(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 October 2013 (24.10.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/156840 A1

(51) International Patent Classification:
A61B 5/02 (2006.01) *A61B 5/022* (2006.01)
A61B 5/021 (2006.01) *A61B 5/00* (2006.01)

(21) International Application Number: PCT/IB20 13/000701

(22) International Filing Date: 17 April 2013 (17.04.2013)

(25) Filing Language: Italian

(26) Publication Language: English

(30) Priority Data:
MN2012A000007 18 April 2012 (18.04.2012) IT

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(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, 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.

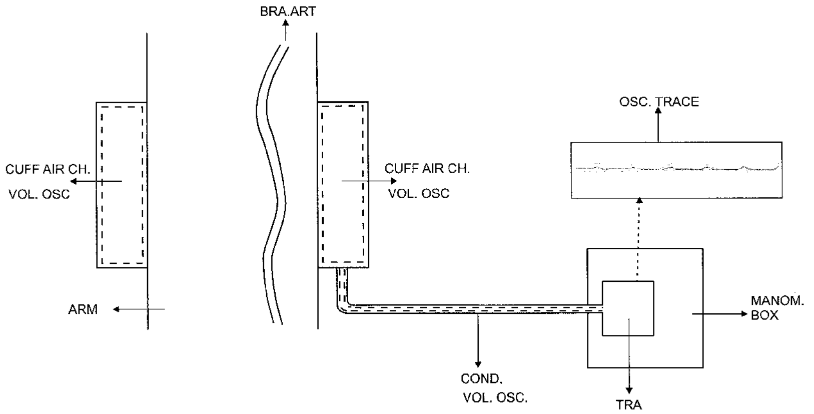
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available):* ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, 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).

Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: HEMODYNAMIC ARTERIOGRAPHIC PRESSURE GAUGE AND METHOD FOR MEASURING ARTERIAL BLOOD PRESSURE AND CARDIAC AND AORTIC FUNCTIONAL PARAMETERS



(57) Abstract: Hemodynamic arteriographic sphygmomanometer using a cutaneous load piezoelectric bimorph multilayer ceramic macro-sensor placed on the external ventral surface of a direct sphygmomanometric air chamber and capable of directly transcutaneously extracting from the brachial artery a brachial arteriographic trace consisting of real arterial pulsatory waves, suitable for the measurement of the systemic arterial pressure; under the pressing action exerted by the air chamber, said sensor being positioned at about 1 cm from the brachial artery course with its axis perpendicular to said artery. The invention also relates to a method for measuring the systemic arterial blood pressure by means of the specific trace recorded by said sphygmomanometer and to the methods for measuring cardiac and central aortic functional parameters.

HEMODYNAMIC ARTERIOGRAPHIC PRESSURE GAUGE AND METHOD FOR MEASURING ARTERIAL BLOOD PRESSURE AND CARDIAC AND AORTIC FUNCTIONAL PARAMETERS

TECHNICAL FIELD

The present invention relates to a hemodynamic arteriographic pressure gauge or sphygmomanometer and to a method for measuring arterial blood pressure and cardiac and central aortic functional parameters, by means of said pressure gauge.

BACKGROUND ART AND RELATED PROBLEMS

Current oscillometric sphygmomanometers develop a very indirect relationship with the brachial artery activity as a consequence of the interposition of the cuff wall and the total absence of a proximal input detector (Table 1).

Owing to these factors the oscillometric trace is not formed by real arterial pulsatory waves but by simple air chamber volume pneumatic oscillations without specific morphologic definition, which do not permit the arterial blood pressure measurement (Table 2).

This can be performed only through the artificial superposition of the positive component of sinusoids, with related problems of inadequate measurement accuracy and development of positive and negative false values.

Similar problems occur when using manual sphygmomanometers, owing to their indirect relationship with the brachial artery occlusion and reopening sector and to the interference of subjective factors.

Today, in the medical field, great attention is devoted to parameters of elasticity index (compliance) and pressure values present at the level of the central aorta, which, together with systolic stroke volume, cardiac output, cardiac index and peripheral vascular resistance values, represent important predictive-diagnostic factors for organ damage, as well as assessment factors for the specific efficiency developed by the various medicament classes during hypertensive and miocardial failure therapy.

At present, the real values of these parameters can be accurately determined only through the invasive methods of hemodynamic catheterization.

Non-invasive known methods provide the above-mentioned values with sometimes questionable accuracy and suffer limitations in terms of dependence with current systemic arterial blood pressure measurement problems, high costs, non-accessibility and non-reproducibility at mass level.

DISCLOSURE OF THE INVENTION

The above-mentioned remarks oriented our study towards a new form of trace, characterized by the maximum direct non-invasive interaction with the brachial artery dynamics, bypassing the wall-cuff interposition and therefore capable of providing a more specific and wider range of information.

We believe that the best result was achieved by using the technology consisting of cutaneous load macro-sensors.

The sensor is located on the external ventral surface of a direct air chamber without covering (Table 3) and, once the cuff is completely wrapped, the cutaneous load sensor is located on the median surface of the arm, perpendicular to the course of the brachial artery (Table 4a).

During the inflation phase, the pressure exerted by the air chamber causes the sensor to be positioned at about 1 cm from the brachial artery course (Table 4b).

Theoretical and practical studies we carried out to find the best functionality of sensors designed for the arteriographic arterial blood pressure detection led to the specific identification of a cutaneous load piezoelectric bimorph multilayer ceramic macro-sensor, whose dimensions are 35 mm length, 12 mm width and 0.8 mm thickness.

Said sensor is positioned on two suspending feet hanging it from its supporting base, which is sealed to the ventral surface of the air chamber.

Said sensor has a rectangular shape with a very extended skin contact area, of 420 mm^2, and with high surface/thickness ratio resulting in an optimal flexibility (Table 5).

These features allow the sensor to obtain performance levels that cannot be achieved with pressure-movement and over- or undersized sensors tested by us.

As a matter of fact, the present load macro-sensor is capable of providing optimal arteriographic traces even a) in subjects with large arm circumference; b) with very deep course of brachial artery; c) with hypo-pulsatility of the same.

Undersized pressure-movement sensors do not have an optimal systematic correlation with the brachial artery course and have shown alterations of the trace, secondary to the rotation about their longitudinal axis and premature wear.

Oversized sensors may have problems in terms of harmonic expansion and contraction of the recorded arteriographic trace.

Conversely, the specific characteristics of the cutaneous load piezoelectric bimorph multilayer ceramic macro-sensor make it able to systematically record traces consisting of real brachial arterial pulsaltory waves that are strictly related to the blood pressure values detected by the synchronous peripheral brachial or radial homolateral intra-arterial catheter.

The load sensor, directly interacting with the brachial artery, operates for converting mechanical energy developed by the dynamic activity of the artery into electrical energy, providing a brachial pulsatory arteriographic recording trace.

The cutaneous load piezoelectric ceramic sensor, upstream positioned at brachial level, and a similar second sensor downstream positioned at digital or radial level (see below), are connected to a hardware system consisting of a group of signal amplitude regulators filters, connected to an analog to digital converter which is connected to a microprocessor, in turn connected to a keyboard, display, micropump driver, micropump, pneumatic valves, pressure transducer and a transmitter which transfers data to a software system (Table 6) capable of properly processing them by displaying them in the form of a brachial pulsatory arteriographic trace and of managing them by means of multiparametric monitoring methods for the systemic arterial blood pressure measurement.

The basal physiological pulsatory brachial arterial waves forming the arteriographic trace are recorded by the cutaneous load sensor directly interacting with the brachial artery dynamics, bypassing the wall cuff interposition.

Said waves show a specific morphologic definition, since they consist of an anacrotic component of larger amplitude, expression of the systolic activity, and a catacrotic component of smaller amplitude, expression of the diastolic activity; these two components being separated by a dicrotic incisure, secondary to the closing of the aortic valve (Table 7).

The morphology of the arteriographic waves is therefore similar in every respect to that of the waves forming the pressure trace provided by the synchronous intra-arterial catheter (Table 8).

After the pump start, during the inflation phase, under the mechanical action of the sphygmomanometric cuff, the arteriographic trace develops a horizontal trend, up to the beginning of a sector of increasing amplitude waves, which includes the real diastolic arterial pressure development phase.

After the development of a maximum amplitude wave has been reached, a trace sector of decreasing amplitude arterial waves begins, which includes the real systolic arterial pressure development phase.

This sector is followed by a tract, which can be defined as isoelectric, consisting of a trace with a horizontal trend, corresponding to the arterial occlusion state (Table 9 a).

The pump stop is followed, during the deflation phase, by an isoelectric tract with features similar to the previous one, after which arterial waves of increasing amplitude start appearing.

Such waves, once stabilized, form a plateau and subsequently show a decreasing amplitude trend up to the final basal stabilization (Table 9 b).

The skyline of the arteriographic waves never suffers from any dorsally acting interference caused by air chamber volume oscillations.

This is due to the fact that each oscillation has a very low pressure value, of about only 1.2% of the total pressure exerted by the air chamber, which firmly stabilizes the sensor.

Moreover, because of its indirect origin, each air volume oscillation develops at a later time than the corresponding direct arteriographic wave.

The specific features of the cutaneous load piezoelectric bimorph multilayer ceramic macro-sensor allow the present sphygmomanometer to obtain a trace consisting of real arterial pulsatory waves, strictly related with the systemic blood pressure values detected by the intra-arterial synchronous catheter.

These waves enable a novel method for the systemic arterial blood pressure measurement, based on their relationship in terms of amplitude, this method having proved to be highly effective and systematically reproducible.

On the contrary, the use of over- or undersized pressure-movement sensors implies the need to adopt complicated and not easily reproducible measurement methods.

Systolic arterial blood pressure measurement method

The detection of the systemic arterial systolic blood pressure value is performed starting from the maximum amplitude wave, reading the inflation arteriographic trace from left to right, within the systolic amplitude contraction sector of the arteriographic trace, on the systolic anacrotic component peak of the first one of a pair of consecutive waves with amplitude decreasing below the threshold of 45% of the maximum amplitude wave, which corresponds to the real systolic pressure value detected by the peripheral homolateral synchronous intra-arterial catheter (Table 10).

Diastolic arterial blood pressure measurement method

The detection of the systemic arterial diastolic blood pressure value is performed starting from the maximum amplitude wave, reading the inflation arteriographyc trace from right to left, within the diastolic amplitude expansion sector of the arteriographic trace, on the diastolic catacrotic peak of the first one of a pair of consecutive arterial waves with amplitude decreasing below the threshold of 50% of the maximum amplitude wave value, which corresponds to the real diastolic pressure value detected by the peripheral homolateral synchronous intra-arterial catheter (Table 11).

Performance

The arteriographic technology by means of cutaneous load piezoelectric ceramic macro-sensors with direct arterial pulsatory interaction, which is opposed to current pneumatic methods with indirect vascular relationship, allows the arteriographic sphygmomanometer to achieve, in comparison with the real target pressure values synchronously expressed by the peripheral homolateral intra-arterial catheter, a mean absolute deviation as low as 4.6 mmHg as regards the systolic pressure values (SBP) and 3.7 mmHg as regards the diastolic pressure values (DBP).

The arithmetic mean deviation resulted as low as +1.2 mmHg for the systolic blood pressure (SBP) and +0.8 mmHg for the diastolic blood pressure (DBP), both with a balanced distribution in the positive and negative trend.

Both the SBP and DBP mean absolute deviation is of 4.1 mmHg.

In 70% of the systolic and diastolic values detected, the arteriographic sphygmomanometer shows single alignments included within an optimal 5 mmHg range compared to the synchronous catheter.

No significant performance variations were detected by the arteriographic sphygmomanometer in patients with atrial fibrillation, a-v dissociation and severe obesity, contrary to the well known relevant deviations shown in such patients by the oscillometry method.

The oscillometric technology shows a SBP and DBP mean absolute deviation of 13.2 mmHg, which rises up to a mean deviation of 21.5 mmHg in 34% of cases for both values, showing single alignments within a 5 mmHg range only in 14.5% of cases.

