively, the pressure transducer may be located remote from the measuring site at the patient's body part (i.e. remote from the gel cushion),

wherein the pressure transducer may be connected to the gel cushion e.g. via a tubing or hose filled with an appropriate gel or other fluid.

5 Arranging the pressure sensor unit that way – instead of measuring the pressure in the fluid bag of the pressurization means, as usually done in known devices – is advantageous, because the measured pressure signal is significantly less affected by attenuation phenomena caused by the fluid bag. Thus, the measurement accuracy can be further increased.

10 Preferably at least the pressurization means and the kinking-proof shell, more preferably all components of the system, are connected to each other in such a way as to form a single unit. Such a configuration allows the system to be wrapped as a single unit around the patient's body part for measuring the patient's blood pressure, which in turn allows for easy and fast application of the system and minimizes the
15 risk of faulty operation thereof.

In the following, the present invention is illustrated with reference to an exemplary embodiment shown in the accompanying drawings, in which:

20 Fig. 1a shows an embodiment of a blood pressure measuring system in a deflated state, wherein the blood pressure measuring system does not comprise a kinking-proof shell, and therefore does not form part of the present invention;

25 Fig. 1b shows the embodiment of Fig. 1a in an inflated state;

Fig. 2a shows an embodiment of a blood pressure measuring system according to the present invention in a deflated state;

30 Fig. 2b shows the inventive embodiment of Fig. 2a in an inflated state;

Fig. 3 shows a cross-sectional view of the inventive embodiment taken along line III-III of Fig. 2b;

Fig. 4a shows a three-dimensional view of the inventive embodiment but without the pressure cuff (comprising the fluid bag) for the sake of clarity;

5 Fig. 4b shows a view similar to the one of Fig. 4a but with the pressure cuff (comprising the fluid bag);

Fig. 5 shows a three-dimensional view of the inventive embodiment in a substantially flat configuration;

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Fig. 6 shows a three-dimensional view of the inventive embodiment wrapped around a patient's body part;

15 Fig. 7a shows a three-dimensional view (similar to the view shown in Fig. 4a) of a second inventive embodiment without the pressure cuff for the sake of clarity; and

Fig. 7b shows a three-dimensional view of the second embodiment of figure 7a in a substantially flat configuration.

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Figures 1a and 1b show an embodiment of a blood pressure measuring system 10' which embodiment does not comprise a kinking-proof shell and therefore does not form part of the present invention. This embodiment is described only to illustrate the disadvantages of blood pressure measuring systems known in the art. The shown
25 blood pressure measuring system 10' comprises a pressurization means which in turn comprises a pressure cuff 12' having a fluid bag 14', the pressure cuff 12' surrounding a patient's body part E, for example a patient's upper arm. Furthermore, the shown blood pressure measuring system 10' also comprises a flexible element 16' having a stiffening element. The flexible element 16' also surrounds the body
30 part E and is sandwiched between the body part E and the pressurization means comprising the pressure cuff 12' with the fluid bag 14'.

To measure the blood pressure of a patient, the blood pressure measuring system 10' is applied to the patient's body part E with the fluid bag 14' of the pressure cuff 12' being in a deflated state, as shown in figure 1a. Then, a pressurized fluid, preferably air, is applied to the fluid bag 14', thereby inflating the fluid bag 14', as illustrated in figure 1b. Afterwards, the flexible element 16' may be stiffened by the stiffening element so as to reduce attenuation effects of the inflated fluid bag 14' during measurement. A pressure sensor unit (not shown in figures 1a and 1b) is preferably provided at least partially between the flexible element 16' and the patient's body part E. The flexible element 16' with the stiffening element is preferably formed by an air-tight pouch that includes essentially incompressible elements, preferably sheets of paper that are layered to form a stack. Preferably each sheet of paper has a cutting pattern so as to provide high flexibility to the flexible element 16' in its non-stiffened state. For stiffening the flexible element 16', a vacuum may be applied to the air-tight pouch, so that the stacked paper layers are pressed against each other, thereby forming a stiff force-fitted compound.

As illustrated in figure 1b, the problem of this blood pressure measuring system 10' is that wrinkles or kinks are formed at a compression acting surface (i.e. the interior surface) of the fluid bag 14' when pressure is applied to the fluid bag 14'. These wrinkles or kinks cause also the flexible element 16' to buckle. Thus, part of the skin of the body part E can be trapped in the valley portions of the kinks of the flexible element 16', which may cause slight subcutaneous bleeding at the measuring site. Moreover, the cavities resulting from the wrinkles and kinks in the compression acting surface of the fluid bag 14' and/or in the flexible element 16' reduce the achievable measurement accuracy.

The wrinkles or kinks shown in figure 1b are formed substantially because the overlapping portions of the flexible element 16' do not (sufficiently) slide with respect to each other when pressure is applied to the fluid bag 14'. One reason for this is that the flexible element 16' in its non-stiffened state is not kinking-proof. Another reason is that the overlapping portions of the flexible element 16' exhibit poor sliding properties, e.g. due to geometric reasons.

