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(54) Title: IMPROVED WEARABLE TONOMETER

(57) Abstract: An improved tonometer (1) for continuously monitoring the arterial blood pressure of a patient for a predetermined period of time comprises a bracelet (10) configured in such a way to be applied to a wrist of a patient (100). It is, furthermore, provided a detection group (20) mounted on the bracelet (10) and arranged to detect a pressure signal. The detection group (20) comprises a plurality of pressure sensors (25) arranged to detect a respective pressure signal associated to the blood pressure wave of the patient (100). At least one pressure sensor (25) is positioned, in use, in proximity of the radial artery of the patient (100), at the opposite side of the radial bone. It is, also, provided a touching group (60) that is interposed, in use, between the detection group (20) and the radial artery of the patient and equipped with a plurality of protuberant members (65a-65d), each of which associated to a respective pressure sensor (25) and arranged to be positioned, in use, into contact with the skin of the patient, in such a way to exert a predetermined force F on the radial artery.

TITLE

IMPROVED WEARABLE TONOMETER

DESCRIPTION

Field of the invention

The present invention relates to the medical field, and, in particular, it relates to a tonometer that is worn by a patient, for continuously and non-invasive monitoring of a superficial artery of a patient, as, for example, the radial artery.

Furthermore, the invention relates to a method for measuring that is carried out by the above mentioned tonometer.

Description of the prior art

As known, the arterial blood pressure is one of the more useful parameters for diagnosing cardiovascular diseases, and for obtaining a *follow-up* in patients suffering from these diseases.

The tonometer is a non-invasive apparatus that allows to detect the arterial blood pressure, by compressing a superficial artery, for example the radial artery, against the bone structures arranged below it. From the arterial blood pressure are, then, determined, by using an appropriate algorithm, both the central arterial blood pressure, and the central aortic pressure, both systolic and diastolic.

A wearable clock-shaped tonometer is disclosed in IL166200. The use of a clock-shaped tonometer allows, on the one hand, to make the tonometer comfortable to be wound, and on the other hand, to motorize the arterial blood pressure in a patient also for a long period of time even far away from a specialized centre, and without the support of a qualified person. In particular, the device of IL166200 comprises a pressure sensor that is immersed in a chamber containing a transmission fluid, for example a gel. The chamber is arranged into contact with the artery and the transmission fluid transmits forces that arise from the deformation of the artery. Opposite to the sensor chamber, a display unit is provided by which the data measured by the sensor can be displayed.

However, this solution provides to use a single pressure sensor, and, therefore, when the device is wound by the patient, it moves away from the starting position, and the artery signal is inevitable lost.

In order to overcome this drawback, devices have been developed that provide an array of sensors. For example, a tonometer of this type is described in US2009069698. In this case, a control unit is provided that, according to the intensity and to the quality of the signals received from each sensor, selects the sensor with the best signal, and carries out the measurement through the sensor so identified. In this way, the reliability of the tonometer is increased with respect to the previous case, because the

pressure sensor is selected that is the one best positioned above the artery.

However, during the measurement of the pressure signal, the device described in US2009069698 is affected by background errors due, in particular, to the cross talk between the different sensors.

Furthermore, due to the movement of the wrist, or due to a push, the tonometer can move from a starting position, whereby the sensor that has been initially selected, can lose the signal becoming a sensor that is not able to correctly detect the blood pressure wave of the patient.

In Edward J. Ciaccio and Gary M. Drzewiecki "Tonometric arterial pulse sensor with noise cancellation" IEEE Transactions on Biomedical Engineering, vol. 55, no. 10, October 2008, a device is described for permanently non-invasively monitoring the pressure wave of an artery. In particular, two piezoelectric sensors are provided in order to eliminate artifacts that reduce the quality of the signal, in particular movement artifacts and background noise. A first sensor is located at the radial artery (p) and another sensor is positioned in such a way that to prevent any overlapping with the artery pulsation (n). A step of noise removal is conventionally carried out using a reference input, or reducing the movement and noise artifacts from the acquired artery pulsation tonometric signal.

Even in this case, the arrangement of the sensor upon

the artery must be carried out with precision, so that the received measurement signal is strong enough.

A further tonometric device of known type provides a detection unit comprising a determined number of sensors immersed in a gel and an interface positioned into contact with the skin and made of plastic and rubber. However, these materials generate a nonlinearity in the transmission of the applied force/pressure, thus deforming the plethysmographic curve and, therefore, possible measurement errors.

In WO2013/068955 in the name of the same Applicant, a tonometer is described comprising a support body that can be wound by a patient and a detection unit mounted on it, and comprising a determined number of sensors. Between the sensors and the wrist of the patient an element made of silicone rubber is provided.

Another example of wearable tonometer, analogous to the previous, is described in US6491647. In this case, linear springs are provided elastically supporting the touching member that is arranged, in use, into contact with the skin of the patient.

Notwithstanding, both these solutions of prior art have some drawbacks. In fact, both the silicone rubber of WO2013/068955, and the linear springs of US6491647 are not capable to transmit the pressure pulses without modifying the signal. In other words, the shape of the pressure signal that is detected by the sensors has, in both the

cases, a high level of noise and, therefore, these solutions do not allow to accurately measure the arterial blood pressure.

Summary of the invention

It is, therefore, an object of the invention to provide a wearable tonometer that allows to improve the sensibility of the sensors, in particular increasing the ratio between the detected signal and the noise, in particular due to the cross talk between the different sensors that are used.

It is also an object of the invention to provide a wearable tonometer that is able to guarantee that the force applied on the wrist of the patient, that is necessary for measuring the blood pressure wave, is constant.

It is another object of the invention to provide a wearable tonometer that is able to guarantee that the same is maintained in a correct position on the wrist of the patient for all the measurement time in such a way to obtain an accurate and reliable measurement signal.

These and other objects are achieved by an improved tonometer for continuously monitoring the arterial blood pressure of a patient for a predetermined period of time, said tonometer comprising:

- a bracelet configured in such a way to be applied to a wrist of a patient;
- a detection group mounted on the bracelet and configured for detecting a pressure signal, said

detection group comprising a plurality of pressure sensors arranged to detect a respective pressure signal associated to the blood pressure wave of the patient, at least a pressure sensor of said plurality being positioned, in use, in proximity of the radial artery of the patient, at the opposite side of the radial bone;

- a touching group interposed, in use, between the detection group and the radial artery of the patient, said touching group equipped with a plurality of protuberant members, each protuberant member of said plurality arranged to be positioned, in use, into contact with the skin of the patient, in such a way to exert a predetermined force F su said radial artery and to transmit the received pressure pulses to a respective pressure sensor associated to it;

- a processing unit arranged to process the pressure signal detected dal detection group in such a way to determine the blood pressure wave of the patient;

whose main characteristic is that the touching group is made of a material having a predetermined elastic constant greater than the elastic constant of the radial artery, that the touching group comprises a base portion that is integral, in use, to the detection group and a plurality of connection portions, each of which arranged to elastically connect a respective protuberant member to the base portion, and that each connection portion comprises a

plurality of connection arms configured in such a way to have a controlled elastic flexibility along a predetermined direction substantially orthogonal a said base portion, such that each protuberant member is able to elastically move along a direction that is substantially orthogonal to the base portion.

In particular, the technical solution according to the present invention allows to have an elastic response, because, with respect to the prior art solutions, the ration between the elastic contribution and the viscous contribution, is increased. In this way, it is possible to reduce the cross talk between the sensors, and, therefore, to increase their sensibility.

Other features of the present invention are described in the dependent claims.

In a first embodiment, both the connection portion and the base portion, and the protuberant members are made of a plastic material having an elastic constant greater than the elastic constant of the radial artery.

Advantageously, the plastic material can be a thermoplastic material, e.g. Acrylonitrile Butadiene Styrene, or ABS. In this way, it is possible to simplify and reduce the costs related to the production process.

In particular, the whole touching group can be produced by moulding of plastic material.

In an alternative embodiment, the connection portion is made of a metallic material, whereas, the base portion and

the protuberant members are made of a plastic material having an elastic constant greater than the elastic constant of the radial artery.

In particular, it is, furthermore, provided an adjusting device arranged to bring/move away the touching group near to/from said radial artery, in such a way to adjust the force F that is exerted by the touching group on the wall of the radial artery.

Advantageously, the adjusting device comprises a worm screw on which the touching group is slidingly mounted along a direction that is substantially orthogonal to the wrist of the patient. In particular, an operating knob can be provided, acting on which the sliding of the touching group along the worm screw is operated.

In a possible embodiment, the detection group comprises at least 3 pressure sensors positioned in a row. Therefore, in this case, the touching group comprises, in its turn, at least 3 respective protuberant members, also these positioned in a row. However, other alternative embodiments are provided comprising, in particular, a different number of sensors positioned along a single row, or positioned according to an array comprising a predetermined number of rows and a predetermined number of columns.

In particular, the bracelet can comprise:

- a support portion arranged to engage, in use, said detection group;
- a strap made of a flexible material and comprising a

first portion and a second portion having a respective first end fixed to the support portion, at opposite sides, and a respective second end, which is free;

- an engagement device arranged to engage, in use, said first and said second portion of said strap.

Advantageously, a locking device is, furthermore, provided that is arranged to maintain in a locking configuration the engagement device and the containing body. In this locking configuration, the first and the second portion of the strap are tightened between the engagement device and the containing body.

Advantageously, the engagement device provides a main body having a first and a second aperture positioned at opposite sides and arranged to tighten, in use, the second end of the first portion and the second end of the second portion of the strap, respectively.

According to another aspect of the invention, an improved tonometer for continuously monitoring the arterial blood pressure of a patient for a predetermined period of time comprises:

- a bracelet configured in such a way to be applied to a wrist of a patient;

- a detection group mounted on the bracelet and arranged to detect a pressure signal, said detection group comprising a plurality of pressure sensors arranged to detect a respective pressure signal associated to the blood pressure wave of the patient,

at least a pressure sensor of said plurality being positioned, in use, in proximity of the radial artery of the patient, at the opposite side of the radial bone;

- a processing unit arranged to process said pressure signal detected da said detection group in such a way to determine the blood pressure wave of the patient;
- a containing body arranged to house, in use, said processing unit;

and wherein the bracelet comprises:

- a support portion arranged, in use, to engage said detection group;
- a strap made of a flexible material and comprising a first portion and a second portion having a respective first end fixed to the support portion at opposite sides, and a respective second end , which is free;
- an engagement device arranged to engage, in use, said first and said second portion del strap;
- a locking device arranged to maintain in a locking configuration said engagement device and said containing body, in said locking configuration said first and said second portion of said strap being tightened between said engagement device and said containing body, in such a way to lock said bracelet in a correct position with respect to the arm of the patient, in which said detection group is positioned at the artery of the patient and said containing body is

positioned at the upper substantially flat of the wrist of the patient.

In particular, the engagement device is positioned, in use, at the opposite side of the support portion with respect to the wrist of the patient.

According to a further aspect of the invention, a system for determining the arterial blood pressure of a patient comprises:

- a tonometer as above described arranged to generate a tonometric curve;
- an ECG device arranged to generate an electrocardiographic curve;
- a microcontroller arranged to process the electrocardiographic curve and the tonometric curve of the patient undergoing examination at determined instants (ti) for determining the pulse transit time, or PTT, i.e. the delay between the 2 curves, in particular by computing the delay between a r-peak of the electrocardiographic curve and a corresponding peak of the tonometric curve, said microcontroller, then, arranged to associate said computed delay to a determined reference value of the arterial blood pressure and a measure a said determined instants (ti), the difference ΔPA(ti) between the value PA1(ti) of the arterial blood pressure of the patient, estimated by the pulse transit time, and the value PA2(ti) of the arterial blood pressure estimated by the tonometric

curve.