The values detected by the oscillometric manometer do not show a balanced distribution in the positive and negative trend, showing a prevalent location in underestimation for SBP and in overestimation for DBP in comparison with the catheter (Tables 12 a, b, c and 13).

Similar problems of inadequate measurement accuracy occur when using mercury type and aneroid sphygmomanometers, for the reasons set out above.

Measurement of central aortic elasticity values: PWV and central aortic compliance index

The hemodynamic arteriographic sphygmomanometer is equipped with a second cutaneous load piezoelectric bimorph multilayer ceramic sensor, similar to the brachial one, which can be easily placed at the level of the digital artery (95% of cases), within a capsule, or at radial level (5% of cases), on the internal side of a wrist band (Table 14), recording from these vases an arteriographic trace similar to the brachial one.

This forms a sequential arrangement consisting of a first sensor, upstream located at brachial level, and a second sensor, downstream located at digital or radial level.

A specific software, during the deflation phase, identifies three monitoring sectors, each lasting 5 seconds, with optimal morphologic similarity of the upstream-downstream wave pairs.

At the level of these wave pairs, said software calculates the chronological latency of the ascendant branch of a same arterial pulsatory wave in its two upstream (brachial) to downstream (digital or radial) transit moments.

By dividing the covered brachial to digital or radial distance expressed in millimetres by the transit time of a same wave expressed in milliseconds, the arterial pulsatory wave transmission speed in meters per second is obtained (Table1 5).

At the level of the ascendant central aortic tract, the physiologic transmission speed of the parietal arterial pulsatory wave, PVW , is 4-5 m/s and increases from this location towards the peripheral sector.

In the tract between brachial artery and radial-digital artery, a transmission speed of 4-7 m/s can be considered as indicative of a physiologic central aortic parietal elasticity.

A speed 8-9 m/s indicates a borderline age-induced parietal stiffness, while values of 10-1 1, 12-13, 14-15 m/s and above correspond to the presence of a moderate, medium and high pathologic degree of central aortic parietal stiffness, respectively.

Our study has shown that the arterial pulsatory wave transmission speed, PVW , finds its specific hemodynamic equivalence correlation with the central aortic compliance numerical index, according to an inversely proportional relationship. Therefore it has been possible to detect the specific central aortic compliance index values, as shown by the following scheme A.

Equivalence correlation between:

Pulse Wave Velocity PWV	Central Aortic Compliance Index
3-4 m/s	1.60
5 m/s	1.50
6 m/s	1.40
7 m/s	1.20
8 m/s	1.10
9 m/s	1.00
10 m/s	0.90
11 m/s	0.85
12 m/s	0.80
13 m/s	0.70
14 m/s	0.60
15-16 m/s	0.50
17 m/s	0.45
18-19-20 m/s	0.40

Measurement of central aortic blood pressure values

The present central aortic pressure measurement method is based on the observation that, at the level of the brachial artery wall, which is the operating area of the cutaneous load ceramic macro-sensor, the collagen fibers prevail over the elastic ones according to a ratio basically remaining unchanged over the years.

This aspect determines the development of brachial artery pulsatory waves with a valley-peak amplitude remaining constant over time, in the various subjects, in connection with the measured pressure values.

These peripheral brachial artery waves of constant amplitude therefore represent a steady basis for comparison, enabling the identification of a relationship with amplitude variations of the same pulsatory waves at their origin in the central aortic sector.

The amplitude of these latter aortic waves, as a matter of fact, increases over time as a result of a gradual increase, over the years, of the collagen fiber percentage compared to the elastic fibers prevailing during the young-adult age.

Owing to these factors, our hemodynamic study has shown the presence of physio-pathological, central-peripheral, systo-diastolic pressure axialities that are related to the PVW values and the central aortic parietal compliance index, and has therefore identified the entities of relationship and the patterns of the relevant typologies.

1) Physiologic pressure axiality diverging from centre to periphery (with PWV 5-7 m/s), in the presence of a central aortic wall with prevalence of elastic fibers, which causes, in the central aortic sector, compared to the peripheral brachial one, the development of lower systolic pressure values due to the higher compliance of systolic expansion and of higher diastolic pressure values due to the presence of a more efficient active parietal elastic return.

In this configuration, the amplitude of the pulsatory parietal arterial waves is therefore less wide in the central sector, compared to the peripheral one.

2) Age-induced borderline pressure axiality, substantially parallel (in the presence of a PWV 8-9 m/s), secondary to an equivalence in the relationship between elastic and collagen parietal fibers and of the systolic expansion and diastolic active return in the central aortic sector compared to the peripheral brachial one, with a consequent substantial equivalence between central and peripheral pressure values and between the amplitudes of the respective arterial pulsatory central and peripheral waves.

3) Pathologic axiality converging from centre to periphery (with PVW 10-11, 12-13, 14-15 m/s and above), in the presence of a central aortic wall with prevalence of collagen fibers compared to the elastic ones, which causes, in the central aorta, compared to the peripheral brachial artery, the development of higher systolic pressure values due to the reduced compliance of systolic expansion and of lower diastolic pressure values due to the reduced active elastic diastolic parietal return.

In this configuration, the arterial wave amplitude is larger at the centre than at the peripheral sector (Tab. 16).

Through the synchronous use of the Judkins pressure catheter positioned in ascendant aorta, our study enabled to identify and define the presence of correlations between systemic brachial differential pressure, central aortic compliance index and central aortic systo-diastolic blood pressure values.

The specific parametric-numerical identification of such correlations enabled to achieve a novel method for measuring central aortic blood pressure values, according to the following scheme B.

Central aortic compliance	Systemic brachial differential pressure	Central aortic pressure	
		Systolic	Diastolic
from 1.60 to 1.20	up to 59 mmHg	-10 mmHg	+5 mmHg
1.10		-4 mmHg	+2 mmHg
1.00		+4 mmHg	-2 mmHg
from 0.90 to 0.40		+10 mmHg	-5 mmHg
from 1.60 to 1.20	from 60 to 68 and from 101 to 110 mmHg	-12 mmHg	+6 mmHg
1.10		-6 mmHg	+3 mmHg
1.00		+6 mmHg	-3 mmHg
from 0.90 to 0.40		+12 mmHg	-6 mmHg
from 1.60 to 1.20	from 69 to 100 mmHg	-16.5 mmHg	+8.5 mmHg
1.10		-6.5 mmHg	+3.5 mmHg
1.00		+6.5 mmHg	-3.5 mmHg
from 0.90 to 0.40		+16.5 mmHg	-8.5 mmHg

Performance

The identification of these correlated factors of arterial pressure axiality between central aortic sector and peripheral brachial sector and the accuracy in measuring the systemic arterial pressure enable the present hemodynamic arteriographic sphygmomanometer to detect central aortic pressure values showing, in comparison with the synchronous values expressed by the Judkins pressure catheter in ascendant aorta, a systolic mean absolute deviation of only 4.3 mmHg and a mean arithmetic deviation of only 0.4 mmHg, as well as a diastolic mean absolute deviation of only 3.6 mmHg and a mean arithmetic deviation of only -0.4 mmHg.

Measurement of cardiac function parameters

The synchronic use of the present hemodynamic arteriographic sphygmomanometer with the Edwards Vigilance System continuous automatic thermo-dilution technique by means of the Swan-Ganz cardio-pulmonary catheter enabled the present hemodynamic sphygmomanometer to identify and define the specific relationships that the central aortic differential blood pressure and the central aortic compliance index show with respect to the systolic cardiac stroke-volume.

Thus it has been possible to provide a novel method for measuring the systolic cardiac stroke volume (SV ml/beat) as the product of central aortic differential pressure by numerical index of central aortic compliance.

The product of systolic cardiac stroke volume by heart rate enables then the present hemodynamic sphygmomanometer to detect the cardiac output (CO liters/minute).

The instrument is equipped with a device for calculating the body surface area (BSA m^2, Haycock method), based on the input of weight and height of the subject being examined, with the consequent possibility of measuring the cardiac index (CI liters-minute-m^2) according to the formula: CI = CO/BSA, with the consequent possibility of correlating the cardiac output with the body mass of the subject being examined.

Performance

In comparison with the values expressed by 91 procedures of automatic continuous thermo-dilution, the present hemodynamic arteriographic sphygmomanometer measured systolic stroke volume values (SV) with a mean absolute percentage correlation of 90.1 % and a mean arithmetic percentage correlation of +96.4%.

The absolute percentage correlation is between 80% and 100% in 96.7% of the detected validations.

The present instrument measured the cardiac output (CO) with a mean absolute correlation of 90.8% and a mean arithmetic correlation of +97.7%.

Similar correlations were consequently determined also for the cardiac index (CI).

The percentage correlation provided by the present instrument compared to the hemodynamic parameters expressed by the automatic continuous thermo-dilution, is not related to the extent of the stroke volume and cardiac output absolute values, while it is related to the measurement precision of the central aortic pressure and compliance index.

Therefore, an "external catheter" has been conceived capable of ensuring for the first time an easy availability and reproducibility at mass level of hemodynamic functional parameters of fundamental predictive, diagnostic and therapeutic clinical importance.

BRIEF DESCRIPTION OF THE DRAWINGS

Table 1 is a schematic drawing that highlights the very indirect relationship of the oscillometric method with respect to the brachial artery activity (BRA ART).

The arterial input is inevitably deprived of its specific features owing to its passage through the cuff air chamber wall, which is under strain, and through the very small diameter of the inflation-deflation conduit, thus resulting only in induced air volume oscillations within these structures (CUFF AIR, CH-COND, VOL, OSC).

The transducer (TRA) contained in the manometer box (MANOM BOX) can thus generate only an oscillometric trace (OSC TRACE) not consisting of real arterial waves but only of air volume oscillations.

Upper limb (ARM).

Table 2 shows the oscillometric trace (OSC TRACE) consisting of air volume oscillations within the cuff air chamber and the conduit. Inflation and deflation phases, INFLATION and DEFLATION.

Table 3 shows the cutaneous load piezoelectric ceramic macro-sensor (LPCMS) located on the external ventral surface of the cuff direct air chamber without cover (CUFF DIR AIR CH VS), and the inflation-deflation conduit (COND).

Table 4 a shows the initial wrapping phase around the arm of the sphygmomanometric cuff equipped with the cutaneous load piezoelectric ceramic macro-sensor (LPCMS), located on the external ventral surface of its direct air chamber (CUFF DIR AIR CH VS).

Once the cuff is completely wrapped, the cutaneous sensor will be located on the median surface of the arm (ARM MS).

Inflation-deflation conduit (COND).

Table 4 b shows, in vascular contrastography, the occlusion phase of the brachial artery induced by the pressure exerted by the direct air chamber of the sphygmomanometric cuff (CUFF DIR AIR CH).

At the border between air chamber and arm tissues (ARM TIS): opacification of the area occupied by the cutaneous load piezoelectric ceramic macro-sensor (LPCMS), which is positioned up to about 1 cm from the brachial artery course (BRA ART).

Occluded brachial artery sector (OCCLUDED BRA ART).

Table 5 shows the cutaneous load piezoelectric bimorph multilayer ceramic macro-sensor (LPCMS), the sensor cable (SC) and the suspending feet (SF) hanging the sensor from its supporting base (SB).

Table 6 shows the instrument hardware scheme.

Table 7 is a schematic drawing showing the direct arterial interaction (↔) performed by the arteriographic method with respect to the brachial artery activity (BRA-ART).

The cutaneous load piezoelectric ceramic macro-sensor (LPCMS) can receive a total and integral vascular input, thus recording a brachial arteriographic trace (BRA ARTERIOGR TRACE) consisting of real pulsatory arterial waves.

Bypassed interposition of the cuff direct air chamber (CUFF DIR AIR CH).

Inflation-deflation conduit (COND).

Upper limb (ARM).

Table 8 shows:

A the pressure trace detected by the synchronous homolateral peripheral intra-arterial catheter;

B the brachial arteriographic trace, consisting of real pulsatory arterial waves, detected by the cutaneous load piezoelectric ceramic macro-sensor;

C the oscillometric trace consisting only of air volume oscillations.