To overcome this problem, the blood pressure measuring system 10 according to the present invention additionally comprises a kinking-proof shell 20 that is arranged between the pressurization means, comprising pressure cuff 12 with the fluid bag 14, and the body part E, as illustrated in figures 2a and 2b. More specifically, in the particular embodiment disclosed in figures 2a and 2b, the kinking-proof shell 20 is arranged (sandwiched) between the pressure cuff 12 with the fluid bag 14 and the flexible element 16. The pressure cuff 12 with the fluid bag 14 and the flexible element 16 can be attached, e.g. by heat welding or by adhesive bonding, to each other at their edge regions so as to securely accommodate the kinking-proof shell 20 in between.

In this embodiment, the kinking-proof shell 20 is preferably made from plastic material, such as polyethylene. The thickness of the kinking-proof shell 20 is chosen so that the kinking-proof shell 20 does not buckle when pressure is applied to the fluid bag 14, while at the same time the kinking-proof shell 20 is flexible enough to allow for a certain deformation of the kinking-proof shell 20. That is, when pressure is applied to the fluid bag 14, overlapping edge regions of the kinking-proof shell 20 move or slide relatively to each other so as to reduce the diameter of the kinking-proof shell 20. However, the kinking-proof shell 20 thereby remains substantially ring-shaped.

Due to the provision of the kinking-proof shell 20 according to the present invention, the formation of wrinkles or kinks in the compression acting surface of the fluid bag 14' can be significantly reduced and the formation of wrinkles or kinks in the flexible element 16 can be even completely avoided, as shown in figure 2b. Therefore, no subcutaneous bleeding at the measuring site occurs and the measurement accuracy is significantly improved.

A cross-sectional view of the blood pressure measuring system 10 according to line III-III of figure 2b is shown in figure 3. As can be seen in figure 3, the kinking-proof shell 20 comprises three individually formed shell elements 20a, 20b and 20c, being arranged substantially in parallel to each other. The shell elements 20a, 20b and 20c exhibit a substantially strap-shaped form surrounding the patient's body part E.

Forming the kinking-proof shell 20 from a plurality of individual elements 20a, 20b and 20c has the advantage that the kinking-proof shell better fits or adapts to the shape of the body part E. Preferably, the individual shell elements 20a, 20b and 20c are slightly spaced from each other so as to provide a high degree of flexibility.

5 Preferably, the individual shell elements 20a, 20b and 20c are attached to the outer surface of the flexible element 16. More preferably, the individual shell elements 20a, 20b and 20c are held in pockets or sleeves formed on the outer surface of the flexible element 16, the pockets or sleeves preferably being made from plastic material. That way, the regions of the flexible element 16 located substantially
10 between the individual shell elements 20a, 20b and 20c can act as hinge portions for the shell elements 20a, 20b and 20c, at least as long as the flexible element 16 is not stiffened by the stiffening element. When the flexible element 16 is stiffened, also the hinge portions are stiffened, thereby inhibiting any (angular) movement of the shell elements 20a, 20b and 20c relative to each other.

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In figure 3, also a (relatively small) gel cushion 18 is shown which forms part of a pressure sensor unit. The pressure sensor unit further comprises a pressure transducer (not shown) which is operatively connected, preferably via a fluid filled tubing, with the gel cushion 18. The gel cushion 18 is arranged between the kinking-proof shell
20 20 and the body part E, and more particularly, in the shown embodiment, between the flexible element 16 and the body part E. That way, both, the flexible element 16, when it is stiffened, and the kinking-proof shell 20 minimize adverse attenuation effects of the fluid bag 14 on the pressure sensor unit, thereby further improving the measurement accuracy.

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Notably, line IIb-IIb in figure 3 indicates the cross-sectional view shown in figure 2b.

Figures 4a and 4b show three-dimensional views of the blood pressure measuring system 10 according to the present invention, wherein – only for the sake of clarity –
30 the pressurization means comprising the pressure cuff 12 with the fluid bag 14 is not illustrated in figure 4a. As can be seen from figures 4a and 4b, the flexible element 16 comprises an evacuation port 16a through which the air-tight pouch of the flexible element 16 can be evacuated thereby stiffening the flexible element 16.

Similarly, the pressure cuff 12 comprises a pressure port 12a to apply pressurized fluid (preferably air) to the fluid bag 14 of the pressure cuff 12. Moreover the pressure cuff 12 comprises fastening means 22, such as hook-and-loop fastener, for attaching (preferably reversibly) the two longitudinally ends of the pressure cuff 12 to each other, which ends usually overlap when performing the blood pressure measurement.

Notably, all the above described components of the inventive blood pressure measuring system 10 are preferably connected to each other in such a way as to form a single unit which can be wrapped around the patient's body part for measuring the patient's blood pressure. Such a configuration of the inventive blood pressure measuring system 10 allows for easy and fast application and minimizes the risk of faulty operation thereof.

Figure 5 shows a three-dimensional view of the blood pressure measuring system 10 according to the present invention, wherein the blood pressure measuring system 10 is shown in a substantially flat, i.e. substantially non-wrapped, configuration. As can be seen from figure 5, the pressure cuff 12 comprises two complementary formed fastening means 22a and 22b, such as hook-and-loop fastener. It should be noted that both ends of the pressure cuff 12 of the blood pressure measuring system 10 according to the present invention may alternatively also be irreversibly be attached to each other. If both ends of the pressure cuff 12 are irreversibly attached to each other, it is not necessary to wrap the pressure cuff 12 around the patient's body part E, thus, making the processes of applying the blood pressure measuring system 10 easier.