In particular, if the above difference between PA1(ti) and PA2(ti) is greater than a predetermined threshold value, the microcontroller operates an oscillometric device arranged to measure an arterial blood pressure value PA3(ti) by oscillometric technique.

Then, the microcontroller is arranged to associate said arterial blood pressure value PA3(ti) both to the value PA2(ti) of the arterial blood pressure estimated by the tonometric curve, and to the value PA1(ti) of arterial blood pressure estimated by the pulse transit time. In other words, the microcontroller is arranged to start a calibration step in which the value of the arterial blood pressure estimated by the sole tonometric curve PA2(ti) and the one estimated by the delay between the tonometric curve and electrocardiographic curve PA1(ti) are aligned with the one estimated with the oscillometric technique PA3(ti).

More precisely, the oscillometric device is arranged to determine the arterial blood pressure of the patient by processing the air oscillations registered inside a muff that is applied to an arm of the patient, during the deflating step. When the microcontroller detects a difference exceeding a predetermined threshold value PA*(ti) between the arterial blood pressure value measured by the tonometer PA1(ti), and the value of the arterial blood pressure estimated by the technique of pulse transit time PA2(ti), it operates the oscillometric device in such

a way to obtain a value of the arterial blood pressure of calibration PAC(ti). The microcontroller proceeds, then, to associate this value of the arterial blood pressure of calibration both to the value of the arterial blood pressure determined by the tonometer and the value of the arterial blood pressure determined by the pulse transit time.

Brief description of the drawings

The invention will now be shown with the following description of its exemplary embodiments, exemplifying but not limitative, with reference to the attached drawings in which:

- Fig. 1 is a perspective view of the tonometer, according to the invention, applied to a wrist of a patient;
- Fig.2 diagrammatically shows, in a sectioned view, the working position of the tonometer of figure 1 with respect to the artery and the radial bone of the patient;
- Figg.3 and 4 show, in perspective views, some details of the strap, and the relative locking device, of the tonometer, according to the invention;
- Figg.5 and 6 show in 2 different perspective views the strap of figure 3 provided with the engagement device according to the invention;

- Figg.7 and 8 show in a plan view and in a perspective view, respectively, a first embodiment of a touching group according to the invention;
- Figg.9 and 10 show in a plan view and in a perspective view, respectively, an alternative embodiment according to the invention, of the touching group shown in the figures 7 and 8;
- Figg.11 and 12 diagrammatically show, in a partially sectioned view, some components of the tonometer, according to the invention, in order to highlight some features;
- Figures from 13 to 17 diagrammatically show an alternative embodiment of the tonometer shown in the figures 1 and from 3 to 6;
- Figg.18 and 19 diagrammatically show the system, according to the invention, for determining the blood pressure wave of a patient.

Detailed description of the invention

With reference to figure 1, an improved tonometer 1 for continuously monitoring the arterial blood pressure of a patient for a predetermined period of time, comprises a bracelet 10 configured in such a way to be applied to a wrist of the patient 100. The tonometer 1 provides, furthermore, a detection group 20 mounted on the bracelet 10 and arranged, in operating conditions, to detect a pressure signal. As diagrammatically shown in the figures

11 and 12, the detection group 20 comprises at least 2 pressure sensors 25, for example of piezoresistive, or piezoelectric type, arranged to detect a respective pressure signal associated to the blood pressure wave of the patient 100. More precisely, at least a pressure sensor 25 of the detection group is positioned, in use, in proximity of the radial artery of the patient 100, at the opposite side of the radial bone. More in detail, the sensors 25 are arranged to provide a pressure signal when the detection group 20 detects the differences of pressures in the artery 101 of the patient 100. This event happens, as will be described in detail below, when artery 101 is subjected to a determined force F that is able of causing a determined flattening level of the same.

The tonometer 1 provides, furthermore, a touching group 60 interposed, in use, between the sensors 25 and the radial artery 101 of the patient. More in detail, the touching group 60 is equipped with a plurality of protuberant members, e.g. 4 protuberant members 65a-65d, each of which associated to a respective pressure sensor 25. The protuberant members 65a-65d are arranged to be positioned, in use, into contact with the skin of the patient, in such a way to exert a predetermined force F on the radial artery. It is, then, provided a processing unit 350 arranged to process the pressure signal detected by the detection group 20 and with which is connected by means of a wire connection 85 (see figure 1), or, alternatively, by

means of a wireless connection, in such a way to determine the blood pressure wave of the patient. The processing unit 350 can be housed, for example, within a containing body 80.

According to the invention, the touching group 60 is made of a stiff material, and comprises a base portion 61 that is integral, in use, to the detection group 20 and a predetermined number of connection portions, for example 4 connection portions 63a-63d. Each connection portion 63a-63d is arranged, in particular, to elastically connect a respective protuberant member 65a-65d to the base portion 61. More precisely, each connection portion 63a-63d is configured such that the respective protuberant member 65a-65d is able to elastically move along a direction 165a-165d substantially orthogonal to the base portion 61, in particular to the plane on which it lays. More in particular, each connection portion 63a-63d comprises a plurality of connection arms, for example 3 connection arms 64a,64b,64c configured in such a way to have a controlled elastic flexibility along said predetermined direction 165a-165d substantially orthogonal to the base portion 61.

In particular, with respect to other solutions of prior art, in particular to the solution described in WO2013/068955 in the name of the same Applicant, where between the detection group and the wrist of the patient an element made of silicone rubber is provided, the present invention allows to obtain an improved signal, greatly

reducing the noise. In fact, the silicone rubber, as well as other materials that are used in the prior art, even though they have mainly an elastic behaviour, however, they always have also a viscoelastic component. This modifies the shape of the pressure signal detected by the sensors and, therefore, does not allow to accurately measure the blood pressure wave.

Therefore, the solution according to the invention, allows to considerably improve the accuracy of the signal "amplifying" the same, and reducing the noise, in particular, due to the cross-talk, between the different sensors.

As known, in fact, a limit of the pressure sensors that are normally used for measuring the blood pressure is to be highly flexible. In particular, these sensors are much more flexible than the artery, therefore, the detected pressure is affected by the flexibility of the artery same. In order to overcome this drawback, the present invention provides to use materials having a high elastic constant, more precisely an elastic constant higher than the one of the artery. However, it is also necessary that the elastic constant at the engagement portions 63a-63d is comparable to that of the artery, in such a way that they can deform according to the pressure signal. This is achieved by the present invention due to the particular geometry of the connection portions 63a-63d that allows to locally reduce the stiffness of the structure and, therefore, to each

protuberant member 65a-65d, to move in a controlled way along a predetermined direction. In this way, the detection by the sensors of the blood pressure wave is optimized up to be highly accurate.

In the figures from 7 to 10 each protuberant member 65a-65d is associated to 3 shaped connection arms 64a-64c, however each protuberant member 65a-65d can be associated to a different number of arms, for example 4, or 5, or 6. In particular, the connection arms 64a-64c work in flexion and/or in torsion. More in particular, each connection arm 64a-64c is a shaped arm, for example substantially S-shaped, and is arranged to lay, in a rest position, on a plane that is substantially orthogonal to the movement direction 165a-165d of the protuberant members 65a-65d.

Advantageously, the connection arms 64a-64c of a same connection portion 63a-63d are symmetrically arranged about the direction 165a-165d that is substantially orthogonal to the base portion 61 and, therefore, with respect to the protuberant member 65a-65d.

In a possible embodiment of the invention, each connection portion 63a-63d is made of a metallic material, whereas, both the base portion 61 and the protuberant members 65a-65d are made of a stiff plastic material, in particular having an elastic constant greater than the elastic constant of the radial artery.

As, for example, shown in the figures 8, 9 and 12, the protuberant members 65a-65d are substantially truncated

cone-shaped. In particular, the transverse section of the protuberant members 65a-65d decreases going from the base portion 61 towards the wrist, and in particular towards the radial artery, of the patient 100.

In the embodiment that is shown in the figures 7 and 8, the touching group 60 comprises 4 protuberant members 65a-65d positioned in a row. Therefore, in this case the detection group 20, that is not shown in the figure, have 4 pressure sensors 25 positioned in a row, each of which associated to a respective protuberant member 65a-65d.

In the alternative embodiment shown in the figures 9 and 10, instead, the touching group 60, still comprises 4 protuberant members 65a-65d, but this time they are positioned according to an array, which provides 2 rows and 2 columns. Therefore, in this case the detection group 20, that is not shown in the figure, have 4 pressure sensors 25 positioned according to the same array 2X2, and in which each sensor 25 is positioned at a respective protuberant member 65a-65d at the opposite side of the wrist of the patient 100.

The tonometer 1, according to the invention, can provide an adjusting device 120 arranged to bring the touching group 60 and the detection group 20, integral to it, near to the radial artery, or to move them away from it. In this way, it is possible to adjust the force F exerted by the touching group 60 on the wall of the radial artery. In fact, as well known, the detection of the signal

of the arterial blood pressure can be carried out by means of a sensor of pressure, only after that a slight flattening of the artery 101 has been provided. There is, in particular, a minimum threshold value of the flattening of the artery 101 below which it is not possible to detect the blood pressure wave, and a maximum threshold value above which the occlusion of the artery 101 is caused.

The adjusting device 120 for adjusting the distance of the detection group 20 from the radial artery 101, for example a worm screw, has, therefore, the function of exerting a pressure on the wrist of the patient 100 that is high enough to produce a flattening of the artery 101 and, therefore, to allow the pressure signal to be detected by the detection group 20, but it is not too high in order to avoid the occlusion of the artery 101.

More precisely, as diagrammatically shown in the figures 11 and 12, the adjustment of the distance d of the detection group 20 from the artery 101 is carried out by acting on the adjusting device 120, in particular on an operating knob 130 of which it is provided, during a starting step of calibration. More precisely, if the knob 130 is rotated in a sense of rotation, for example in a clockwise sense, the sensors 25 are brought near the artery of the patient (figure 11). Instead, if the knob 130 is rotated in the opposite sense, for example in a counter-clockwise sense, the sensors 25 are moved away from the artery (figure 12).

The starting positioning of the sensors 25 with respect to the artery of the patient is generally carried out during a starting calibration step, during which a worker adjusts the distance of the detection group 20 from the radial artery 101 as above disclosed, visualizing, at the same time, the blood pressure wave on a monitor and blocking the detection group 20 in the position corresponding to a predetermined shape of the curve displayed on the monitor.

As diagrammatically shown in figure 4, in a particular embodiment of the invention, the bracelet 10 comprises a support portion 12 and a strap 15. This is made of a flexible material and comprises a first portion 16 and a second portion 17. In particular, the portions 16 and 17 have a respective first end 16a, 17a fixed to the support portion 12 at opposite sides, and a respective second end 16b, 17b, which is free.

An engagement device 40 is, furthermore, provided (figures 5, 6 and 13 to 17) arranged to engage, in use, the first and the second portion 16 and 17 of the strap 15. More precisely, in the embodiment shown in the figures 1 and 3 to 6, the portions 16 and 17 of the strap 15 are fixed to the support portion 12 at opposite sides in such a way to be out of alignment. Therefore, in this case, the engagement device 40 is arranged to engage the portions 16 and 17 in a position in which they are arranged side by side (figures 5 and 6). In the alternative embodiment of

the invention shown in the figures 13 to 16, instead, the 2 portions 16 and 17 are fixed at opposite sides to the support portion 12, but differently from the previous case, they are arranged aligned. Therefore, in this case, the engagement device 40 is arranged to engage the portions 16 and 17 in a position in which they are overlapped one another.