Table 9 A shows the morphological skyline of the brachial arteriographic trace under an inflation action exerted by the sphygmomanometric cuff (INFL BRA ARTERIOGR TRACE).

The lack of a specific morphologic definition shown by the associated oscillometric trace (OSC TRACE) is clearly visible.

Table 9 B shows the morphological skyline of the brachial arteriographic trace under a deflation action (DEFL ARTERIOGR TRACE) exerted by the sphygmomanometric cuff.

The lack of a specific morphologic definition shown by the associated oscillometric trace (OSC TRACE) is clearly visible.

Table 10 shows the detection of systolic arterial blood pressure values by means of the brachial arteriographic trace, during the inflation phase (INF BRA ARTERIOGR TRACE), at the level of the decreasing amplitude wave sector.

The trace reading direction is from left to right (→ TRACE READ DIRECT), starting from the maximum amplitude wave (MAX AMP WA).

The detection of the systolic blood pressure value is performed within the sector characterized by systolic amplitude contraction of the arteriographic trace, on the peak of the systolic anacrotic component of the first one of a pair of consecutive waves having an amplitude decreasing below the threshold of 45% (SBP WA) of the maximum amplitude wave, which corresponds to the real systolic pressure value detected by the synchronous homolateral peripheral intra-arterial catheter.

Associated oscillometric trace (OSC TRACE).

Table 11 shows the detection of the diastolic arterial blood pressure value by means of the brachial arteriographic trace during the inflation phase (INFL BRA ARTERIOGR TRACE) at the level of the increasing amplitude wave sector.

The trace reading direction is from right to left («- TRACE READ DIRECT), starting from the maximum amplitude wave (MAX AMP WA), within the sector of diastolic amplitude expansion of the arteriographic trace, on the diastolic catacrotic peak of the first one of a pair of consecutive arterial waves having an amplitude decreasing below the threshold of 50% (DBP WA) of the maximum amplitude wave, which corresponds to the real diastolic pressure value detected by the synchronous homolateral peripheral intra-arterial catheter.

Associated oscillometric trace (OSC TRACE).

Tables 12 A, B, C show the performance of the arteriographic and oscillometric sphygmomanometer in comparison with the systemic systolic and diastolic blood pressure values (SBP - DBP values) detected by the synchronous homolateral peripheral intra-arterial catheter (CATHET), in a typical overview on 20 patients.

A) It is clear that the values expressed by the arteriographic method show a much higher alignment and a much more balanced distribution than the oscillometric values, compared to the synchronous intra-arterial catheter.

B) shows the very reduced SBP-DBP mean absolute deviation of the arteriographic sphygmomanometer compared to the oscillometric sphygmomanometer in respect of pressure values detected by the synchronous intra-arterial catheter.

C) shows a higher percentage of single SBP and DBP values within an optimal range of 5 mmHg compared to the catheter, detected by the arteriographic sphygmomanometer in comparison with the oscillometric sphygmomanometer.

Table 13 shows the performance of the arteriographic, oscillometric and mercury-type sphygmomanometers with regard to systo-diastolic arterial blood pressure critical threshold values, detected by the synchronous homolateral peripheral intra-arterial catheter.

On the ordinate axis are indicated the mean absolute excursions toward the optimal ±5 mmHg range from the catheter.

On the abscissa axis are indicated the mean absolute mmHg deviations from the catheter.

Table 14 shows the second cutaneous load piezoelectric bimorph multilayer ceramic macro-sensor placed at digital artery level (95% of cases) (DOW DIG LPCMS), within a capsule containing it (CONE CAP), or at radial level (5% of cases) (DOW RAD LPCMS), on the internal side of a wrist-band (WR-BAND), and a sensor cable (SC).

Table 15 shows the chronological latency of the ascendant branch of a same arterial pulsatory wave in the two moments of its transit from upstream brachial level (ASC BRANCH UPS BRA WA) to downstream digital or radial level (ASC BRANCH DOW DIG-RAD WA), which enables the arterial pulse wave transmission velocity calculation (PWV) expressed in meters per second.

Table 16 shows the systo-diastolic pressure axiality between central aortic and peripheral brachial sectors as a function of their relationship, at level of parietal systolic expansion and active parietal diastolic return, with the pulse wave velocity (PWV). Central aortic parietal systolic expansion (CAPSE), brachial artery parietal systolic expansion (BAPSE), central aortic active parietal diastolic return (CAAPDR), brachial artery active parietal diastolic return (BAAPDR).

A) shows physiologic diverging systo-diastolic central-peripheral pressure axiality (SBP-DBP) owing to prevailing central aortic parietal systo-diastolic excursions (Ce Ao) over the brachial artery parietal ones (Brach Art), in the presence of an arterial pulse wave velocity PWV of 3-7 m/s.

B) shows the parallel systo-diastolic central-peripheral pressure axiality owing to substantially equivalent parietal systo-diastolic central-peripheral excursions, in the presence of an arterial pulse wave velocity PWV of 8-9 m/s.

C) shows the converging systo-diastolic central-peripheral pressure axiality owing to reduced central aortic parietal systo-diastolic excursions compared to the brachial parietal ones, in the presence of an arterial pulse wave velocity PWV of

10-20 m/s.

It has been found that the invention fully achieves the intended aim and objects.

CLAIMS

1. Hemodynamic arteriographic sphygmomanometer **characterized in that** said sphygmomanometer comprises a cutaneous load piezoelectric bimorph multilayer ceramic macro-sensor, located on the external ventral surface of the sphygmomanometric direct air chamber and able to transcutaneously directly extract from the brachial artery a brachial arteriographic trace consisting of real arterial pulsatory waves, said trace being suitable for the systemic arterial blood pressure measurement; under the pressing action exerted by the air chamber said sensor being positioned up to about 1 cm from the brachial artery course, with its longitudinal axis perpendicular to said artery.

2. Arteriographic sphygmomanometer, according to claim 1, **characterized in that** the sensor is placed on two suspending feet hanging it from its supporting base, which is fixed on the ventral surface of the air chamber.

3. Arteriographic sphygmomanometer, according to claim 1, **characterized in that** said sphygmomanometer comprises a hardware component for detecting the arterial pulsatory wave transmission speed, by means, in a sequential upstream-downstream arrangement, of two cutaneous load piezoelectric ceramic macro-sensors, the upstream sensor of which is placed at brachial artery level on the ventral external surface of the direct air chamber, while the downstream sensor is placed at digital artery level (95% of cases) within a truncated cone capsule into which a finger is introduced, or at radial artery level (5% of cases) by wrapping a wristband on which the sensor is placed.

4. Method for high-precision arterial blood pressure measurement, by means of the load sensor according to the preceding claims, **characterized in that** said method uses the specific morphology and functionality of the brachial arteriographic trace extracted from the artery by said sensor under the pressing action exerted by the direct air chamber on which it is located; said method including the specific morphology of the real brachial arterial basal pulsatory waves that form the trace; said waves having a larger amplitude anacrotic systolic component and a smaller amplitute catacrotic diastolic component, separated by a dicrotic incisure secondary to the closing of the aortic valve; said waves being in every respect similar to and strictly functionally related with the pressure trace waves recorded by the synchronous brachial-radial intra-arterial catheter; said brachial arteriographic trace, during the inflation phase, being induced to develop a rhomboidal skyline consisting of a first sector characterized by increasing amplitude arterial waves, which are strictly related with the development time of the real diastolic arterial pressure value expressed by the synchronous homolateral brachial or radial catheter; said arteriographic trace, after reaching a maximum amplitude wave, developing, in the same inflation phase, a second terminal sector of decreasing amplitude arterial waves, which are strictly related with the development time of the real systolic pressure value expressed by the synchronous homolateral intra-arterial catheter.

5. Method, according to claim 4, **characterized in that** said method is used for the systolic systemic arterial blood pressure measurement by means of said brachial arteriographic trace, by using only the inflation phase; a software reading the trace, proceeding from left to right starting from the maximum amplitude wave; the measurement being performed within the terminal amplitude contraction sector of the pulsatory arterial waves, with pressure relief on the systolic anacrotic peak of the first one of a pair of consecutive waves whose amplitude decreases below the threshold of 45% of the maximum amplitude wave.

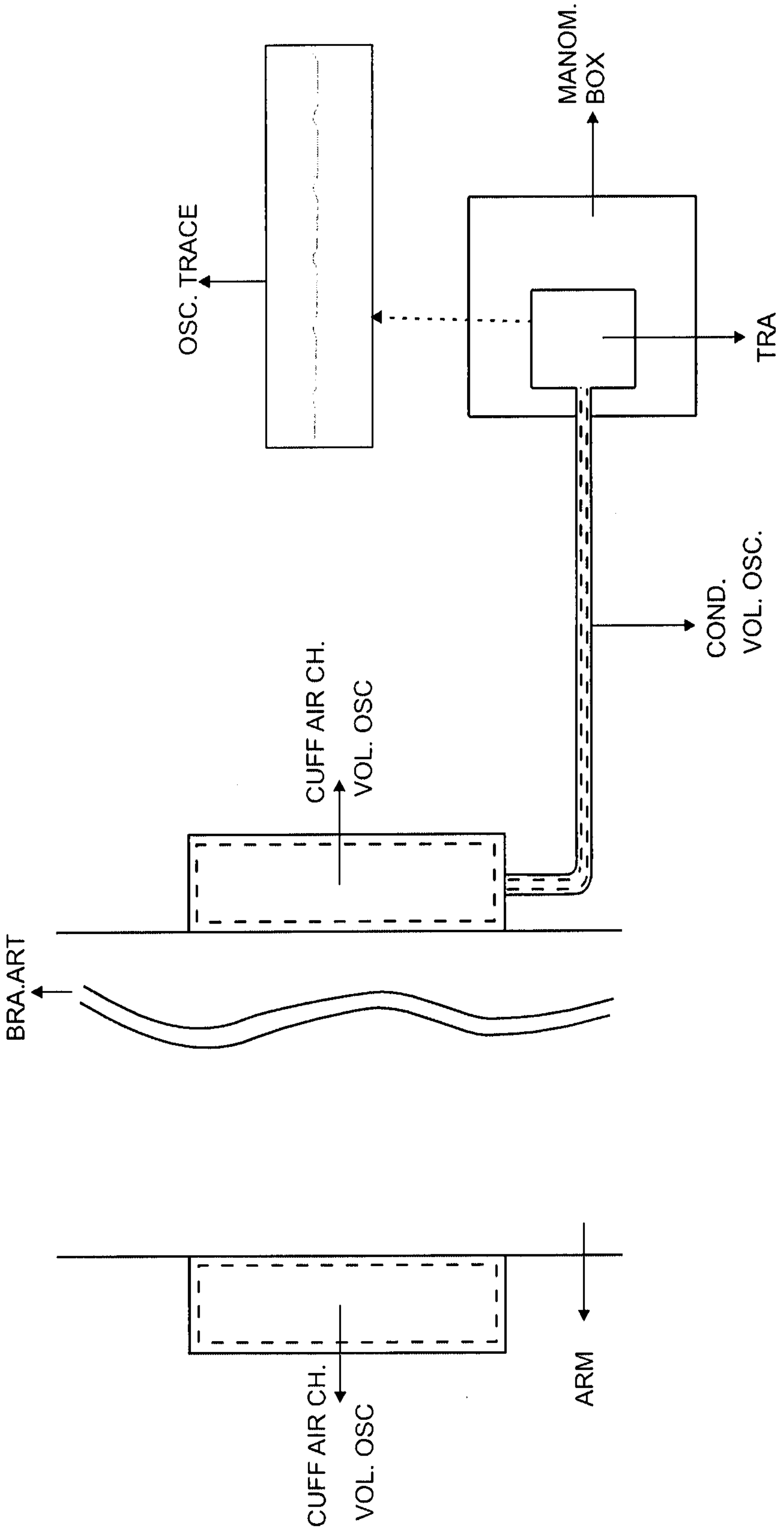
6. Method, according to claim 4, **characterized in that** said method is used for the detection of the diastolic systemic arterial blood pressure, by means of said brachial arteriographic trace, by using only the inflation phase; a software reading the trace proceeding from right to left starting from the maximum amplitude wave; the measurement being performed within the initial amplitude expansion sector of the pulsatory arterial waves, with pressure relief on the diastolic catacrotic peak of the first one of a pair of consecutive waves, whose absolute amplitude decreases below the threshold of 50% of the maximum amplitude wave.