Figure 6 shows a three-dimensional view of the blood pressure measuring system 10 according to the present invention, when applied to the patient's body part E, preferably to a patient's upper arm.

It should be generally noted that providing the flexible element 16 with the stiffening element to the blood pressure measuring system 10 is beneficial but not essential for the present invention. The known blood pressure measuring systems may equally be

improved according to the present invention if no flexible element 16 (that can be stiffened) is provided.

Finally, figures 7a and 7b show three-dimensional views of another (second) embodiment of the blood pressure measuring system according to the present invention. The same reference signs as in the description of the first embodiment are used for the same components. In the following, in particular the differences in view of the first embodiment are described in more detail.

Figure 7a shows a view of the second embodiment similar to the view of the first embodiment shown in figure 4a. Figure 7b shows the second embodiment of figure 7a in a substantially flat configuration. Only for the sake of clarity, the pressurization means (comprising the pressure cuff 12 with the fluid bag 14) is not illustrated in figures 7a and 7b. However, as will be apparent to those skilled in the art, the pressurization means equally form part of the second embodiment.

As can be seen from figures 7a and 7b, the flexible element 16 of the second embodiment also comprises the evacuation port 16a through which the air-tight pouch of the flexible element 16 can be evacuated thereby stiffening the flexible element 16. The second embodiment also comprises three individually formed shell elements 20a, 20b and 20c of the kinking-proof shell 20 which exhibit a substantially strap-shaped form for surrounding the patient's body part E. However, the second embodiment differs from the first embodiment in that the three individually formed shell elements 20a, 20b and 20c of the kinking-proof shell 20 are each further divided into three sub-elements 20a_1, 20a_2, 20a_3, 20b_1, 20b_2, 20b_3, 20c_1, 20c_2, and 20c_3. Thus, the kinking-proof shell 20 of the second embodiment in total comprises nine shell elements.

The three sub-elements of each of the three shell elements 20a, 20b and 20c are arranged adjacent to each other in a circumferential direction of the body part E when the blood pressure measuring system 10 surrounds the body part E. Furthermore, these adjacent sub-elements are connected to each other by flexible links 21. The shown embodiment, always two adjacent sub-elements are connected

to each other by two flexible links 21. However, another number of flexible hinges may equally be chosen. Even though the links 21 are flexible, they are designed to restrict the maximal bending angle range between two adjacent shell elements. The maximal bending angle range may be restricted to 90°, preferably to 45° or even less. Additionally or alternatively, at least one link 21 – preferably each link 21 – may comprise a backing member which allows for angles between two adjacent sub-elements smaller than a predetermined maximal angle (e.g. 180°) while at the same time inhibiting any bending angles greater than the predetermined maximal angle.

10 This way, a shape of the system 10 different from circular, e.g. an elliptic shape, is enabled and mechanical stress in the shell material is reduced, while kinking is still inhibited. In addition, the body part is not forced to a circular cross-section.

Consequently, with the second embodiment, the inventive system 10 is particularly designed to adapt very well to the natural form of the patient's body part E, both in the circumferential direction of the body part E and a direction substantially perpendicular thereto, while inhibiting at the same time the generation of kinks, so that the measurement of the patient's blood pressure can be performed with high accuracy.

Claims:

1. Blood pressure measuring system (10) configured to surround a patient's body part (E), comprising pressurization means (12, 14) for applying pressure to the
5 body part (E), and comprising a kinking-proof shell (20), characterized in that the kinking-proof shell (20) is arranged so as to be located between the pressurization means (12, 14) and the body part (E), when the blood pressure measuring system (10) surrounds the body part (E).
- 10 2. Blood pressure measuring system (10) according to claim 1, wherein the pressurization means (12, 14) comprises a pressure cuff (12) with a fluid bag (14).
- 15 3. Blood pressure measuring system (10) according to claim 1 or 2, wherein the kinking-proof shell (20) is dimensioned so as to overlap when surrounding the body part (E).
4. Blood pressure measuring system (10) according to any one of the preceding
20 claims, wherein the blood pressure measuring system (10) is designed so that overlapping portions thereof can easily slide relatively to each other.
5. Blood pressure measuring system (10) according to any one of the preceding
25 claims, further comprising a flexible element (16) configured to at least partially surround the body part (E) and having a stiffening element configured to stiffen the flexible element (16).
6. Blood pressure measuring system (10) according to claim 5, wherein the
30 kinking-proof shell (20) is sandwiched between the pressurization means (12, 14) and the flexible element (16) having the stiffening element.
7. Blood pressure measuring system (10) according to claim 5 or 6, wherein the kinking-proof shell (20) is attached to an outer surface of the flexible element (16) having the stiffening element.