The engagement device 40 and the portions 16 and 17 of the strap 15 provide mutual engagement members. For example, in the case shown in the figures 5 and 6, and in the figures 13 to 17, the engagement device 40 can provide one, or more teeth, for example 2 teeth 48, arranged to engage respective holes 18, in particular elongated holes, which are made in the portions 16 and 17.

A locking device, then, contributes to provide a firm anchorage of the bracelet 10 to the arm of the patient 100, the locking device comprising, for example, a tooth 51 that is integral to the containing body 80 arranged to engage in a removable way in a respective aperture 52 provided in the engagement device 40.

More in detail, the locking device 51, 52 is arranged to maintain the engagement device 40 and the containing body 80 in a mutual locking configuration (figures 5 and 17). In this configuration, the first and the second portion 16, 17 of the strap 15, in particular at the respective free ends 16b, 17b, are tightened between the engagement device 40 and the containing body 80, in such a

way to lock the bracelet 10 in a correct position with respect to the arm of the patient. In this correct position, the detection group 20 is arranged at the artery of the patient and the containing body 80 is positioned at the upper, substantially flat, part of wrist of the patient.

In the embodiment shown in the figures 5 and 6, the engagement device 40 provides a main body 41. This can provide a first aperture 42 and a second aperture 43 positioned at opposite sides, and passed through, in use, respectively, by the second end of the first portion 16 and the second end of the second portion 17 of strap 15.

In both the embodiments above described, the combined use of the engagement device 40 and of the locking device 51, 52, as provided by the present invention, allows to avoid accidental movements of the bracelet 10 and, therefore, of tonometer 1 with respect to the correct position identified during the above described calibration step. Therefore, the tonometer 1, according to the invention, can be used also at home environment assuring, anyhow, a high level of accuracy in the measuring of the blood pressure wave of the patient. More precisely, the engagement device 40 allows to adjust both the length of portion 17, and the length of portion 16. Therefore, the relative position can be adjusted between the containing body 80 and the detection group 20 can be adjusted and, in particular, contributing in a determinant way to arrange

the bracelet 10 in the correct position with respect to the arm of the patient. As above described, with correct position is intended the position in which the detection group 20 is positioned at the artery of the patient 100, and, at the same time, the containing body 80 is positioned at the upper, substantially flat, part of the wrist of the patient, that means in a position in which it is firm, and, at the same time, comfortable.

Furthermore, the containing body 80 and the engagement device 40, in particular its main body 41, can be hinged each other such that, as can be easily deduced, for example by examining the figures 5 and 6, or the figures 15-17, the containing body 80 can rotate about the axis 149 of the hinge 49 (see figure 3) with respect to the engagement device 40 in order to move from a distant position (figures 6 and 16) to the locking configuration (figures 5 and 17), in which the two components 40 and 80 are overlapped one another and tighten between them, as above described, the two portions 16 and 17 of the strap 15.

As diagrammatically shown in figure 11, the detection group 20 can provide a plurality of housings 24, each of which arranged to house a respective sensor 25. Each housing can be made of a material having a predominantly non-viscoelastic behaviour, advantageously flexible. This is arranged to transmit the external forces to the sensor contained in the housing 24.

Alternatively, each housing can be made of a stiff

material inside of which a fluid material, in particular non-viscoelastic, is introduced, this on its turn polymerized, transmits the external forces to sensor 25 embedded in it. The sensitive member 25 comprises, in general, a membrane deforms according to the pressure change transmitted by the radial artery 101, with which the respective protuberant member 65a-65d is into contact.

As diagrammatically shown in figure 12, each protuberant member 65a-65d, therefore, transmits the detected pressure pulses to a corresponding sensor 25 through a layer of a predetermined material having a behaviour prevalently non-viscoelastic 24. In particular, at the side opposite to the one arranged in into contact with the skin of the patient undergoing examination, the protuberant member 65a-65d provides transmission portion 66. Preferably, still with reference to figure 12, the transmission portion 66 is substantially truncated cone-shaped. In a possible embodiment of the invention, the protuberant members 65a-65d and the connection portions 63a-63d are produced in a single piece.

As diagrammatically shown in figure 18, a system 500 for determining the arterial blood pressure of a patient comprises a tonometer 1 as above described with reference to figures 1 to 17 arranged to generate a tonometric curve 220, and a ECG device 90 comprising 2 electrodes 91 and 92, and arranged to generate an electrocardiographic curve 220. The system 500 provides, furthermore, a microcontroller 300

arranged to process the electrocardiographic curve 210 and the tonometric curve 220 of the patient undergoing examination at determined instants (ti), each of which corresponding to cardiac pulse of the patient, for determining the pulse transit time, o PTT, i.e. the delay between le due curve. More in detail, by using known algorithms, by the tonometric curve 220 and by the pulse transit time PTT, the microcontroller 300 is arranged to measure a respective value PA2(ti) and PA1(ti) of the arterial blood pressure.

As diagrammatically shown in the figures 18 and 19 the microcontroller 300, the processing unit 350 processing the data of the tonometer 1, and the ECG device 90 can be provided as 3 independent components, which are operatively connected by an appropriate wiring, or in wireless communication each other, or at least 2, or all of them, can be housed within the containing body 80 (figure 19). According to the invention, the microcontroller 300 can also be arranged to measure the difference ΔPA(ti) between the value PA1(ti) of the arterial blood pressure of the patient estimated by the pulse transit time and the value PA2(ti) of the arterial blood pressure estimated by tonometric curve.

The system 500 can comprise, furthermore, an oscillometric measurement device 160 operatively connected to the microcontroller 300. As known, the oscillometric device 160 is arranged to measure the arterial blood

pressure of the patient 100 by processing the air oscillations inside a muff 170 applied to the arm of the patient, during the deflating step. When the microcontroller 300 detects a difference ΔPA(ti) between the value PA1(ti) of the arterial blood pressure measured by the pulse transit time technique, and the value PA2(ti) of the arterial blood pressure measured by the tonometer, greater than a predetermined threshold value, it operates the oscillometric device 160 obtaining in response a value of the arterial blood pressure PA3(ti) that is used by the microcontroller 300 as calibration value PAC(ti). More precisely, the microcontroller 300 associates the value PA3(ti) of the arterial blood pressure both to the arterial blood pressure value PA2(ti) determined by the tonometer 1, and to the value PA1(ti) of the arterial blood pressure determined by the pulse transit time.

The above described calibration procedure is carried out because, as known, the measurement of the arterial blood pressure value estimated by the tonometric technique, and the measurement of the arterial blood pressure value estimated by the PPT technique, are subjected to different errors. More precisely, the values PA2(ti) of the arterial blood pressure determined by the tonometer 1 are subjected to artefacts of movement, i.e. due to the movement of the bracelet 10 of the tonometer 1 with respect to the artery of the patient 100. This type of condition, as well as the flattening of the tonometric curve, or the relaxation of

the strap of the bracelet 10, that affect the measurement of the arterial blood pressure through the tonometer 1 and, therefore, cause errors of measurement, do not affect the measurement of the arterial blood pressure carried out by the PTT technique, because they do not significantly modify the above described delay. On the other hand, the measurement of the values PA1(ti) estimated by the PTT technique, is affected by an artery relaxation that is caused, for example, by administering drugs, in particular a vasodilator, or adrenaline, that can cause a large error in the measurement. This event has no effect on the measurement of the values of the arterial blood pressure through tonometer 1.

In the light of the above, the tonometric technique and the PTT technique are subjected to different errors and, therefore, their combined use, as provided by the invention, allows to avoid the measurement errors due to events, or of the other type.

In fact, if any of the events above described happens, an inconsistency would be registered between the values PA1(ti) and PA2(ti), because it would affect only one of the arterial blood pressure values estimated by the 2 techniques. This inconsistency is, however, promptly corrected starting the above described calibration procedure that avoid, therefore, to incorrectly measure the values of the arterial blood pressure.

The foregoing description exemplary embodiments of the

invention will so fully reveal the invention according to the conceptual point of view, so that others, by applying current knowledge, will be able to modify and/or adapt for various applications such embodiment without further research and without parting from the invention, and, accordingly, it is therefore to be understood that such adaptations and modifications will have to be considered as equivalent to the specific embodiments. The means and the materials to realize the different functions described herein could have a different nature without, for this reason, departing from the field of the invention. It is to be understood that the phraseology or terminology that is employed herein is for the purpose of description and not of limitation.

CLAIMS

1. An improved tonometer (1) for continuously monitoring the arterial blood pressure of a patient for a predetermined period of time, said tonometer (1) comprising:

– a bracelet (10) configured in such a way to be applied to a wrist of a patient (100);

– a detection group (20) mounted on said bracelet (10) and configured for detecting a pressure signal, said detection group (20) comprising a plurality of pressure sensors (25) arranged to detect a respective pressure signal associated to the blood pressure wave of the patient (100), at least a pressure sensor (25) of said plurality being positioned, in use, in proximity of the radial artery (101) of the patient (100), at the opposite side of the radial bone;

– un touching group (60) interposed, in use, between said detection group (20) and said radial artery of said patient, said touching group (60) equipped with a plurality of protuberant members (65a-65d), each said protuberant member (65a-65d) of said plurality arranged to be positioned, in use, into contact with the skin of said patient, in such a way to exert a predetermined force F on said radial artery and to transmit the received pressure pulses to a respective pressure sensor (25) associated to it;

– a processing unit (350) arranged to process said

pressure signal detected by said detection group (20) in such a way to determine the blood pressure wave of the patient;

said improved tonometer (1) **characterised in that** said touching group (60) is made of a predetermined material having an elastic constant greater than elastic constant of the radial artery (101), **in that** said touching group (60) comprises a base portion (61) that is integral, in use, to said detection group (20) and a plurality of connection portions (63a-63d) each of which arranged to elastically connect a respective protuberant member (65a-65d) to said base portion (61) **and in that** each said connection portion (63a-63d) of said plurality comprises a plurality of connection arms (64a,64b,64c) configured in such a way to have a controlled elastic flexibility along a predetermined direction (165a-165d) substantially orthogonal to said base portion (61) such that, each protuberant member (65a-65d) of said plurality is suitable to elastically move along said direction substantially orthogonal to said base portion (61).

2. Il tonometer (1), according to claim 1, wherein said connection arms (64a,64b,64c) are substantially S-shaped, each of said connection arms (64a,64b,64c) being configured in such a way to lay, in a rest position, on a plane orthogonal to said movement direction (165a-165d) of said protuberant members (65a-

65d).

3. The tonometer (1), according to claim 1, or 2, wherein said connection arms (64a,64b,64c) are symmetrically arranged about said movement direction (165a-165d) of the respective protuberant member (65a-65d).

4. The tonometer (1), according to any previous claim, wherein at least 3 connection arms (64a,64b,64c) are provided.

5. The tonometer (1), according to claim 1, wherein said base portion (61) and said protuberant members (65a-65d) are made of a plastic material having an elastic constant greater than the elastic constant of the radial artery, and wherein said connection portions (63a-63d) are made of a material selected from the group consisting of:

- a metallic material;
- a plastic material.

6. The tonometer (1), according to any previous claim, wherein between each said protuberant member (65a-65d) and the respective sensor (25) a layer (24) is provided of a predetermined non-viscoelastic material.