7. Method, according to claim 4, **characterized in that** said method comprises the arterial pulsatory wave transmission speed PVW calculation; during the deflation phase, three monitoring sectors, each lasting 5 seconds, optimal for the morphological similarity of the upstream-downsteam wave pairs, being identified; at the level of said wave pairs, said software calculating the chronological latency of the ascendant branch of a same wave in its two upstream (brachial) and downstream (digital or radial) transit moments; by dividing the brachial-digital or radial distance in millimetres by the transit time of a same wave in milliseconds, the arterial pulse wave transmission speed (PWV) in meters per second being obtained.

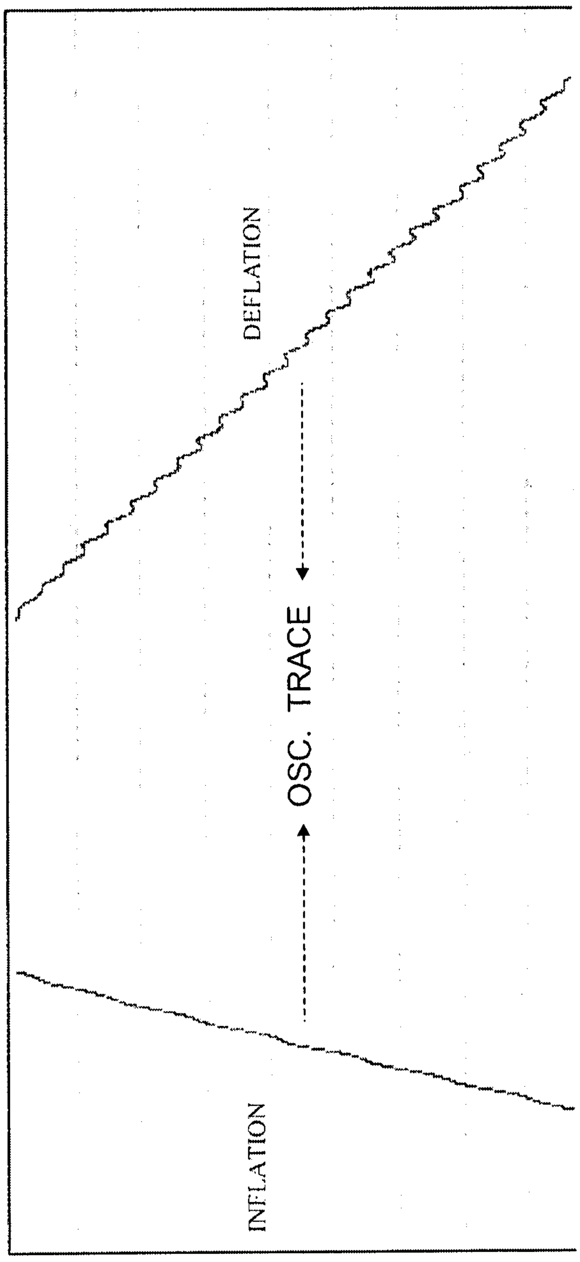
8. Method, according to claim 4, **characterized in that** said method comprises the identification of the specific numerical correlation among arterial pulsatory wave velocity PWV values and central aortic compliance numerical index values according to the specific equivalence scheme A.

9. Method, according to claim 4, **characterized in that** said method comprises the measurement of systolic and diastolic central aortic pressure values, based on the identification of the specific, strict pressure correlations between differential brachial arterial pressure and central aortic compliance numerical index compared to systolic and diastolic central aortic pressure values, according to the specific central-peripheral pressure correlation scheme B derived by our study through the synchronous use of the hemodynamic arteriographic sphygmomanometer with the Judkins central intra-aortic pressure catheter.

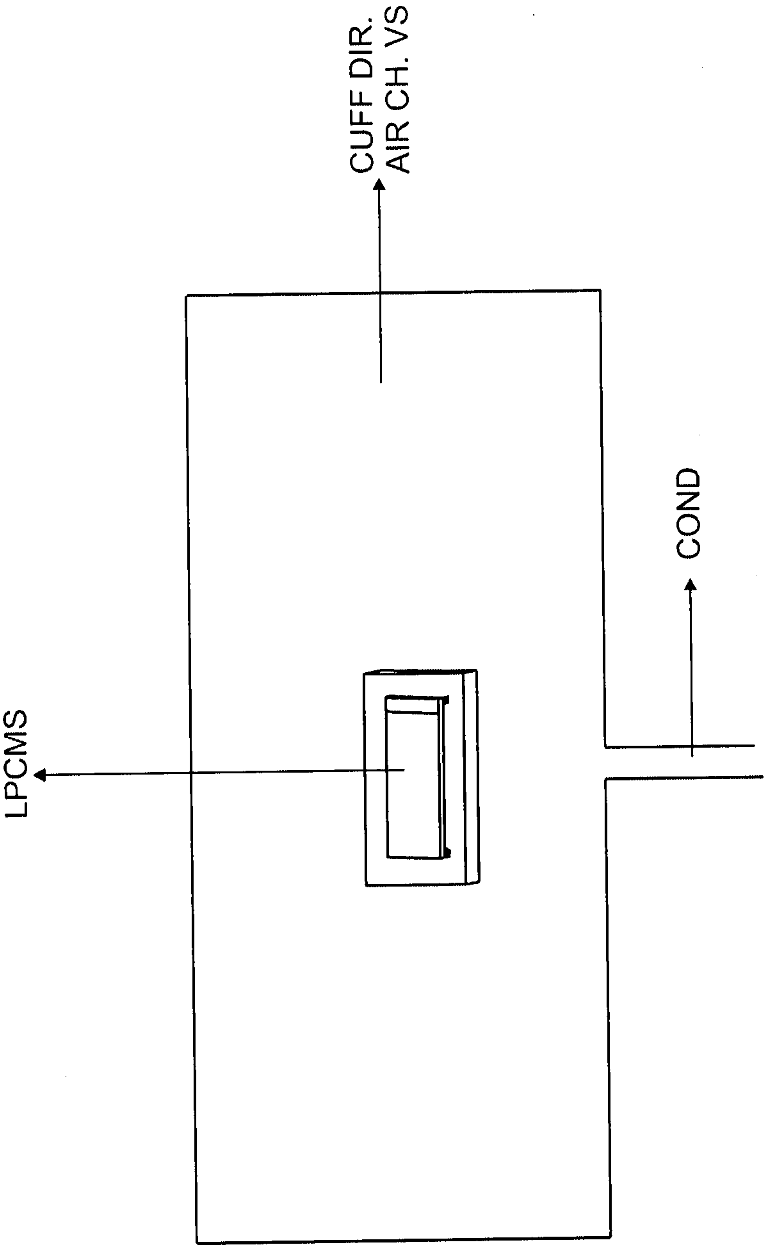
10. Method, according to claim 4, **characterized in that** said method comprises the measurement of the cardiac systolic stroke volume (ml/beat), as the product of central aortic differential pressure by central aortic compliance numerical index, derived by our study through the synchronous use of the hemodynamic arteriographic sphygmomanometer compared to the invasive continuous automatic thermodilution method.