8. Blood pressure measuring system (10) according to any one of the preceding claims, wherein the kinking-proof shell (20) is made from metal and/or plastic, in particular fiber-reinforced plastic, wherein the kinking-proof shell (20) is preferably made from a thermoplastic material, more preferably from a polyolefin, even more preferably from polyethylene and/or polytetrafluorethylene.
9. Blood pressure measuring system (10) according to any one of the preceding claims, wherein the kinking-proof shell (20) exhibits a thickness of between about 0.25mm and about 6mm, preferably between about 1mm and about 3mm, more preferably between about 1.5mm and about 2.5mm, wherein the kinking-proof shell (20) is preferably substantially made from plastic material.
10. Blood pressure measuring system (10) according to any one of the preceding claims, wherein the kinking-proof shell (20) exhibits a modulus of elasticity of more than 50MPa, preferably of between about 100MPa and about 10GPa, more preferably of between about 200MPa and about 1GPa.
11. Blood pressure measuring system (10) according to any one of the preceding claims, wherein the kinking-proof shell (20) exhibits a substantially cylindrical or conical configuration.
12. Blood pressure measuring system (10) according to any one of the preceding claims, wherein the kinking-proof shell (20) comprises a plurality of individual shell elements (20a, 20b, 20c; 20a_1, 20a_2, 20a_3, 20b_1, 20b_2, 20b_3, 20c_1, 20c_2, 20c_3).
13. Blood pressure measuring system (10) according to claim 12, wherein at least two elements of the plurality of individual shell elements (20a, 20b, 20c; 20a_1, 20a_2, 20a_3, 20b_1, 20b_2, 20b_3, 20c_1, 20c_2, 20c_3) are arranged substantially parallel to each other, each extending in a

circumferential direction of the body part (E) when the blood pressure measuring system (10) surrounds the body part (E).

14. Blood pressure measuring system (10) according to claim 12 or 13, wherein
5 at least two elements of the plurality of individual shell elements (20a_1, 20a_2, 20a_3, 20b_1, 20b_2, 20b_3, 20c_1, 20c_2, 20c_3) are arranged adjacent to each other in a circumferential direction of the body part (E) when the blood pressure measuring system (10) surrounds the body part (E).
- 10 15. Blood pressure measuring system (10) according to claim 14, wherein the adjacent shell elements (20a_1, 20a_2, 20a_3, 20b_1, 20b_2, 20b_3, 20c_1, 20c_2, 20c_3) are connected to each other by at least one flexible link (21), wherein the at least one flexible link (21) preferably restricts the maximal
15 bending angle range between the adjacent shell elements (20a_1, 20a_2, 20a_3, 20b_1, 20b_2, 20b_3, 20c_1, 20c_2, 20c_3).
16. Blood pressure measuring system (10) according to any one of the preceding claims, further comprising a pressure sensor unit, wherein the pressure sensor unit is preferably arranged so as to be at least partially located between the
20 kinking-proof shell (20) and the body part (E), more preferably next to the body part (E), when the blood pressure measuring system (10) surrounds the body part (E).
17. Blood pressure measuring system (10) according to any one of the preceding
25 claims, wherein at least the pressurization means (12, 14) and the kinking-proof shell (20), preferably all components of the system (10), are connected to each other in such a way as to form a single unit.