7. The tonometer (1), according to any previous claim, wherein an adjusting device (120) is, furthermore, provided arranged, in use, to bring/move away said touching group (60) near to/from said radial artery (101) of said patient (100) up to position said

touching group (60) in a position where the force F exerted by said touching group (60) on the wall of said radial artery (101) causes a predetermined flattening of said radial artery (101).

8. The tonometer (1), according to claim 7, wherein said adjusting device (120) comprises a worm screw on which said touching group (60) is slidingly mounted and wherein an adjusting handle (130) is provided acting on which a sliding of said touching group (60) is operated along said worm screw.

9. The tonometer (1), according to claim 1, wherein each protuberant member (65a-65d) of said plurality is substantially truncated cone-shaped where the transverse section decreases going from said base portion (61) towards said radial artery of said patient (100).

10. The tonometer (1), according to any previous claim, wherein said detection group (20) comprises at least 3 pressure sensors (25) positioned in a row and said touching group (60) comprises at least 3 respective protuberant members (65a-65d) positioned in a row.

11. The tonometer (1), according to claim 1, wherein said bracelet (10) comprises:

- a containing body (80) arranged to house, in use, said processing unit (350);
- a support portion (12) arranged, in use, to engage

said detection group (20);

- a strap (15) made of a flexible material and comprising a first portion (16) and a second portion (17) having a respective first end (16a, 17a) that is fixed to said support portion (12) at opposite sides, and a respective second end, which is free (16b, 17b);
- an engagement device (40) arranged to engage, in use, said first and said second portion (16,17) of said strap (15);
- a locking device (51,52) arranged to maintain in a locking configuration said engagement device (40) and said containing body (80), in said locking configuration said first and said second portion (16,17) of said strap (15) being tightened between said engagement device (40) and said containing body (80), in such a way to maintain said bracelet (10) in a correct position with respect to the arm of the patient, in which said detection group (20) is positioned at the artery of the patient, and said containing body (80) is positioned at the upper part of the wrist of the patient that is substantially flat.

12. The tonometer (1), according to claim 11, wherein said first and said second portion (16,17) of said strap (15) are fixed to said support portion (12) at opposite sides, said first and said second portion (16,17) of said strap (15) configured in such a way to be positioned side by side when fixed to said engagement

device (40).

13. The tonometer (1), according to claim 11, wherein said first and said second portion (16,17) of said strap (15) are fixed to said support portion (12) at opposite sides, said first and said second portion (16,17) of said strap (15) configured in such a way to be overlapped one another when fixed to said engagement device (40).

14. The tonometer (1), according to claim 11, wherein said engagement device (40) provides at least one tooth (48) arranged, in use, to engage in a respective hole (18) made in said portions (16,17) of said strap (15), and wherein a locking device (51,52) is, furthermore, provided arranged to maintain said containing body (80) and said engagement device (40) in a mutual locking configuration.

15. The tonometer (1), according to claim 12, o 13, wherein said engagement device (40) provides a main body (41) having a first aperture (42) and a second aperture (43) positioned at opposite sides, and passed through, in use, by said second free end (16b) of said first portion (16), and by said second free end (17b) of said second portion (17), respectively.

16. The tonometer (1), according to claim 11 wherein said containing body (80) and said engagement device (40) are connected by means of a hinge (49) having a

rotation axis (149), said containing body (80) configured for rotating about said rotation axis (149) with respect to said engagement device (40) in such a way to move from a distant position to a locking configuration, or vice versa.

17. An improved tonometer (1) for continuously monitoring the arterial blood pressure of a patient for a predetermined period of time, said tonometer (1) comprising:

- a bracelet (10) configured in such a way to be applied to a wrist of a patient (100);
- a detection group (20) mounted on said bracelet (10), and arranged to detect a pressure signal, said detection group (20) comprising a plurality of pressure sensors (25) arranged to detect a respective pressure signal associated to the blood pressure wave of the patient (100), at least a pressure sensor (25) of said plurality being positioned, in use, in proximity of the radial artery of the patient (100), at the opposite side of the radial bone;
- a processing unit (350) arranged to process said pressure signal detected da said detection group (20) in such a way to determine the blood pressure wave of the patient;
- a containing body (80) arranged to house, in use, said processing unit (350);

said improved tonometer (1) **characterised in that** said

bracelet (10) comprises:

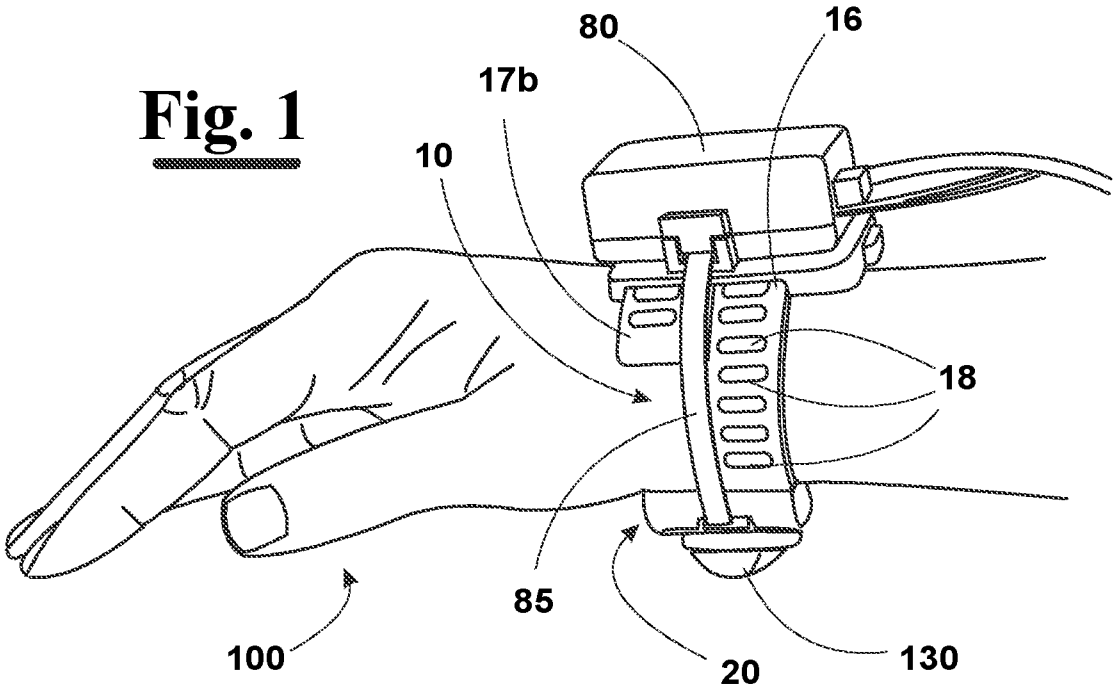
- a support portion (12) arranged, in use, to engage said detection group (20);
- a strap (15) made of a flexible material and comprising a first portion (16) and a second portion (17) having a respective first end (16a, 17a) fixed to said support portion (12) at opposite sides and a respective second end , which is free (16b, 17b);
- an engagement device (40) arranged to engage, in use, said first and said second portion (16,17);
- a locking device (51,52) arranged to maintain in a locking configuration said engagement device (40) and said containing body (80), in said locking configuration said first and said second portion (16,17) of said strap (15) being tightened between said engagement device (40) and said containing body (80), in such a way to maintain said bracelet (10) in a correct position with respect to the arm of the patient, in which quale said detection group (20) is positioned at the artery of the patient and said containing body (80) is positioned at the upper part of the wrist of the patient that is substantially flat.

18. A system for determining the arterial blood pressure of a patient **characterised in that** it comprises:

- a tonometer, according to any claim 1 to 18, said tonometer arranged to generate a tonometric curve (220);

- an ECG device (90) arranged to generate an electrocardiographic curve (210);
- an oscillometric device (250) arranged to measure an arterial blood pressure value PA3(ti) by the oscillometric technique;
- a microcontroller (300) arranged to process said electrocardiographic curve (210) and said tonometric curve (220) of the patient undergoing examination at determined instants for determining the pulse transit time, or PTT, i.e. the delay between said electrocardiographic curve (210) and said tonometric curve (220), said microcontroller (300) being, then, arranged to associate said computed delay to a determined reference value of the arterial blood pressure and to measure, therefore, at said determined instants (ti), the difference ΔPA(ti) between the value PA1(ti) of the arterial blood pressure of the patient, that is estimated by using the pulse transit time, and the value PA2(ti) of the arterial blood pressure that is estimated by said tonometric curve (220), said microcontroller arranged to operate said oscillometric device, and to associate said arterial blood pressure value PA3(ti) both to the value PA2(ti) of arterial blood pressure that is estimated by the tonometric curve, and to the value PA1(ti) of arterial blood pressure that is estimated by pulse transit time.