OSC. TRACE
MANOM. BOX
TRA
COND. VOL. OSC.
CUFF AIR CH. VOL. OSC
BRA.ART
CUFF AIR CH. VOL. OSC
ARM

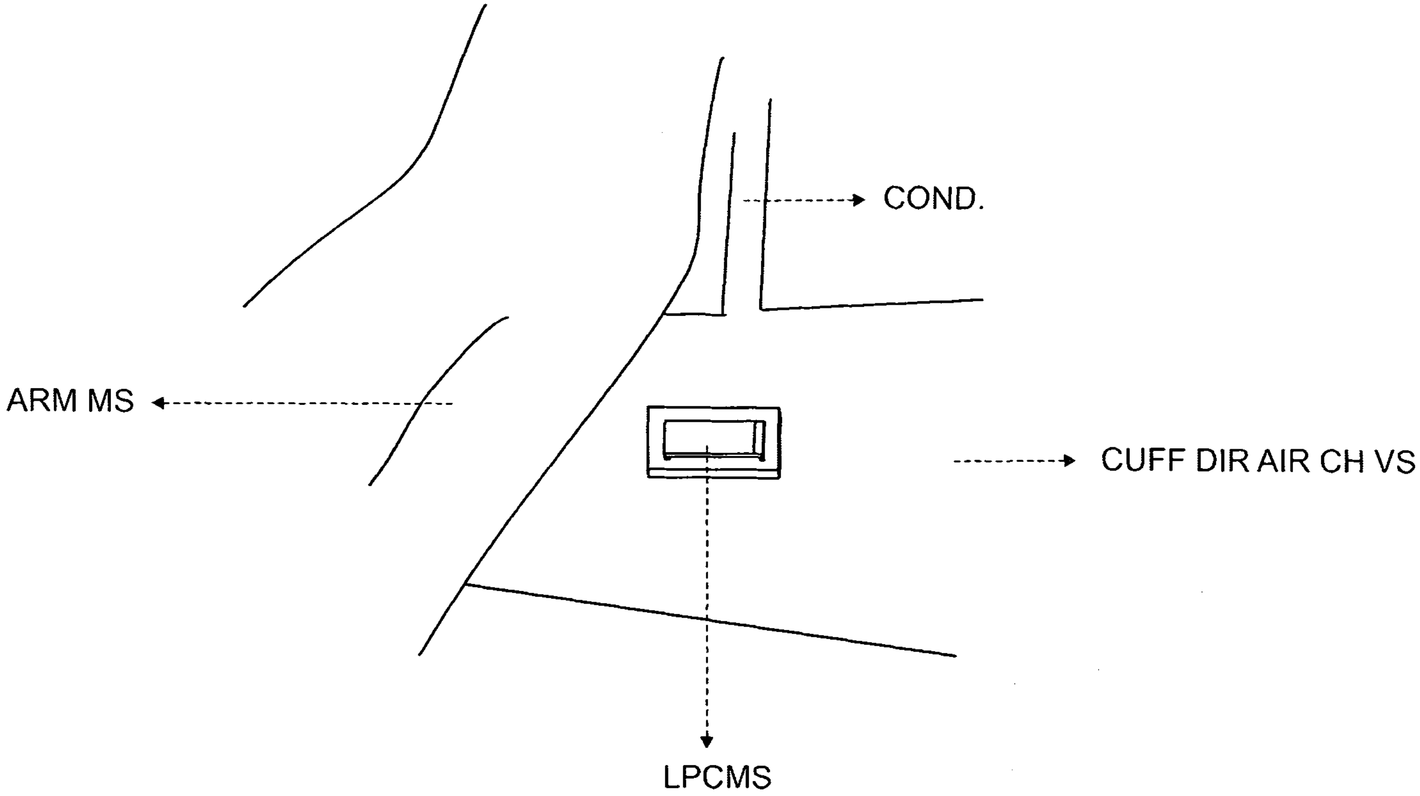
Tab. 1



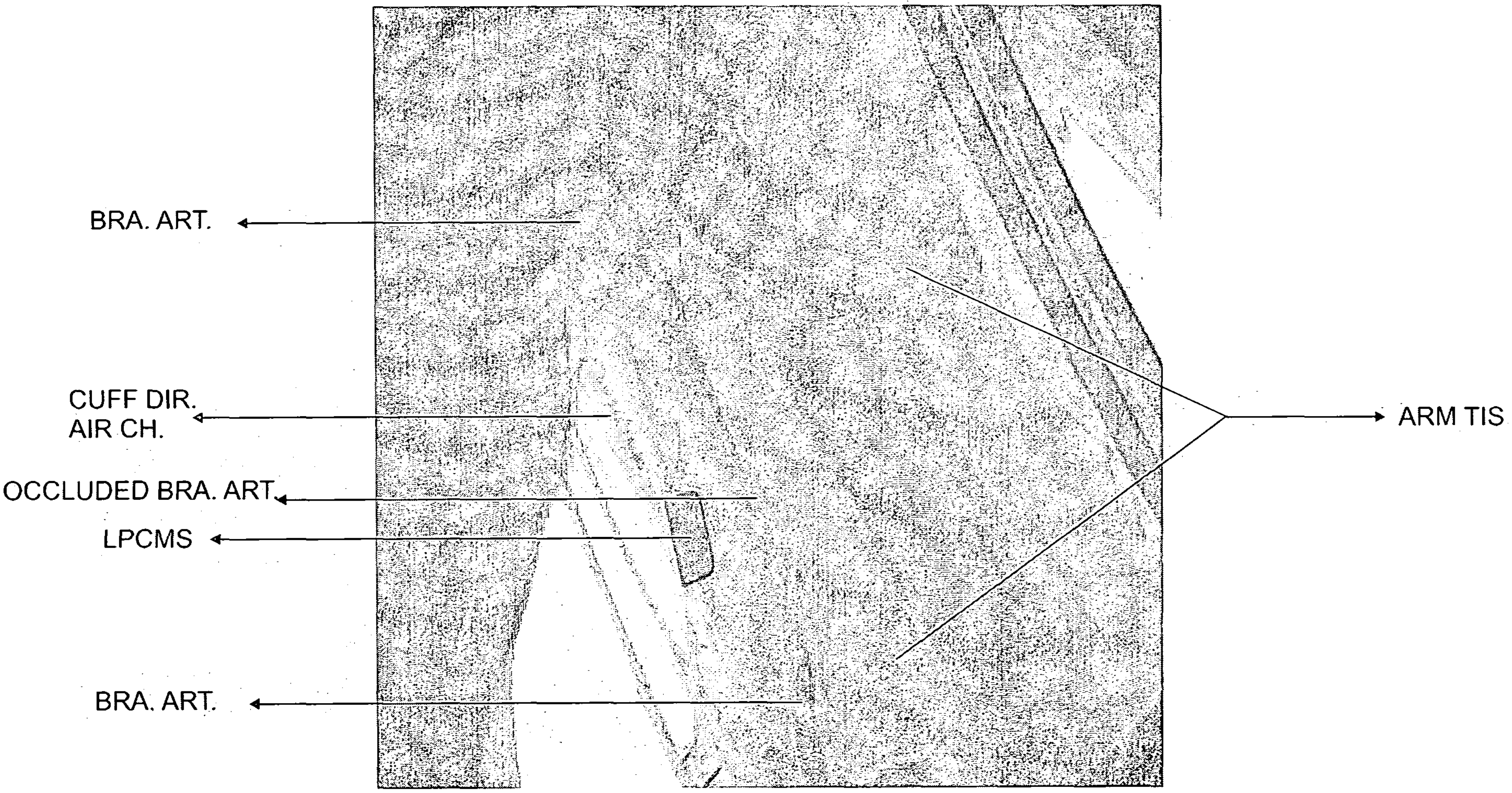
Tab. 2



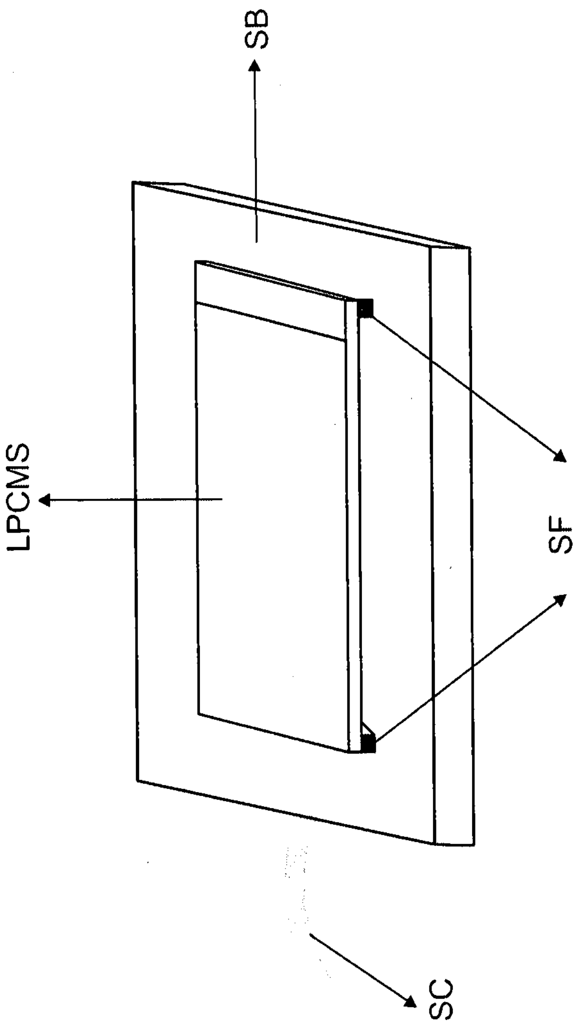
Tab.3



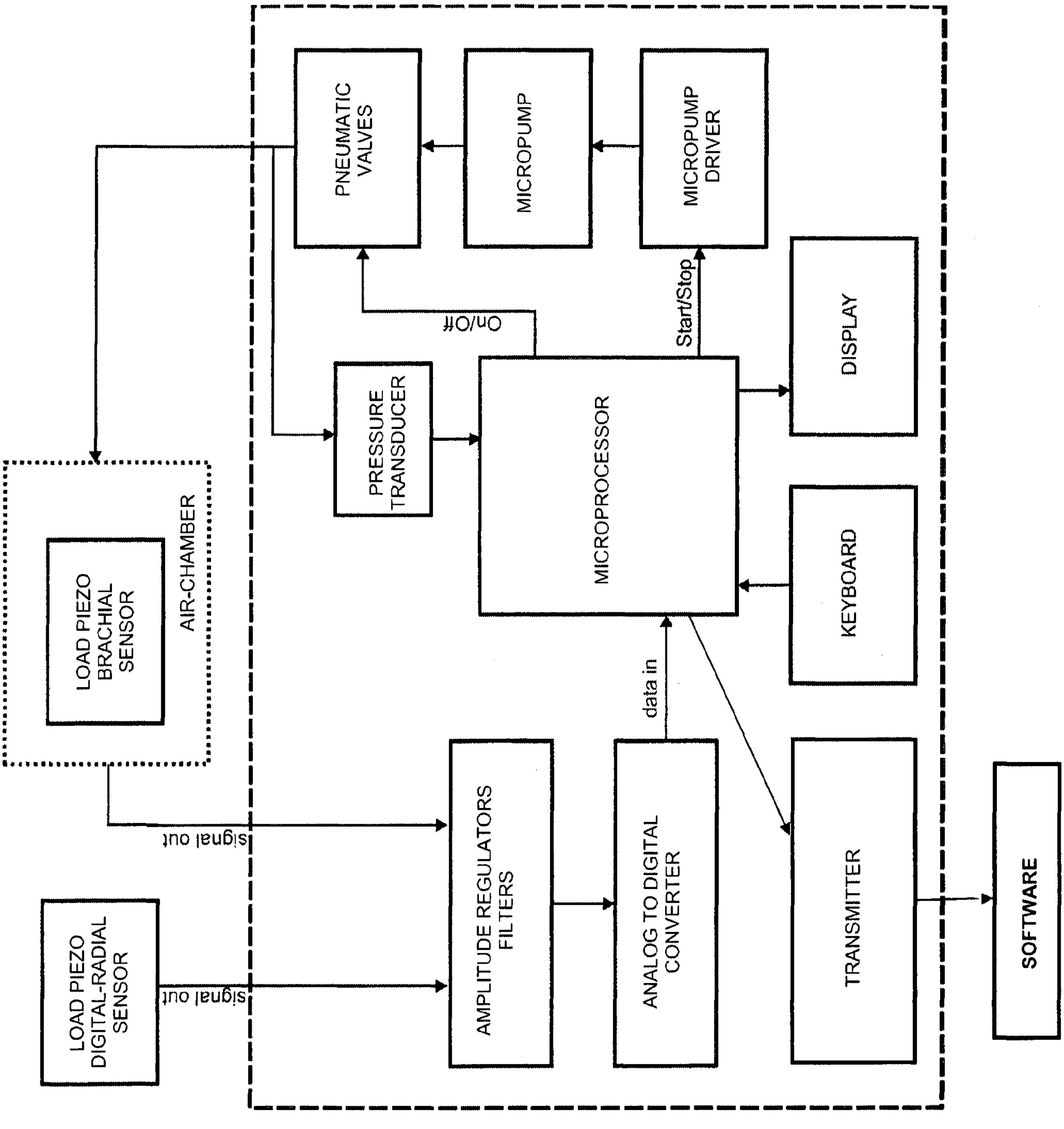
Tab.4 a



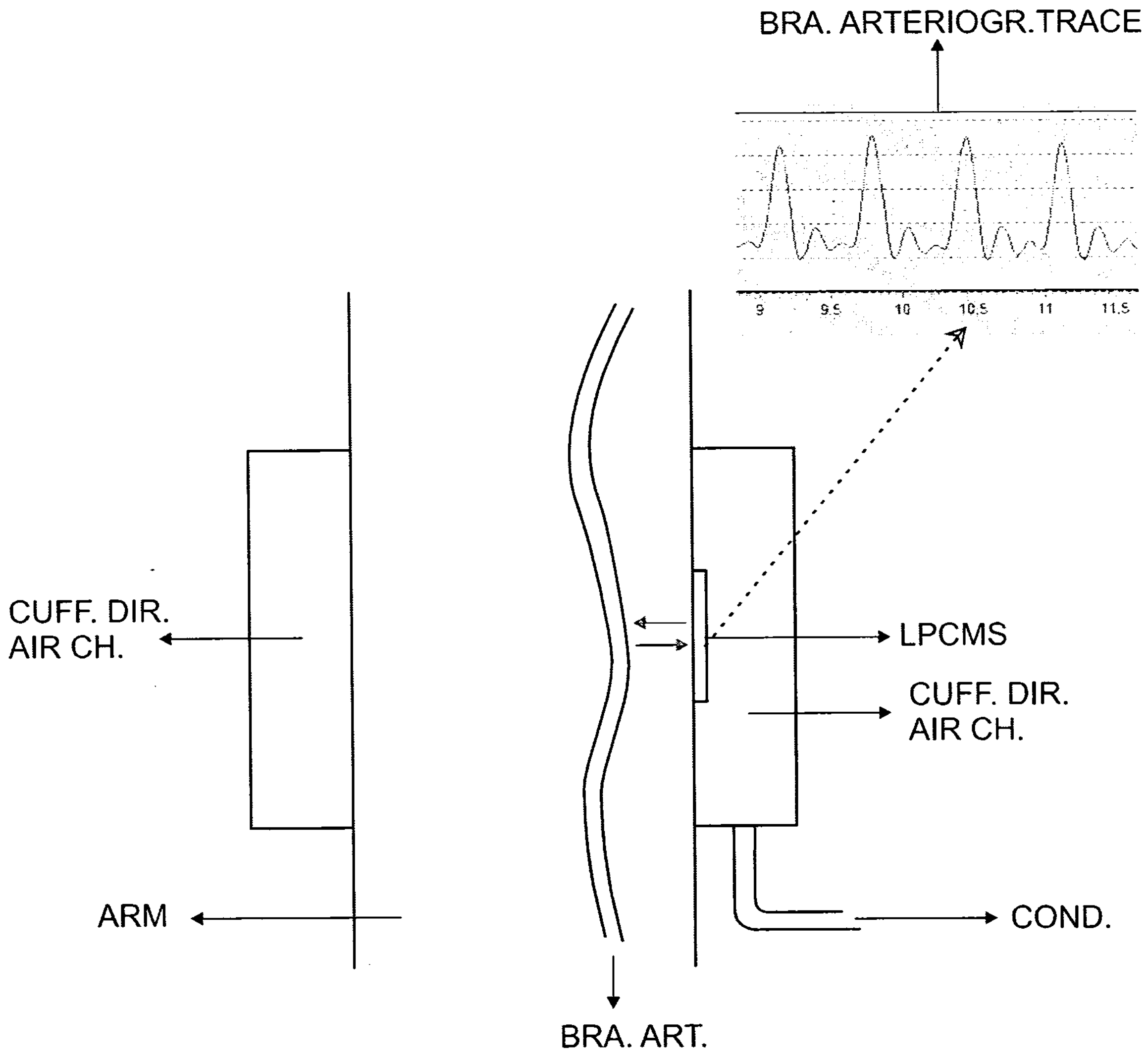
Tab. 4 b



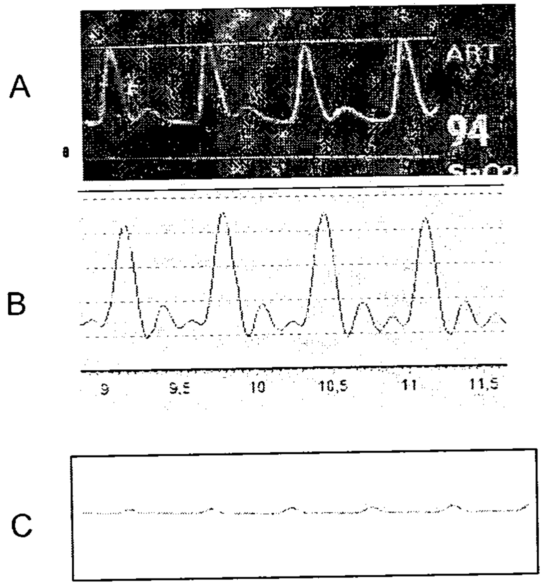
Tab. 5


PNEUMATIC VALVES
MICROPUMP
MICROPUMP DRIVER
On/Off
Start/Stop
PRESSURE TRANSDUCER
MICROPROCESSOR
DISPLAY
KEYBOARD
LOAD PIEZO BRACHIAL SENSOR
AIR-CHAMBER
data in
signal out
AMPLITUDE REGULATORS FILTERS
ANALOG TO DIGITAL CONVERTER
TRANSMITTER
SOFTWARE