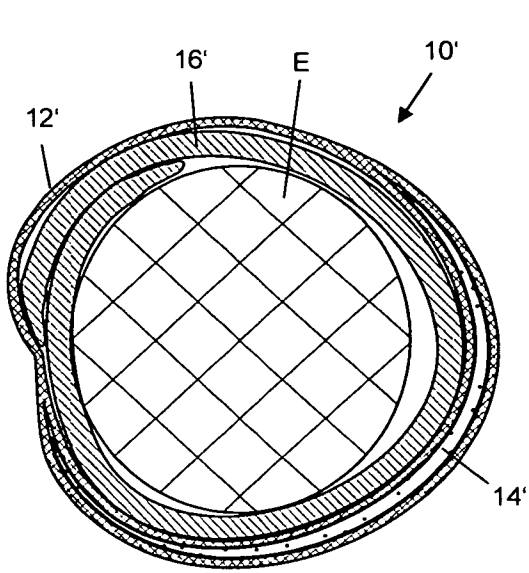


Fig. 1a

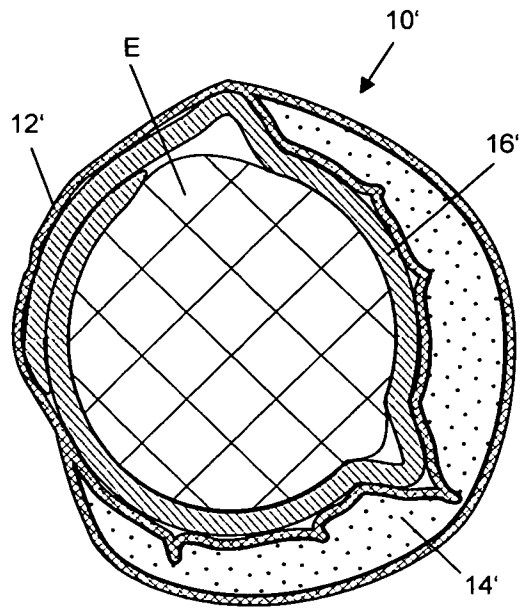


Fig. 1b

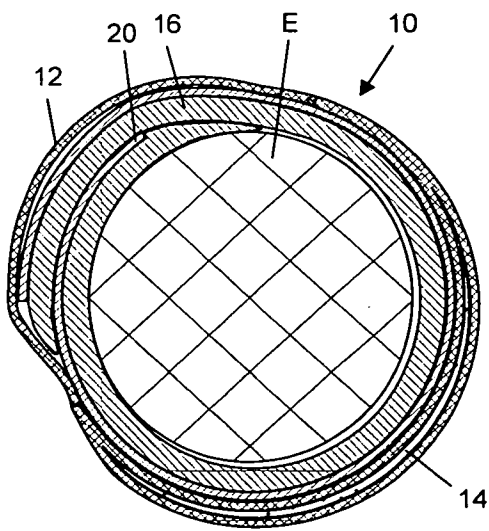


Fig. 2a

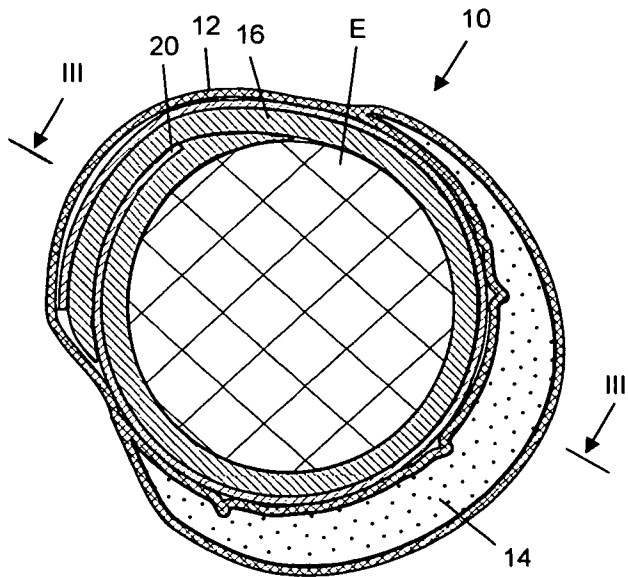


Fig. 2b

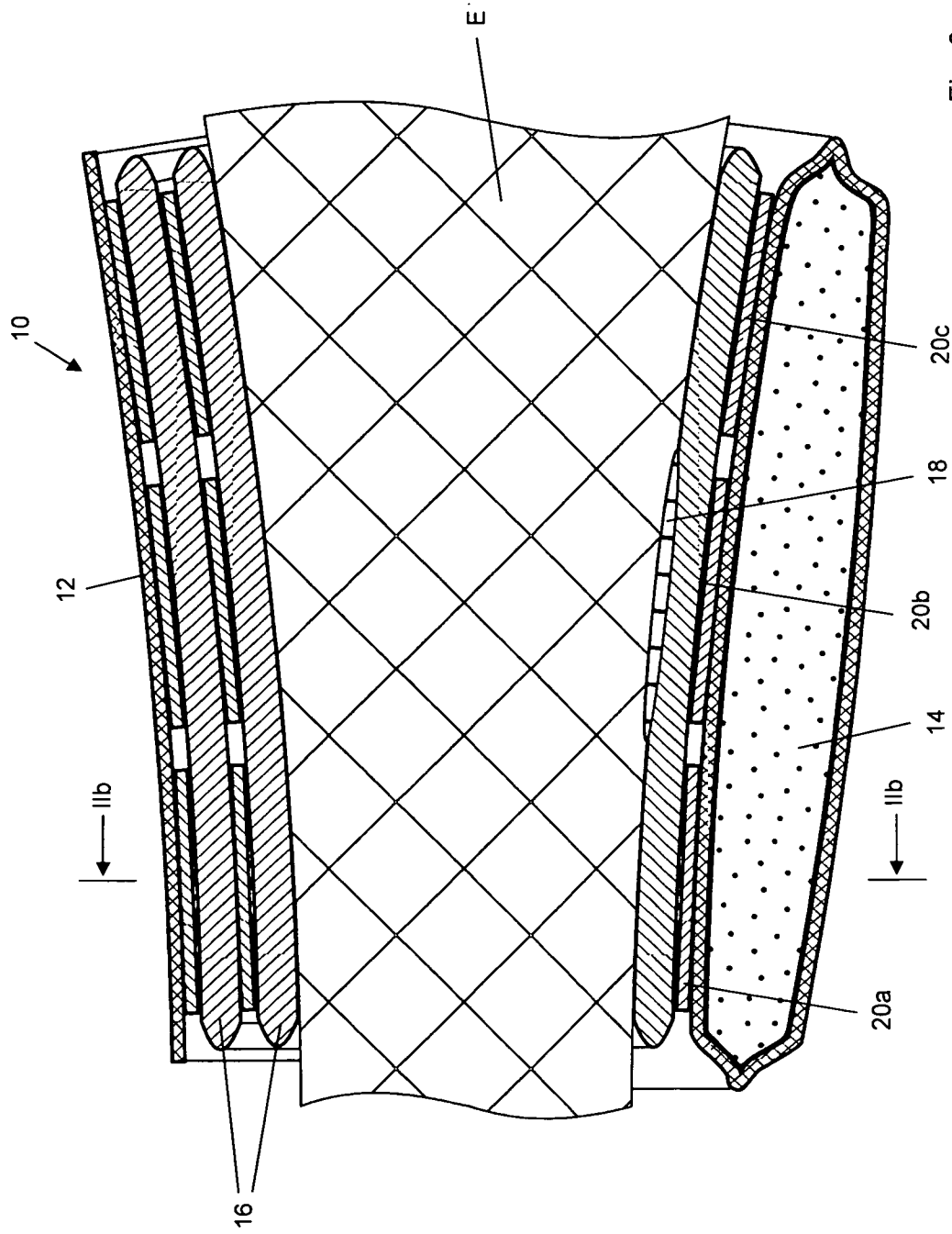


Fig. 3

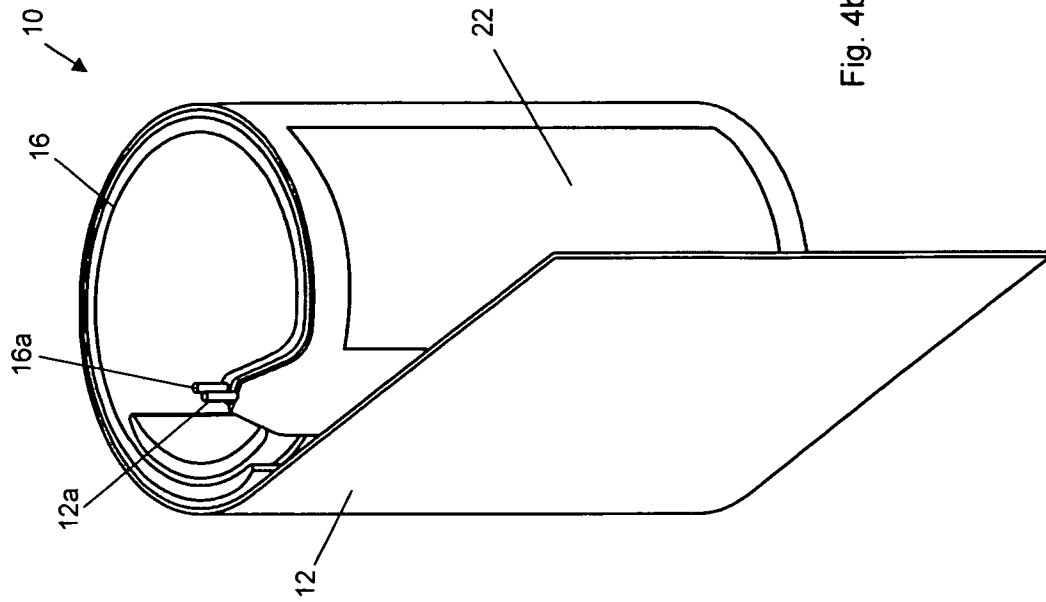


Fig. 4b

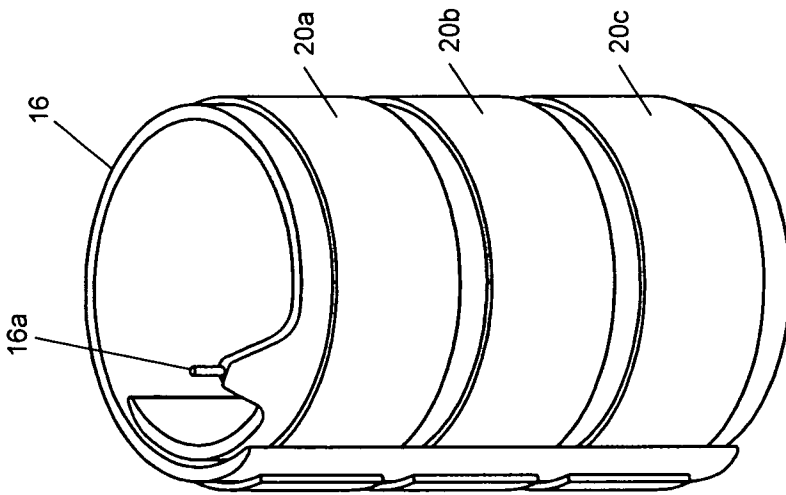


Fig. 4a

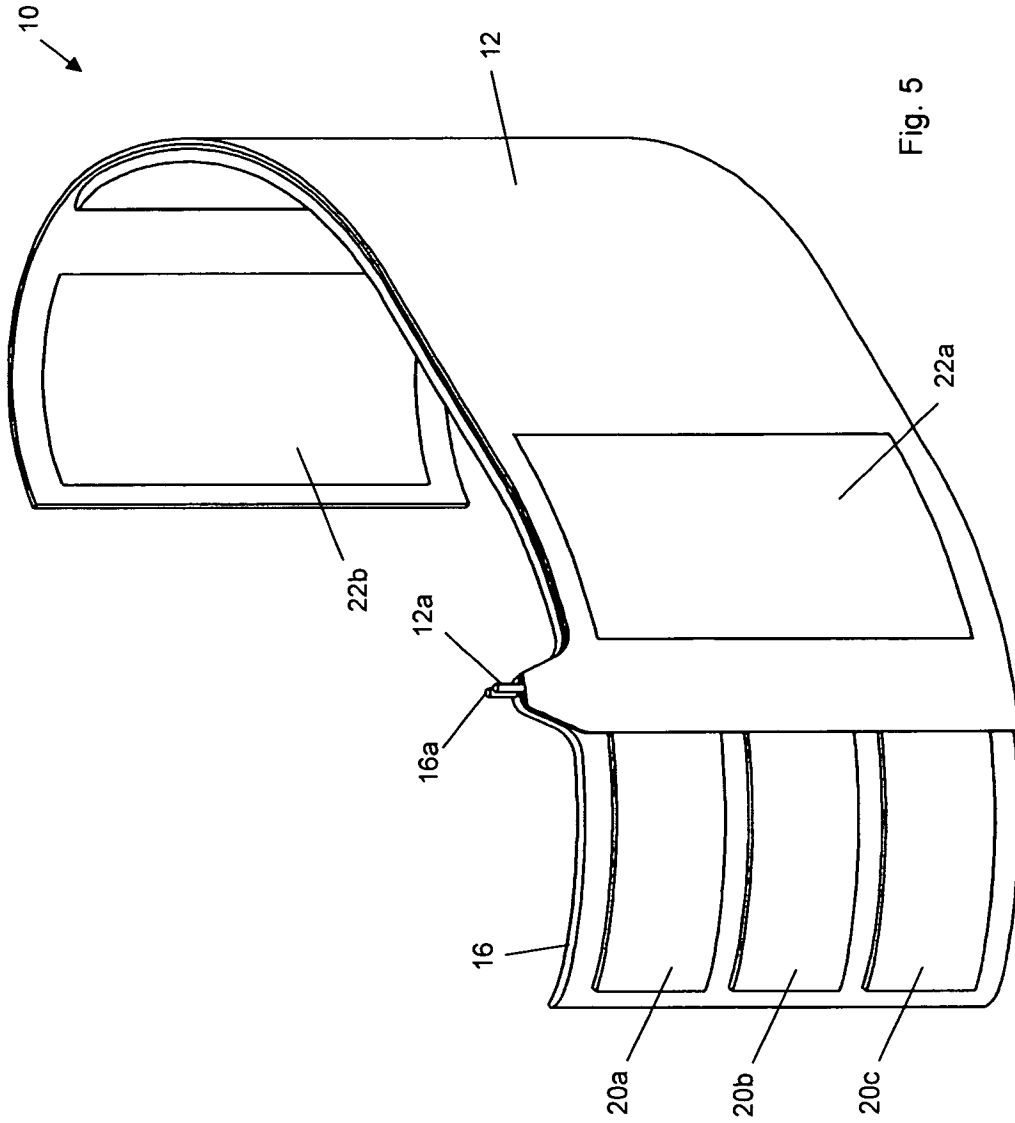


Fig. 5

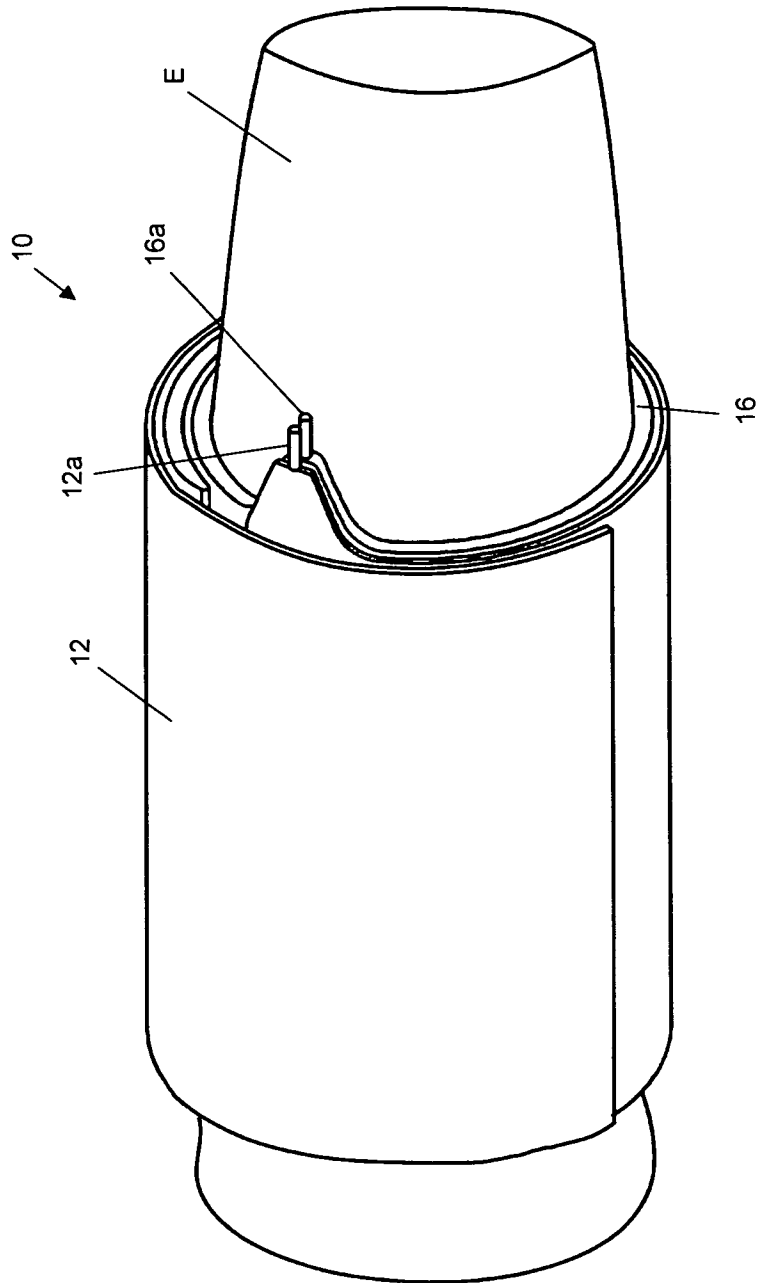