Fig. 1



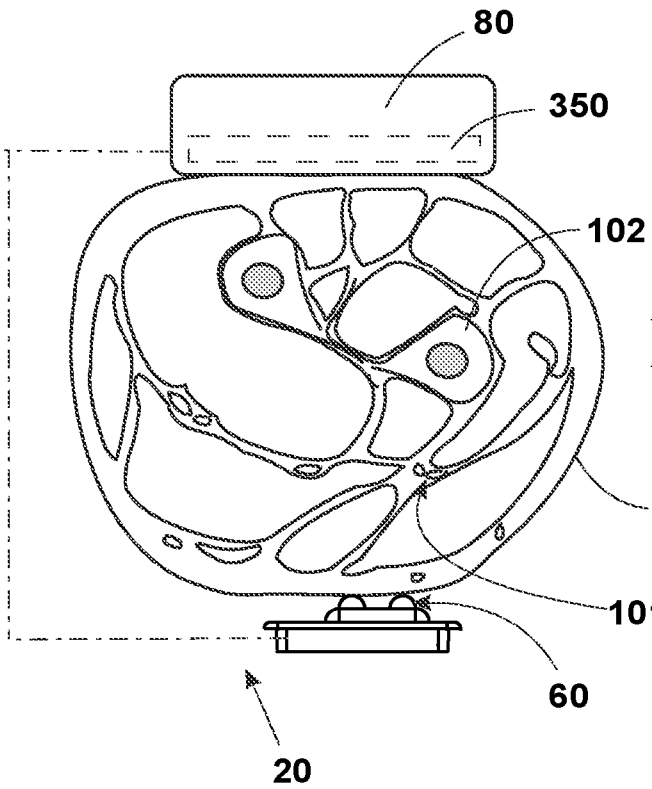


Fig. 2

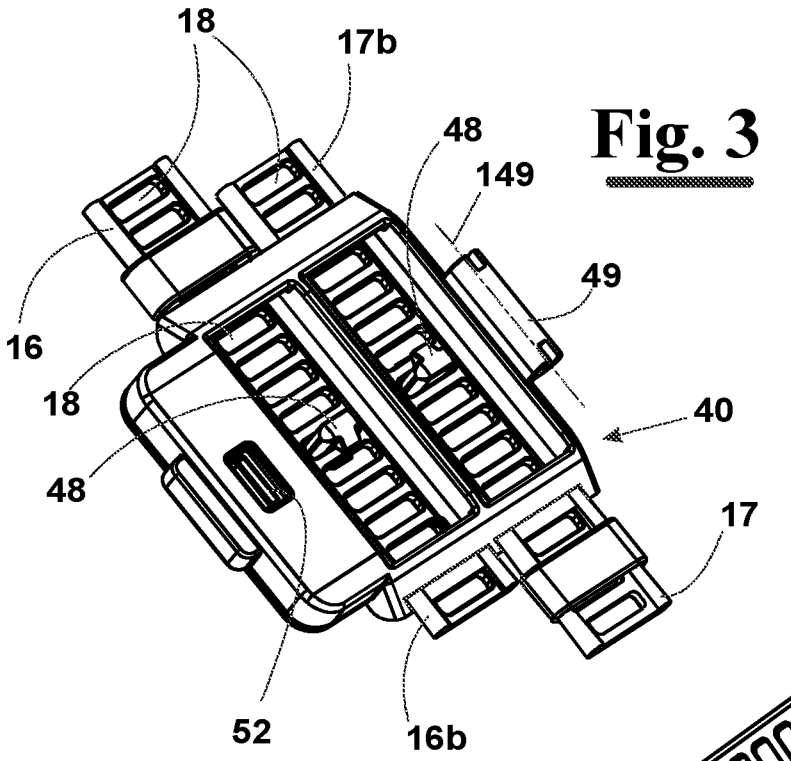

18
17b
48
149
49
16
18
40
48
17
52
16b

Fig. 3

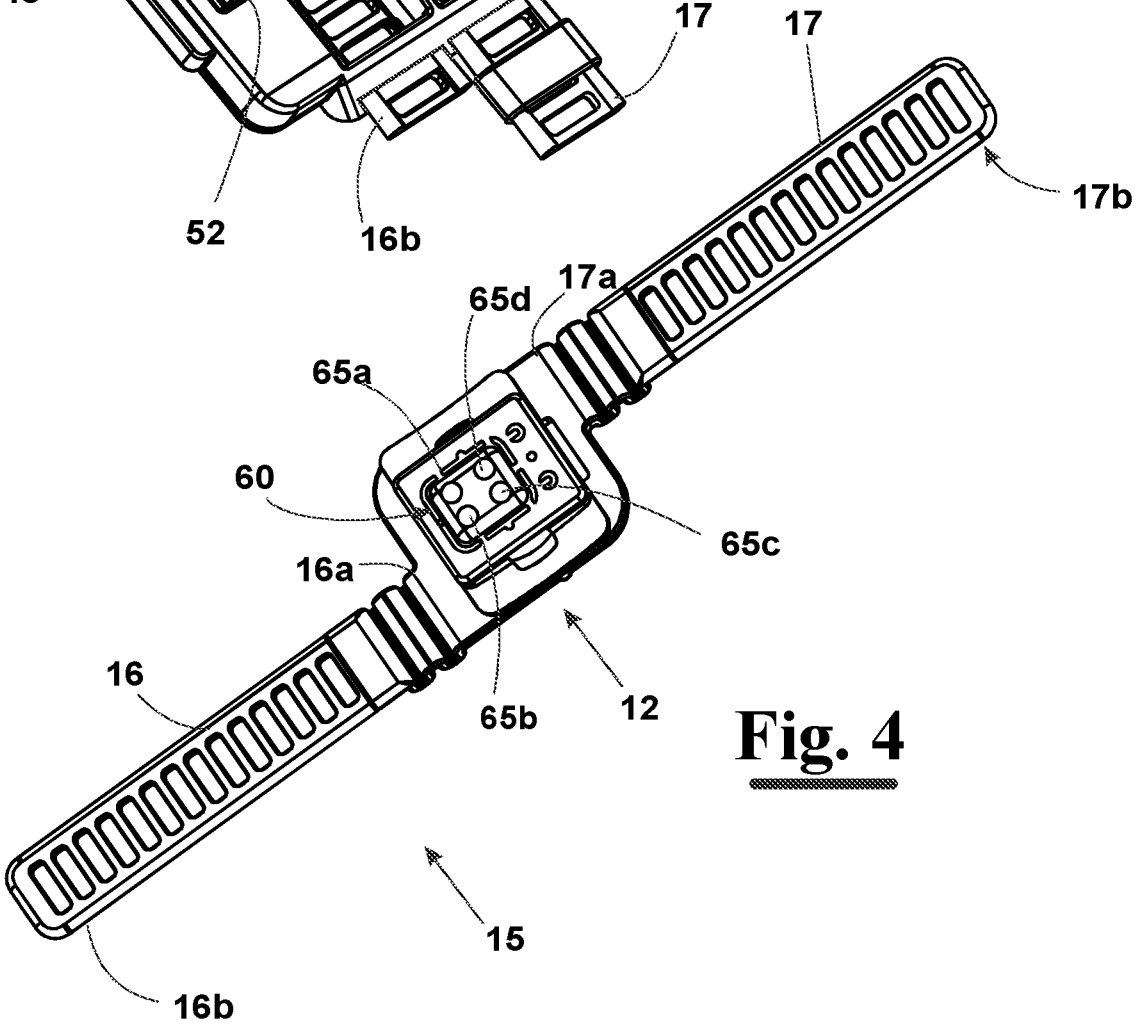

17
17b
17a
65d
65a
60
65c
16a
16
65b
12
15
16b

Fig. 4

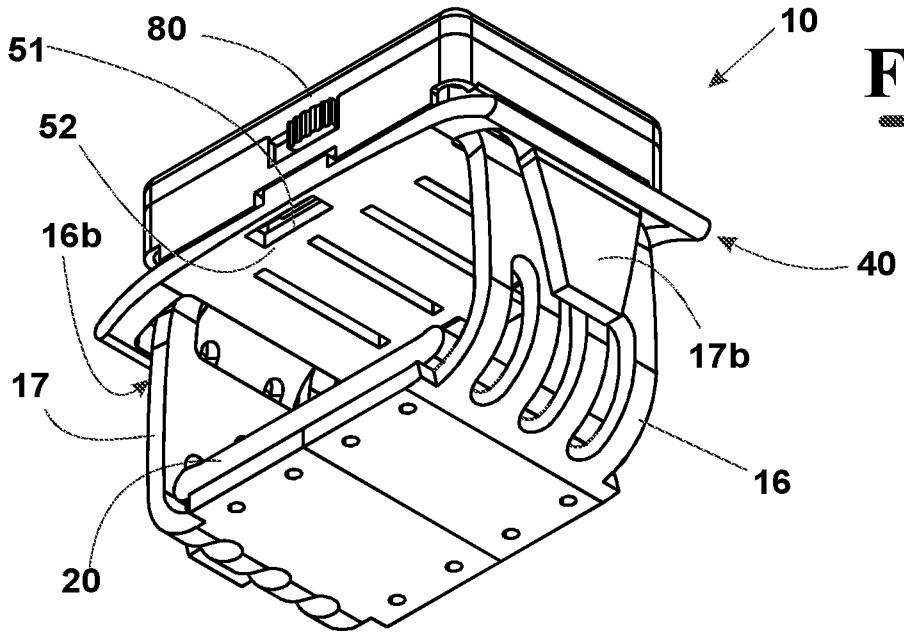


Fig. 5

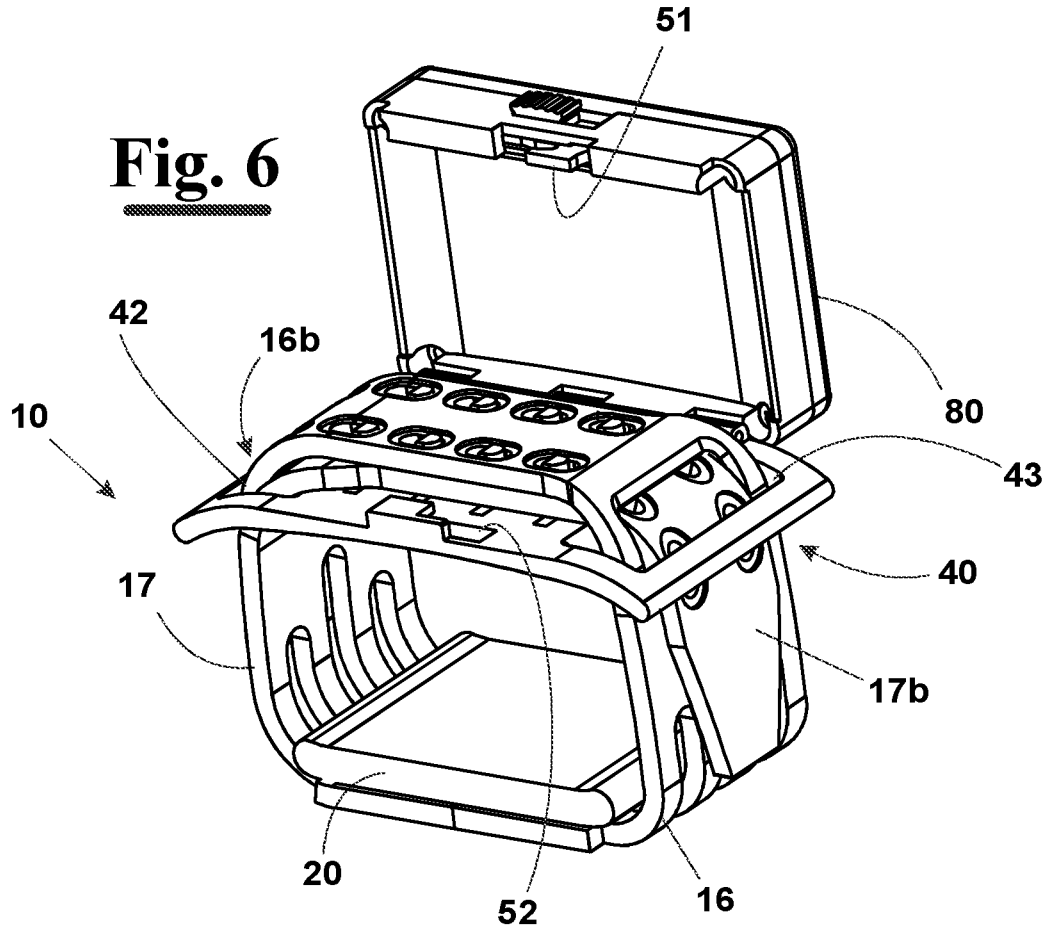


Fig. 6

Fig. 7

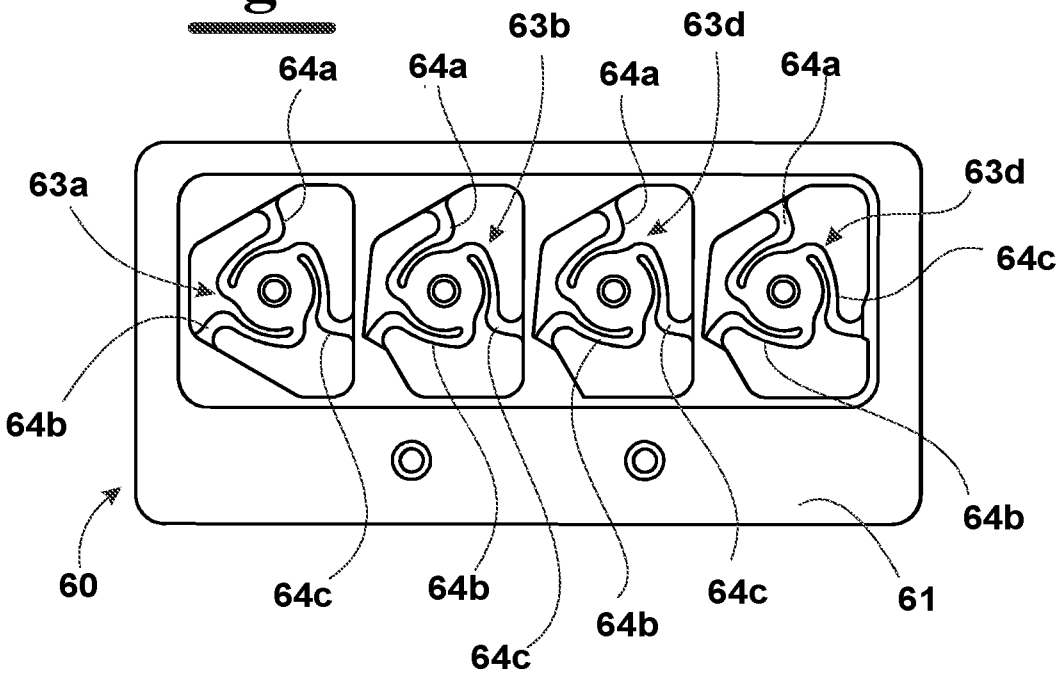