LOAD PIEZO DIGITAL-RADIAL SENSOR
signal out

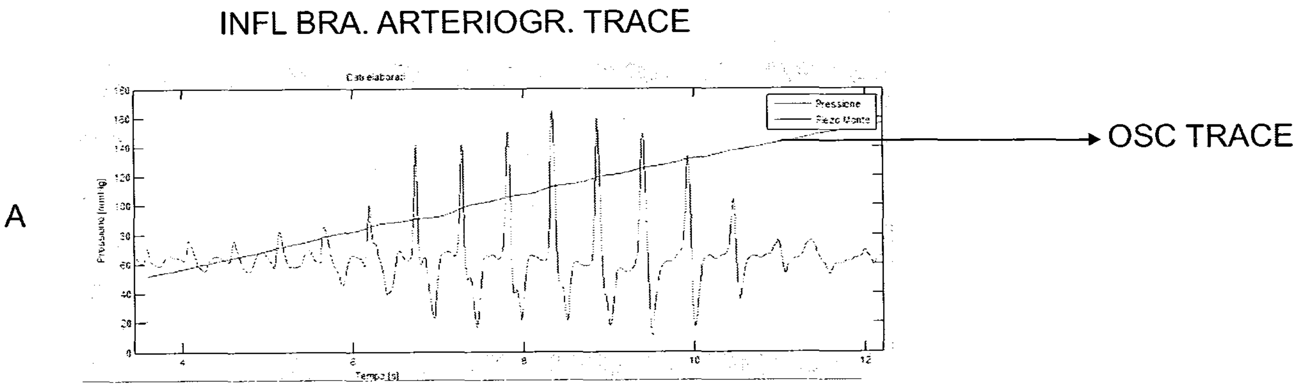
Tab. 6

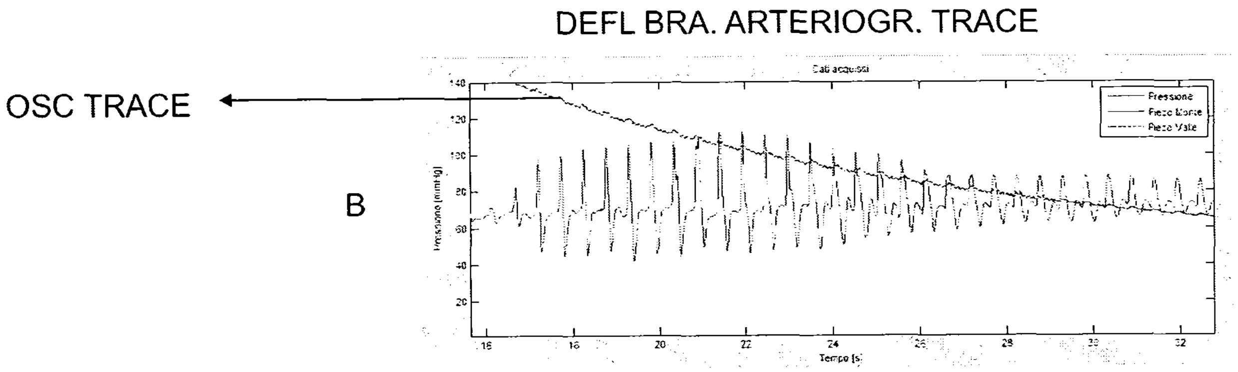

BRA. ARTERIOGR.TRACE
9
9.5
10
10.5
11
11.5
CUFF. DIR.
AIR CH.
LPCMS
CUFF. DIR.
AIR CH.
ARM
COND.
BRA. ART.

Tab. 7

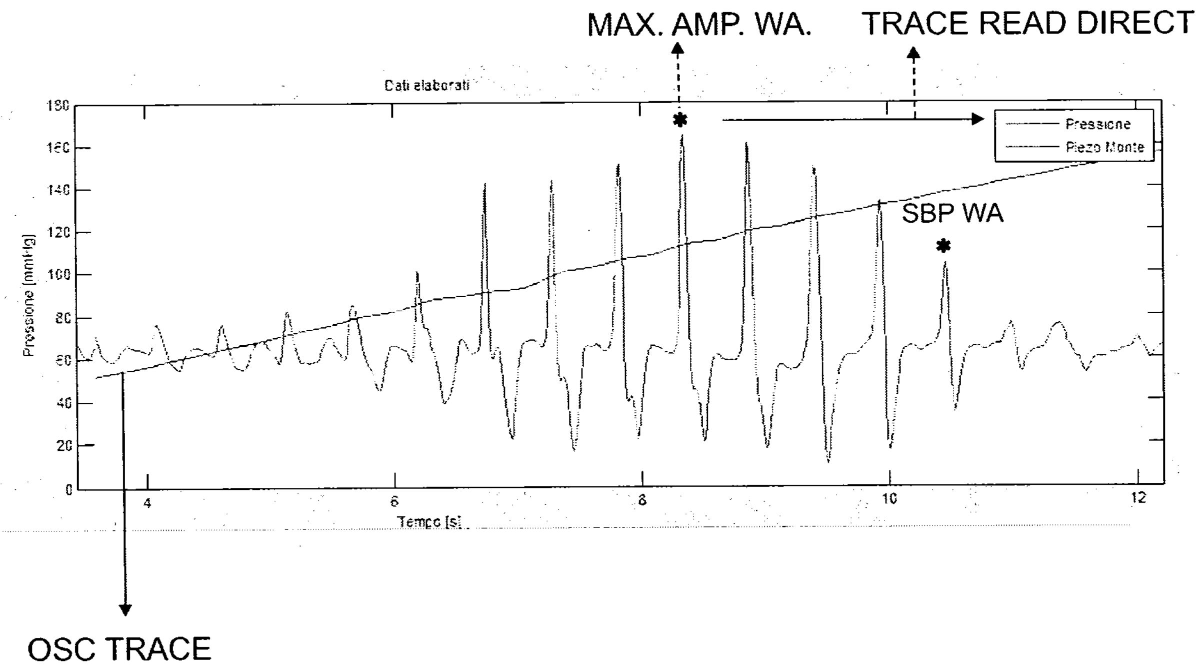


Tab. 8


INFL BRA. ARTERIOGR. TRACE
A
Dati elaborati
Pressione [mmHg]
Tempo [s]
Pressione
Piezo Monte
OSC TRACE
0
20
40
60
80
100
120
140
160
180
4
6
8
10
12

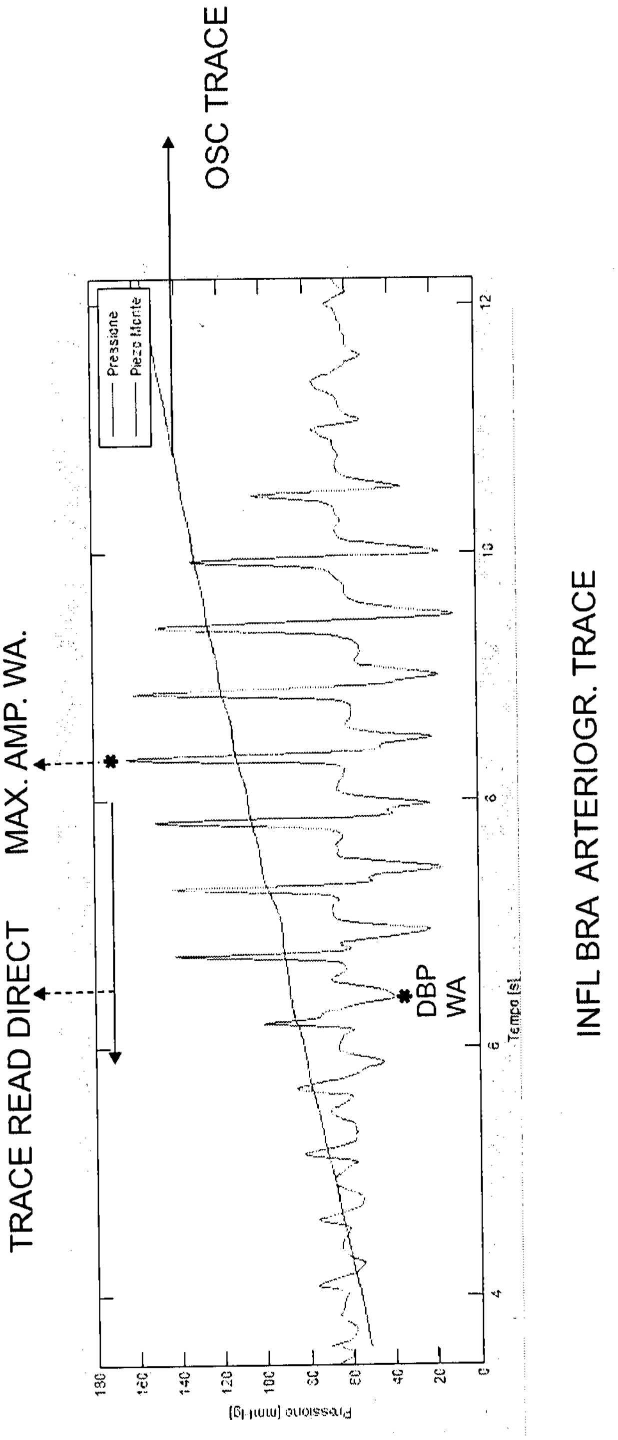

DEFL BRA. ARTERIOGR. TRACE
B
OSC TRACE
Dati acquisiti
Pressione [mmHg]
Tempo [s]
Pressione
Piezo Monte
Piezo Valle
20
40
60
80
100
120
140
16
18
20
22
24
26
28
30
32