Fig. 6

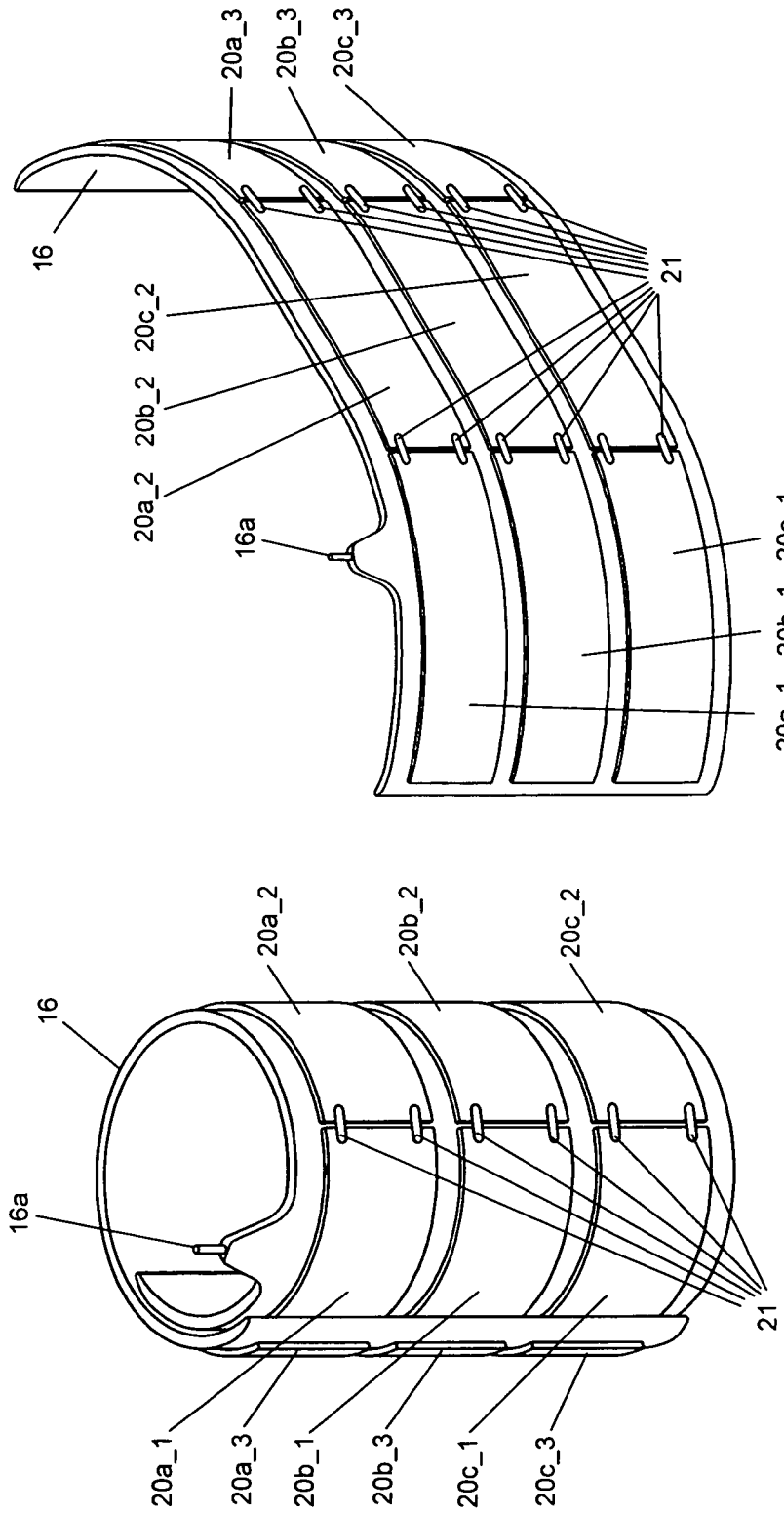


Fig. 7b

Fig. 7a

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/000386

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B5/022 ADD.		
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 practicable, 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 2009/234381 A1 (KARO HIROMICHI [JP]) 17 September 2009 (2009-09-17) paragraph [0045] - paragraph [0054] paragraph [0058] - paragraph [0066]; figures -----	1-5,10, 11,16,17
X	US 2009/062668 A1 (TODOKORO NORIAKI [JP] ET AL) 5 March 2009 (2009-03-05) paragraph [0044] - paragraph [0054]; figures -----	1-4,8,9, 12,13,17
X	US 2011/054330 A1 (PFEIFFER ULRICH [DE] ET AL) 3 March 2011 (2011-03-03) paragraph [0143] - paragraph [0192]; figures ----- -/--	1-5,11, 16,17
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> 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	"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	
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"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	
"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 3 December 2013	Date of mailing of the international search report 10/12/2013	
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Strubel, Christine	

INTERNATIONAL SEARCH REPORT

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