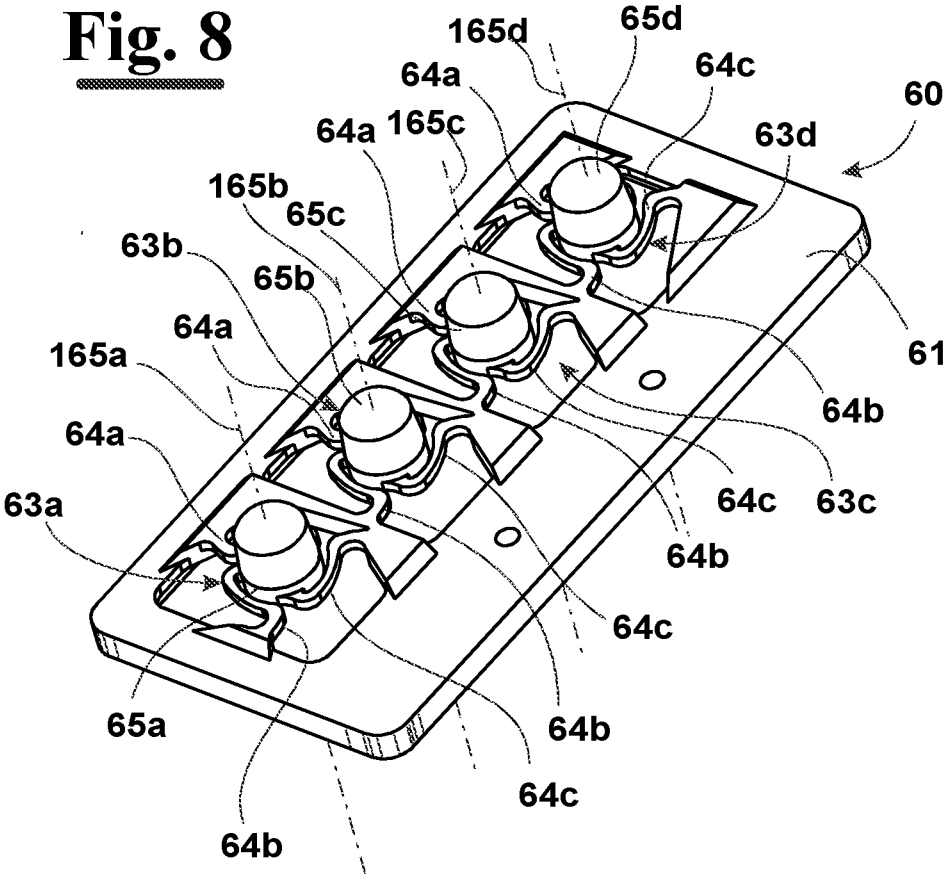

63b
63d
64a
64a
64a
64a
63a
63d
64c
64b
64b
60
64c
64b
64c
64b
64c
61

Fig. 8


165d
65d
64c
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64a
165c
63d
165b
65c
63b
65b
64a
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64b
64c
65a
64b
64c
64b

Fig. 9

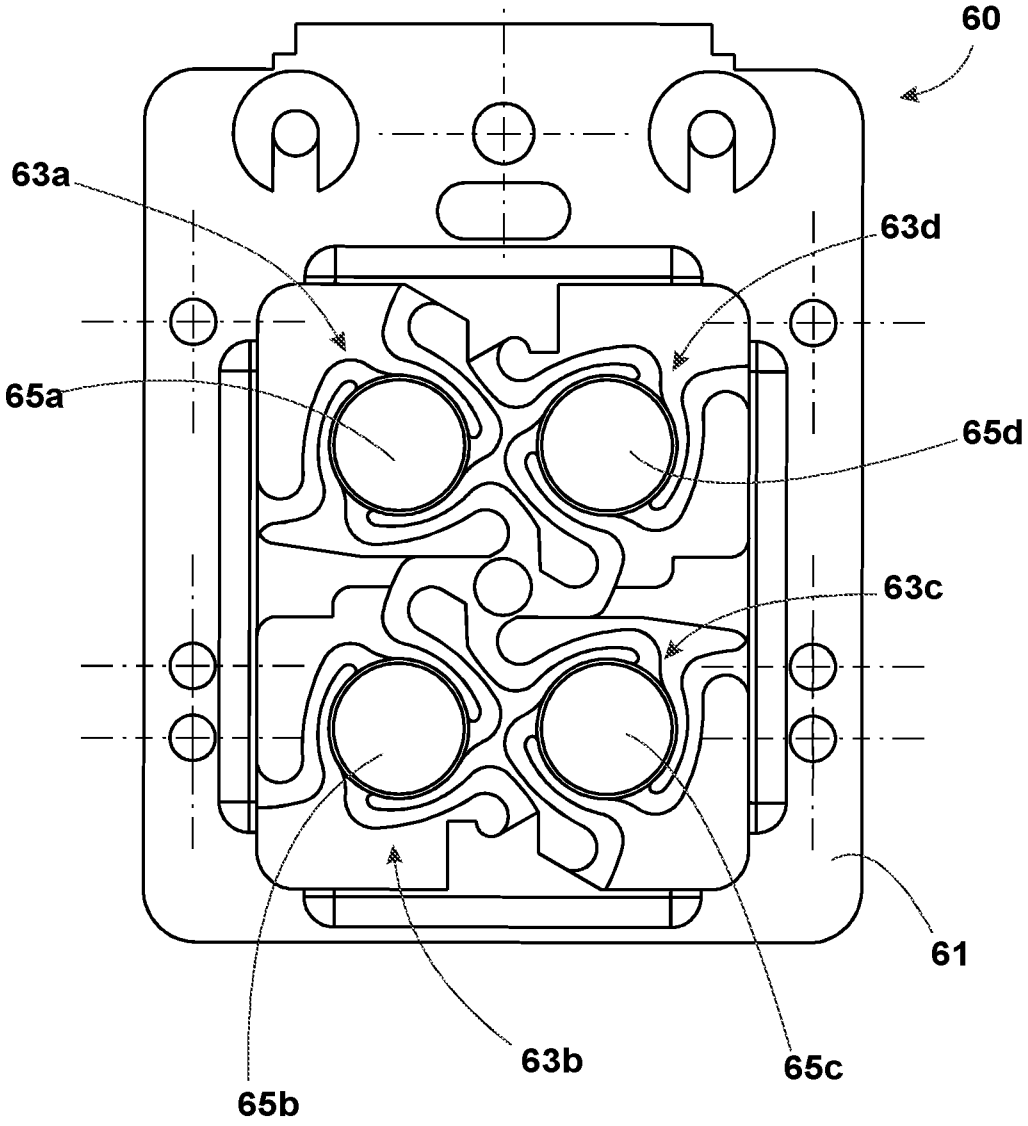
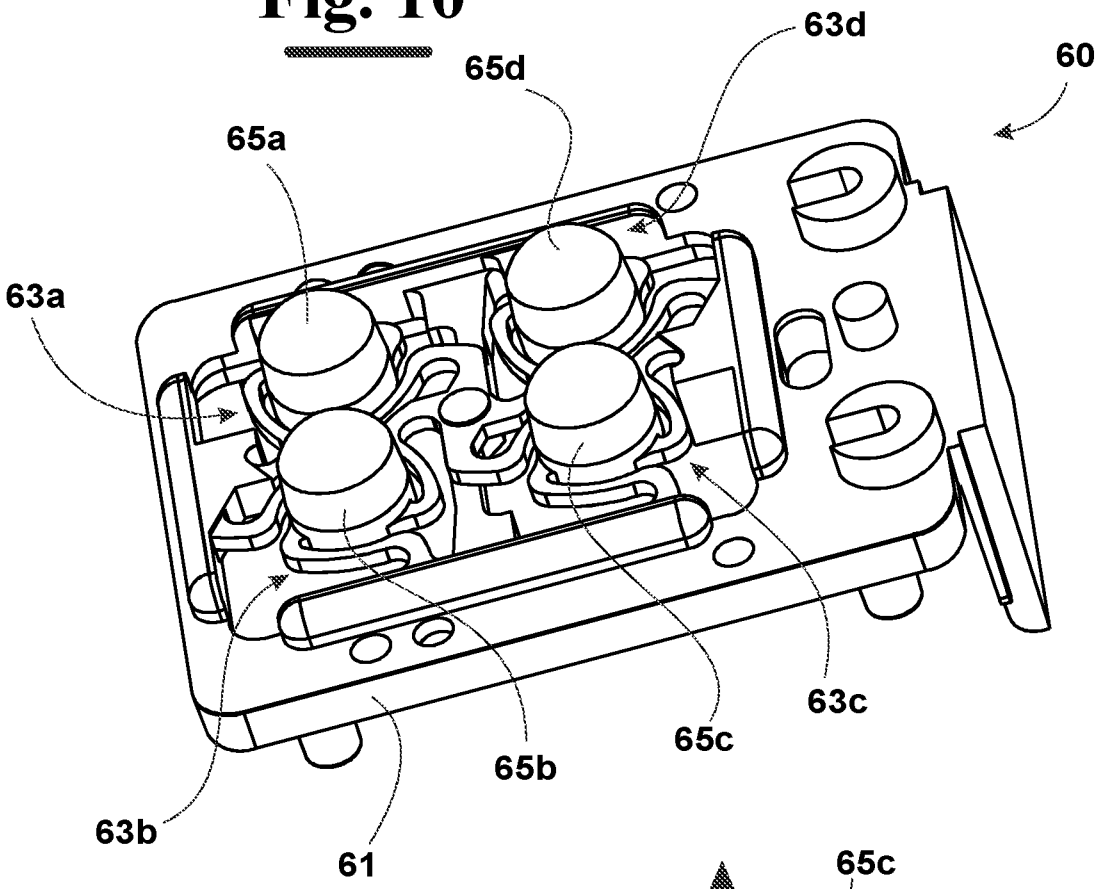