Tab. 9 A, B

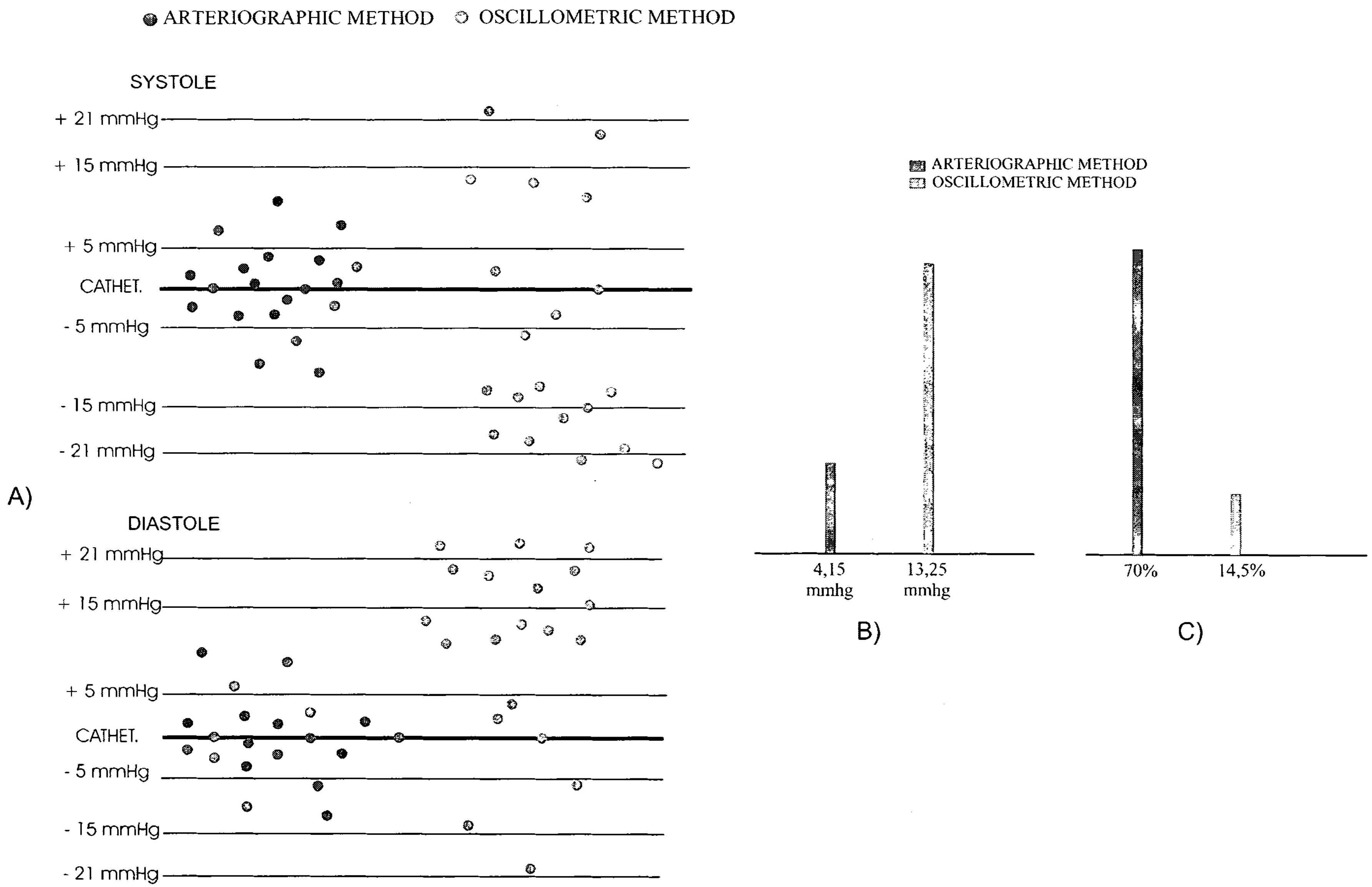


INFL BRA ARTERIOGR. TRACE

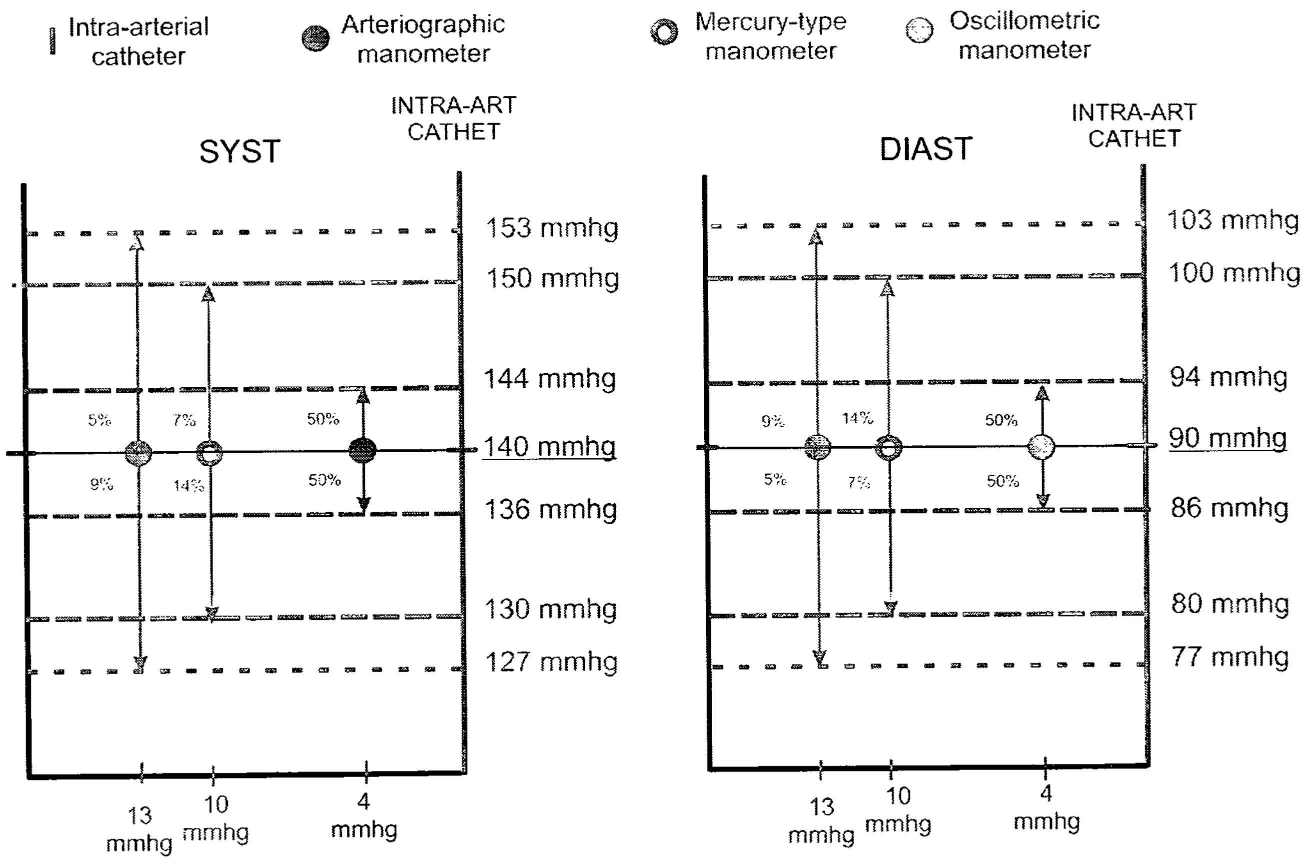
Tab. 10


OSC TRACE
MAX. AMP. WA.
TRACE READ DIRECT
DBP
WA
INFL BRA ARTERIOGR. TRACE
Pressione
Piezo Monte
Pressione [mmHg]
180
160
140
120
100
80
60
40
20
0
Tempo [s]
4
6
8
10
12

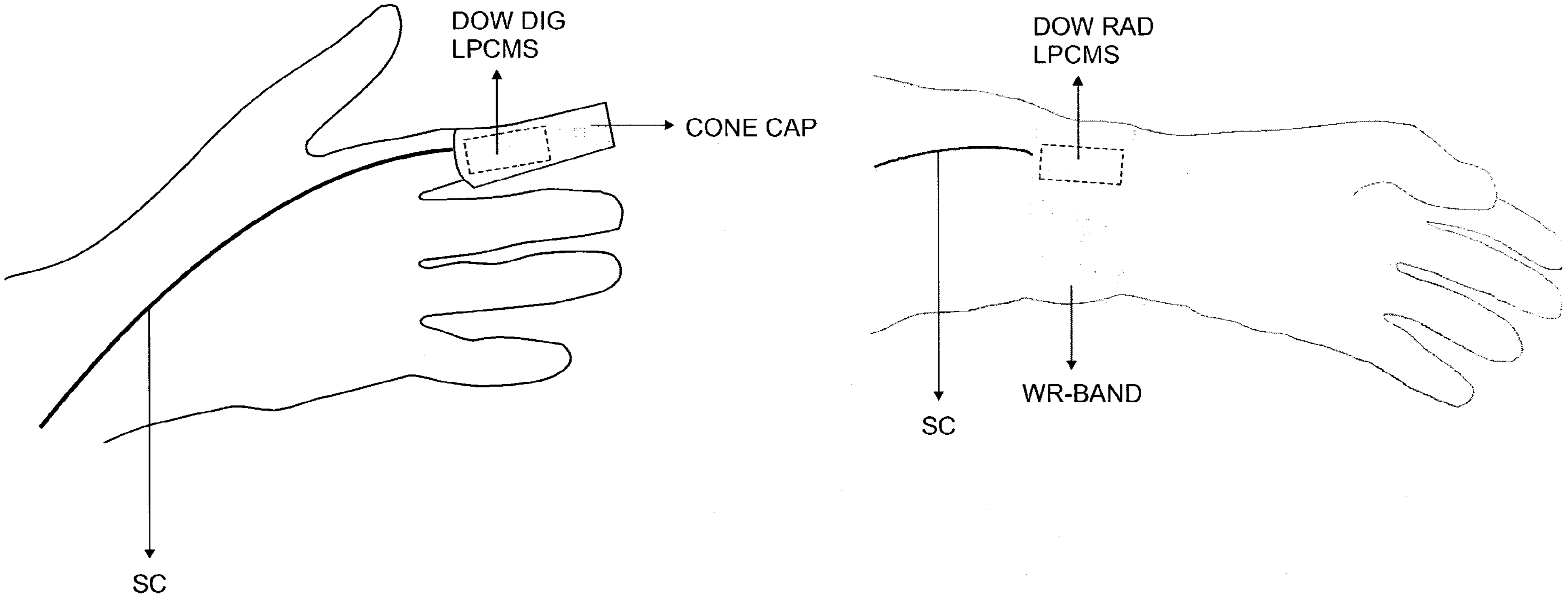
Tab. 11


ARTERIOGRAPHIC METHOD
OSCILLOMETRIC METHOD
SYSTOLE
+ 21 mmHg
+ 15 mmHg
+ 5 mmHg
CATHET.
- 5 mmHg
- 15 mmHg
- 21 mmHg
A)
DIASTOLE
+ 21 mmHg
+ 15 mmHg
+ 5 mmHg
CATHET.
- 5 mmHg
- 15 mmHg
- 21 mmHg
ARTERIOGRAPHIC METHOD
OSCILLOMETRIC METHOD
4,15 mmhg
13,25 mmhg
B)
70%
14,5%
C)