Fig. 10


63d
60
65d
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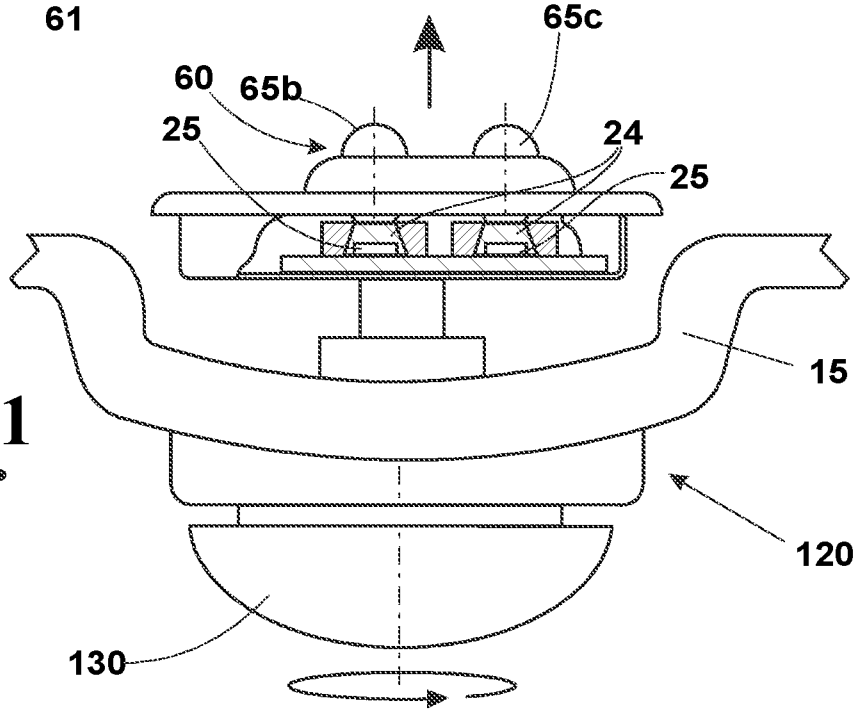
63a
63c
65c
65b
63b
61

Fig. 11


65c
60
65b
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24
25
15
120
130

Fig. 12

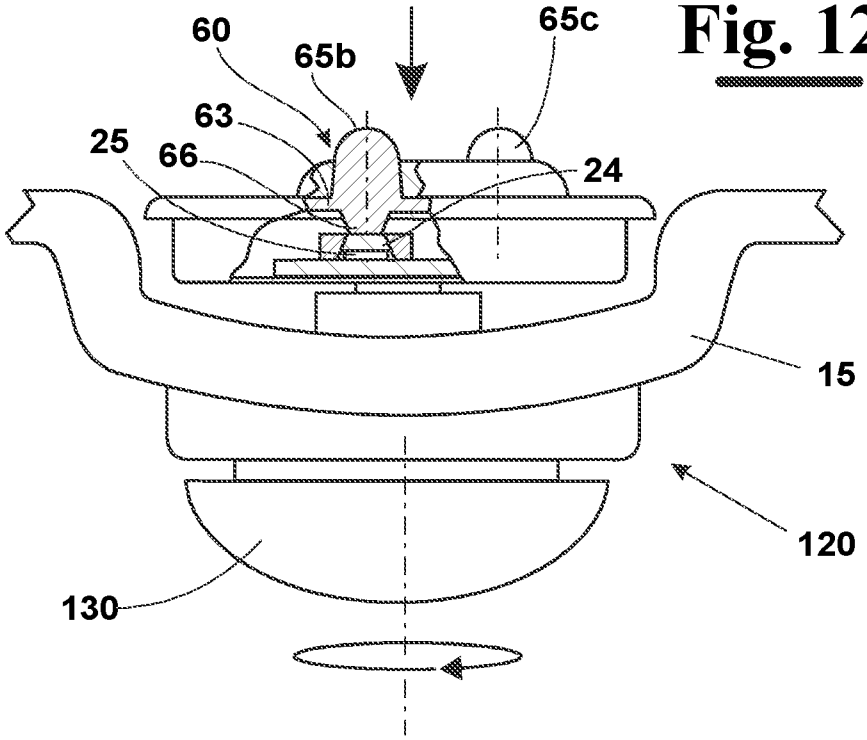


Fig. 13

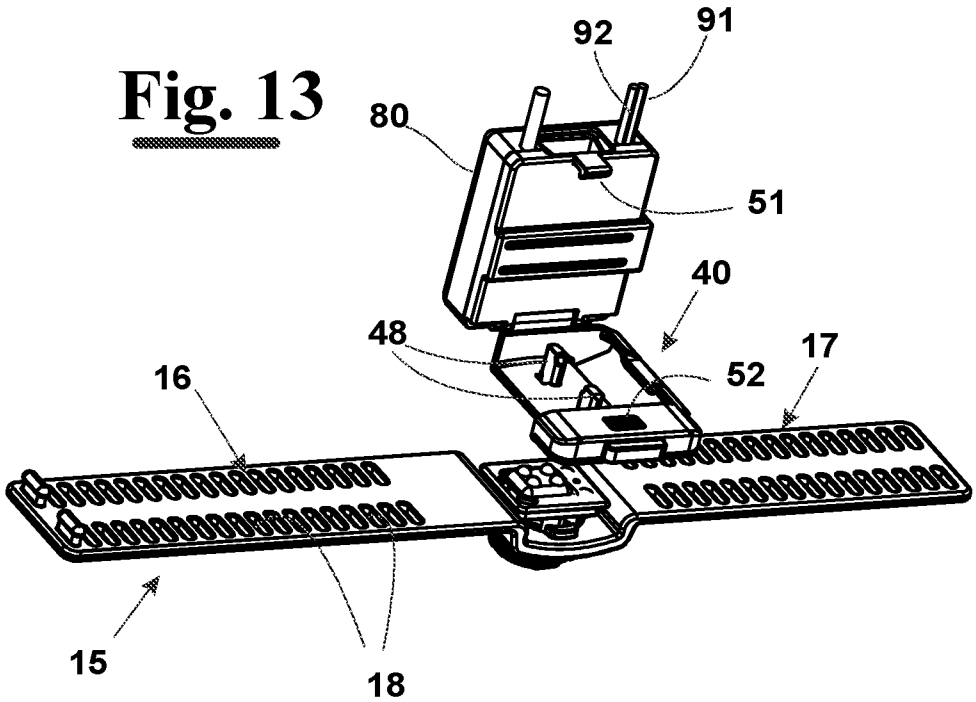
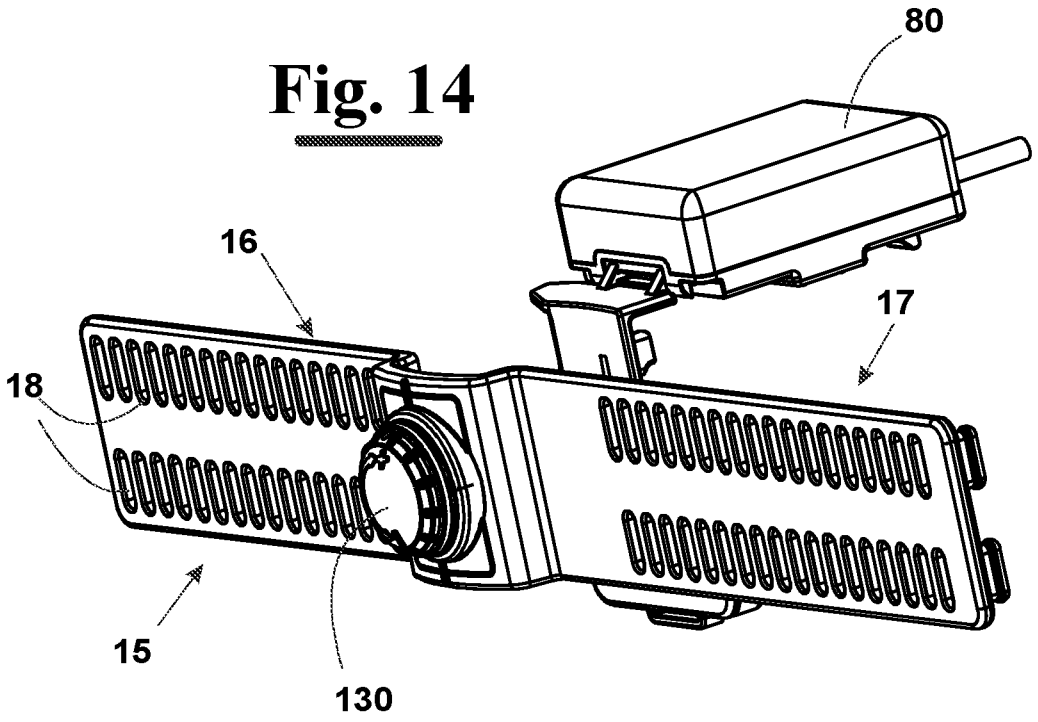


Fig. 14



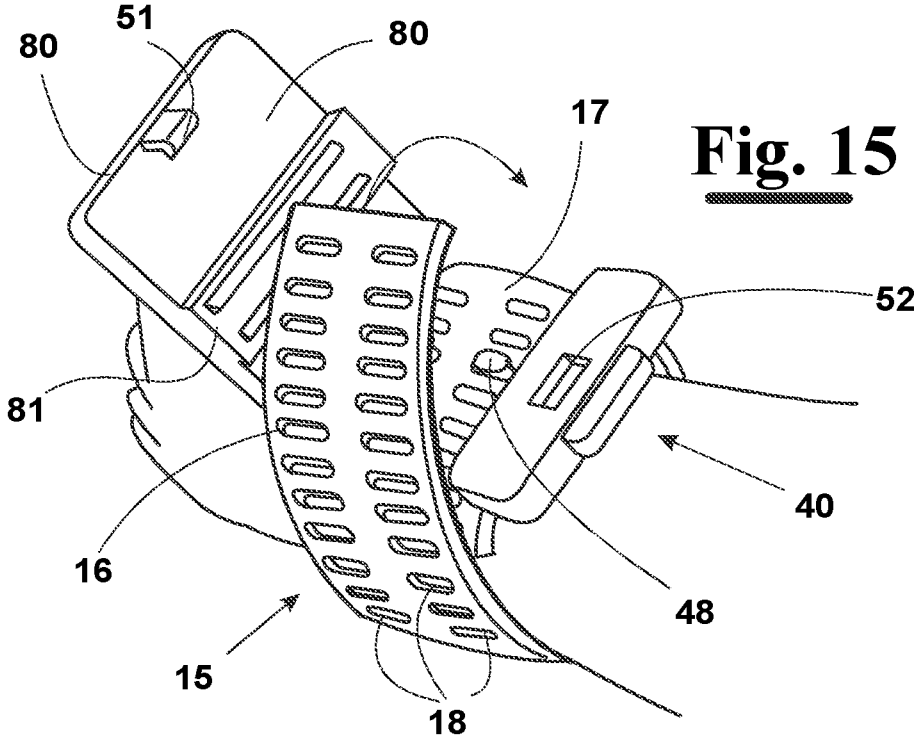


Fig. 15

Fig. 16

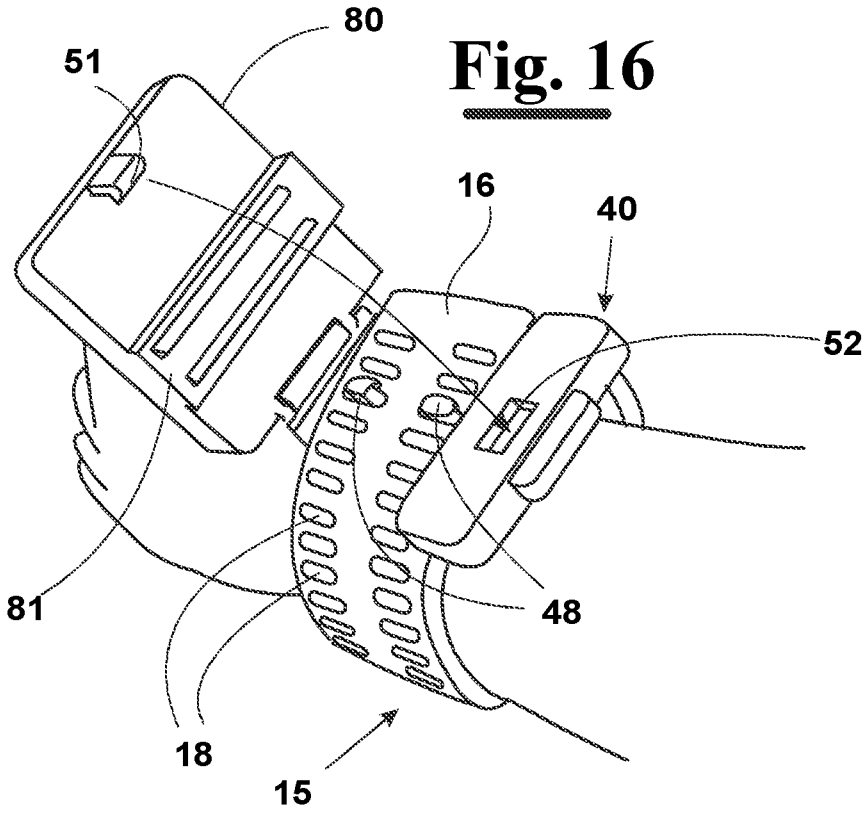


Fig. 17

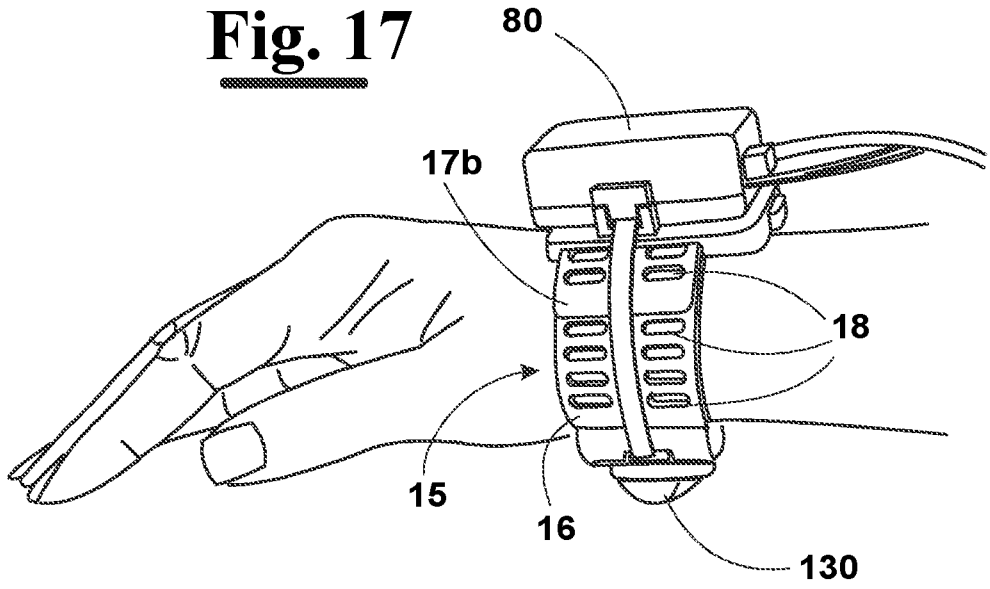


Fig. 18

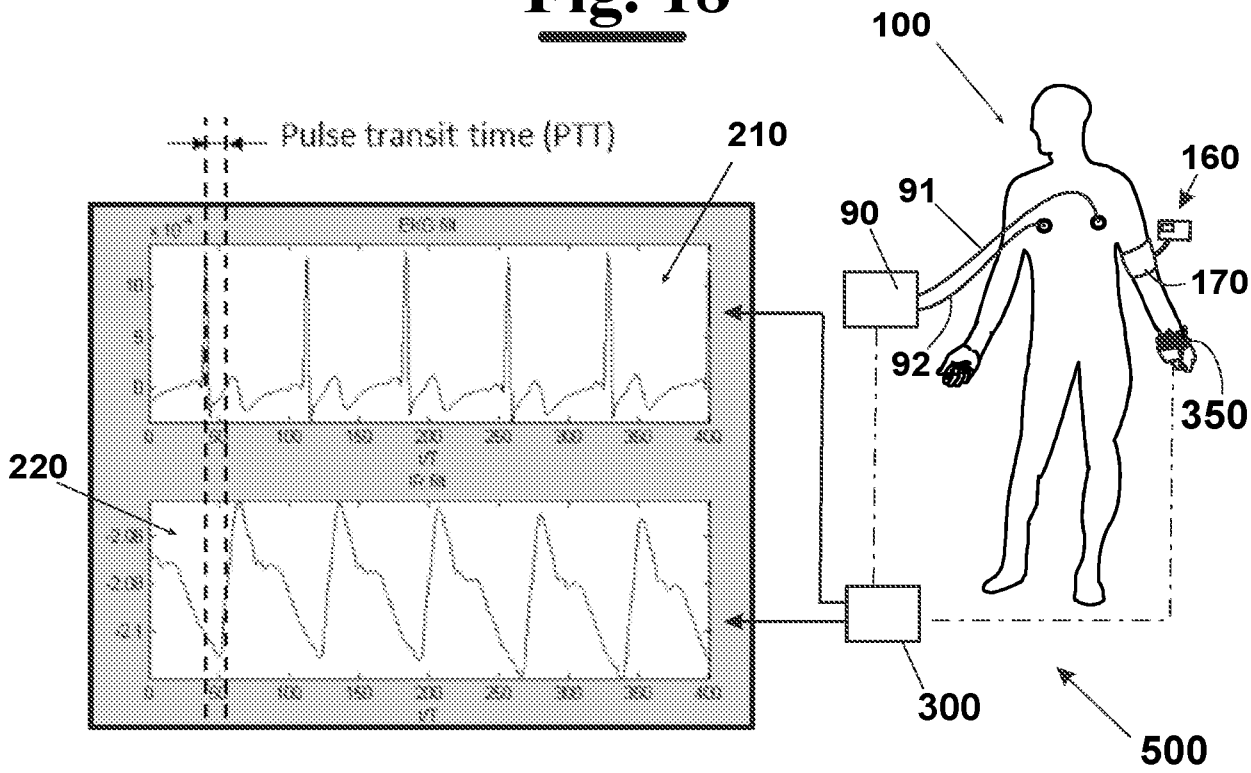
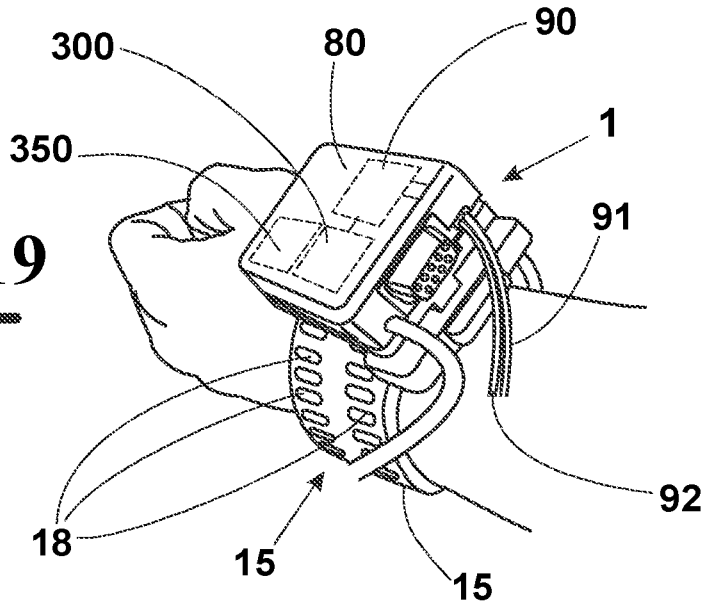

Pulse transit time (PTT)
210
220
100
160
91
90
170
92
350
300
500

Fig. 19


300
80
90
1
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91
92
18
15
15

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2017/051904

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/021 A61B5/022
ADD. A61B5/00 A61B5/0402

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.
A	WO 2013/068955 A1 (WINMEDICAL S R L [IT]) 16 May 2013 (2013-05-16) page 15, lines 4-30; figures 1-2 page 23, line 24 - page 24, line 30; figures 9-15 page 26, line 13 - page 27, line 14	1-16,18
A	US 2013/144176 A1 (LEC RYSZARD M [US]) 6 June 2013 (2013-06-06) paragraphs [0027] - [0028]; figure 1 paragraphs [0059] - [0063]; figure 2 paragraphs [0077] - [0083]; figures 3-5	10
A	WO 96/11625 A1 (VITAL INSITE INC [US]) 25 April 1996 (1996-04-25) page 7, line 27 - page 9, line 7; figures 4-5 page 6, lines 2-5	18

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 July 2017	25/09/2017

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	Sarcia, Regis

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2017/051904

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 2010/228311 A1 (NAQVI TASNEEM ZEHRA [US] ET AL) 9 September 2010 (2010-09-09) paragraphs [0015], [0023], [0024]; figure 1 paragraph [0027]; figure 5	18
A	US 5 179 956 A (HARADA CHIKAO [JP] ET AL) 19 January 1993 (1993-01-19) column 3, line 35 - column 4, line 32; figures 1-2	1-16,18
X	US 6 491 647 B1 (BRIDGER KEITH [US] ET AL) 10 December 2002 (2002-12-10) column 10, line 49 - column 11, line 4 column 11, line 65 - column 12, line 11 column 15, line 39 - column 16, line 52; figure 1 column 16, line 56 - column 17, line 17; figure 2 column 19, lines 59-61; figure 13D column 22, lines 45-57; figures 22-23	1-16,18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2017/051904

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

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

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

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applioant. Consequently, this international search report is restrioted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-16(completely); 18(partially)

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

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

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-16(completely); 18(partially)

   tonometer comprising a bracelet and a feeler device made of stiff material

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2. claims: 17(completely); 18(partially)

   tonometer comprising a bracelet, a strap and a locking device

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2017/051904

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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专利名称(译)	改进的可穿戴眼压计		
公开(公告)号	EP3439548A1	公开(公告)日	2019-02-13
申请号	EP2017725766	申请日	2017-04-04
[标]发明人	VALDASTRI PIETRO DE NEGRI FERDINANDO		
发明人	VALDASTRI, PIETRO DE NEGRI, FERDINANDO		
IPC分类号	A61B5/021 A61B5/022 A61B5/00 A61B5/0402		
CPC分类号	A61B5/02225 A61B5/021 A61B5/02108 A61B5/02125 A61B5/022 A61B5/02233 A61B5/0402 A61B5/681 A61B5/6831 A61B5/6843 A61B5/6844 A61B5/7203 A61B2562/0247 A61B2562/04 A61B2562/043 A61B2562/046 A61B2562/14		
优先权	UA2016002283 2016-04-04 IT		
外部链接	Espacenet		

摘要(译)

一种改进的眼压计（1），用于连续监测患者的动脉血压达预定的时间段，包括手镯（10），其配置成应用于患者的手腕（100）。此外，还提供了一个安装在手镯（10）上并设置成检测压力信号的检测组（20）。检测组（20）包括多个压力传感器（25），其布置成检测与患者（100）的血压波相关联的相应压力信号。在使用中，至少一个压力传感器（25）定位在患者（100）的桡动脉附近，在桡骨的相对侧。还提供了触摸组（60），其在使用中插入在检测组（20）和患者的桡动脉之间并且配备有多个突出构件（65a-65d），每个突出构件（65a-65d）与相应的压力传感器（25）相关联并且布置成在使用中定位成与患者的皮肤接触，以便在桡动脉上施加预定的力F.