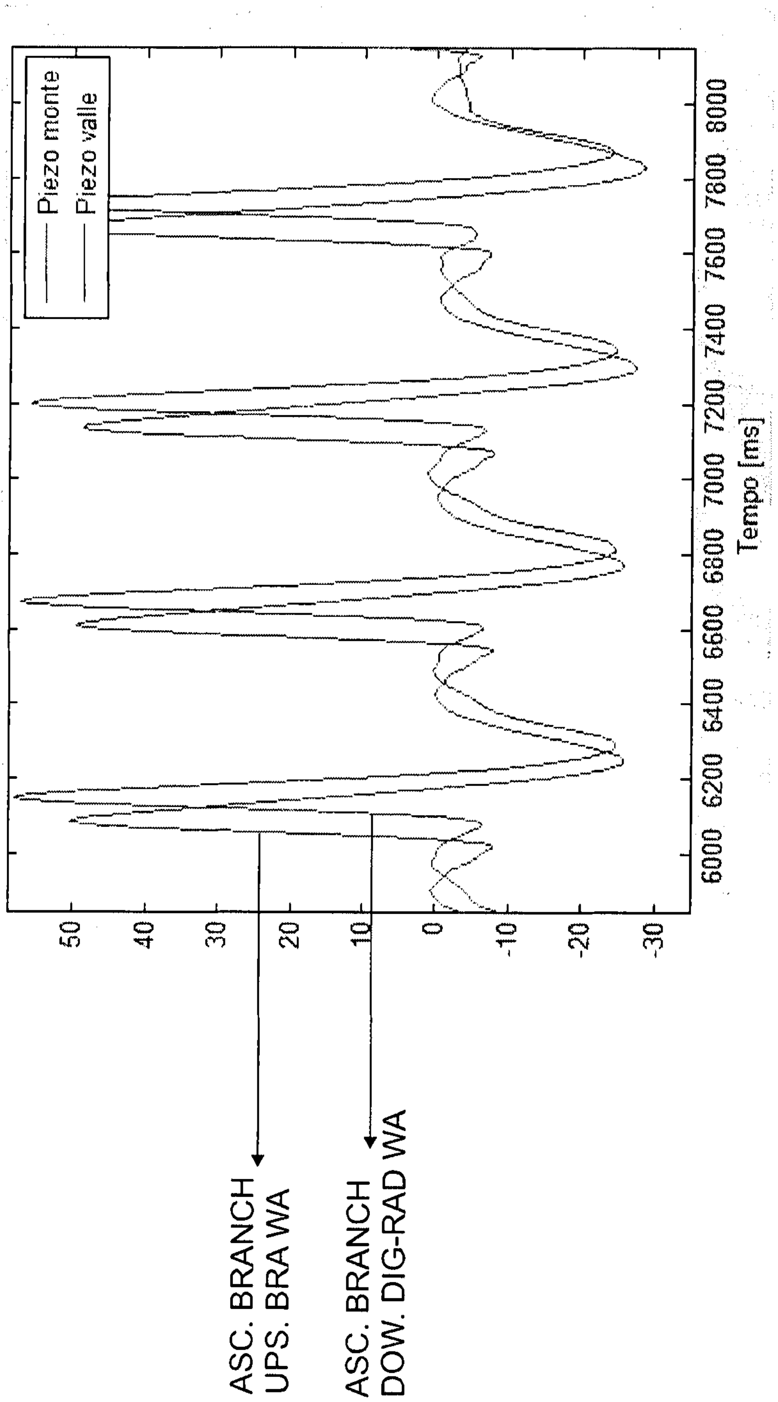
Tab. 12


Intra-arterial catheter
Arteriographic manometer
Mercury-type manometer
Oscillometric manometer
SYST
INTRA-ART CATHET
153 mmhg
150 mmhg
144 mmhg
140 mmhg
136 mmhg
130 mmhg
127 mmhg
5%
7%
50%
9%
14%
50%
13 mmhg
10 mmhg
4 mmhg
DIAST
INTRA-ART CATHET
103 mmhg
100 mmhg
94 mmhg
90 mmhg
86 mmhg
80 mmhg
77 mmhg
9%
14%
50%
5%
7%
50%
13 mmhg
10 mmhg
4 mmhg

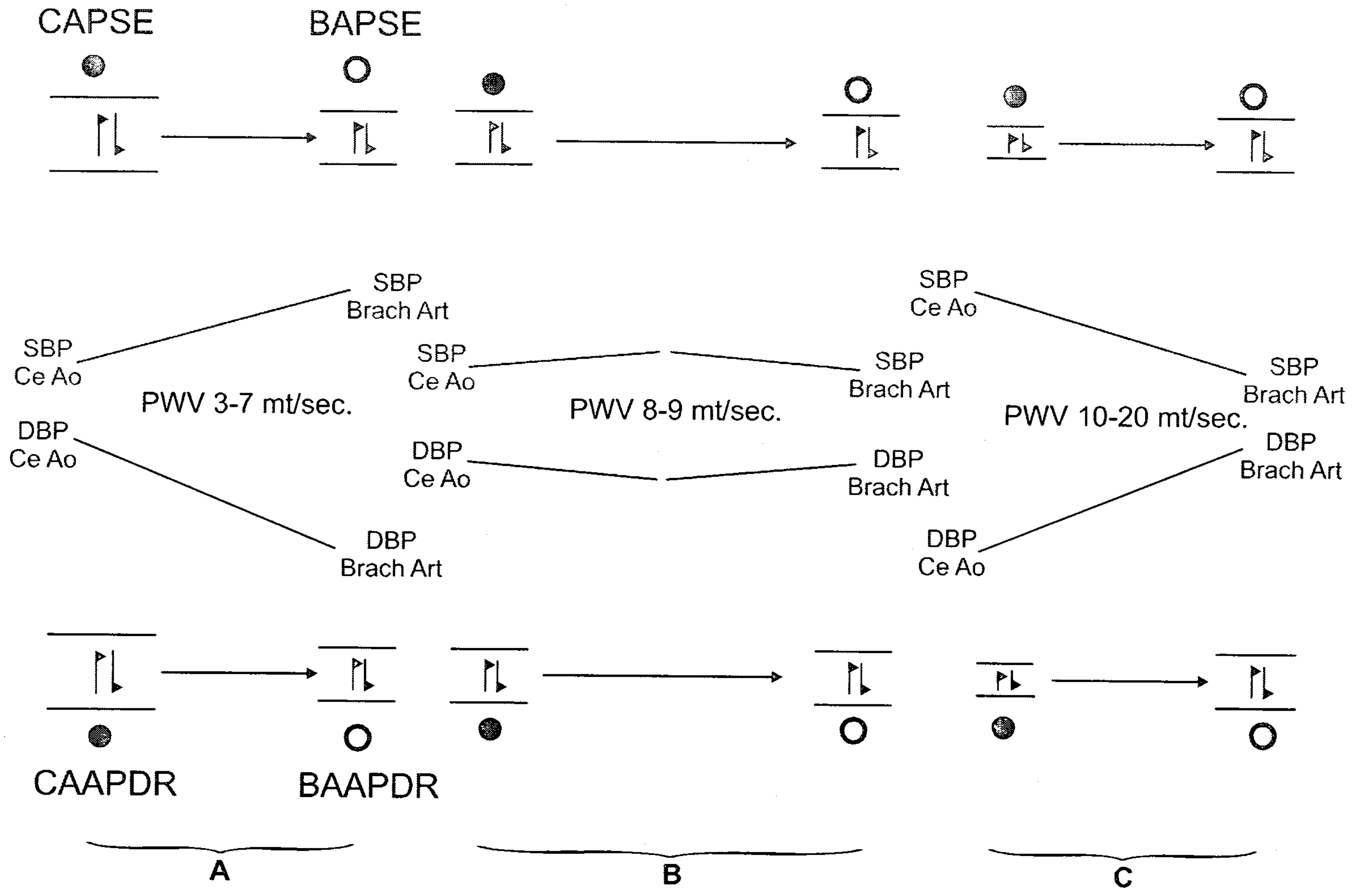
Tab. 13



Tab. 14


Piezo monte
Piezo valle
50
40
30
20
10
0
-10
-20
-30
6000
6200
6400
6600
6800
7000
7200
7400
7600
7800
8000
Tempo [ms]
ASC. BRANCH
UPS. BRA WA
ASC. BRANCH
DOW. DIG-RAD WA

Tab. 15


CAPSE
BAPSE
SBP Ce Ao
SBP Brach Art
PWV 3-7 mt/sec.
DBP Ce Ao
DBP Brach Art
SBP Ce Ao
SBP Brach Art
PWV 8-9 mt/sec.
DBP Ce Ao
DBP Brach Art
SBP Ce Ao
SBP Brach Art
PWV 10-20 mt/sec.
DBP Brach Art
DBP Ce Ao
CAAPDR
BAAPDR
A
B
C

Tab. 16

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/000701

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/02 A61B5/021 A61B5/022 A61B5/00
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/116430 A2 (AGOSTA ROBERTO [IT]) 18 October 2007 (2007-10-18)	1,2,4
Y	page 2, line 29 - page 4, line 102 page 13, line 295 - page 17, line 405; figures -----	3,5-10
Y	US 5 368 039 A (MOSES JOHN A [US]) 29 November 1994 (1994-11-29) column 11, line 61 - column 12, line 30 -----	5,6
Y	US 2006/079791 Al (LETREMY ROLAND [FR] ET AL) 13 April 2006 (2006-04-13) paragraphs [0057] - [0060] -----	3,7
Y	US 2010/016736 Al (HAHN JIN-0H [CA] ET AL) 21 January 2010 (2010-01-21) paragraphs [0035] - [0039] -----	8,10
	-/- ·	

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

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search 23 August 2013	Date of mailing of the international search report 05/09/2013
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 Manschot, Jan

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/000701

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2006/072776 AI (MICRO MEDICAL LTD [GB]; CHOWIENCZYK PHILIP JAN [GB]; MILLASSEAU SANDRI) 13 July 2006 (2006-07-13) the whole document -----	9
A	US 2011/275944 AI (QASEM AHMAD M [AU]) 10 November 2011 (2011-11-10) paragraphs [0017] - [0022] -----	9

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2013/000701

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007116430 A2	18-10-2007	EP 2330974 A2	15-06-2011
		WO 2007116430 A2	18-10-2007
US 5368039 A	29-11-1994	US 5368039 A	29-11-1994
		US 5551438 A	03-09-1996
US 2006079791 A1	13-04-2006	EP 1596713 A1	23-11-2005
		FR 2851449 A1	27-08-2004
		JP 2006519045 A	24-08-2006
		US 2006079791 A1	13-04-2006
		WO 2004075744 A1	10-09-2004
US 2010016736 A1	21-01-2010	NONE	
WO 2006072776 A1	13-07-2006	EP 1835851 A1	26-09-2007
		US 2008255463 A1	16-10-2008
		WO 2006072776 A1	13-07-2006
US 2011275944 A1	10-11-2011	EP 2566387 A2	13-03-2013
		JP 2013525055 A	20-06-2013
		US 2011275944 A1	10-11-2011
		WO 2011138683 A2	10-11-2011

专利名称(译)	血流动力学动脉压力计和测量动脉血压和心脏和主动脉功能参数的方法		
公开(公告)号	EP2844132A1	公开(公告)日	2015-03-11
申请号	EP2013730927	申请日	2013-04-17
[标]申请(专利权)人(译)	阿戈斯塔ROBERTO		
申请(专利权)人(译)	阿戈斯塔，ROBERTO		
当前申请(专利权)人(译)	阿戈斯塔，ROBERTO		
[标]发明人	AGOSTA ROBERTO		
发明人	AGOSTA, ROBERTO		
IPC分类号	A61B5/02 A61B5/021 A61B5/022 A61B5/00		
CPC分类号	A61B5/02007 A61B5/02125 A61B5/02225 A61B5/02233 A61B5/6824 A61B5/6826 A61B2562/0247		
代理机构(译)	CICOGNA，FRANCO		
优先权	102012902042864 2012-04-18 IT		
外部链接	Espacenet		

摘要(译)

血流动力学血管造影计使用皮肤负载压电双晶陶瓷多层陶瓷宏观传感器放置在直接血压计气室的外腹面上，能够直接从肱动脉经皮提取由真实动脉搏动波组成的臂动脉造影，适用于测量全身动脉压;在气室施加的按压作用下，所述传感器位于距肱动脉路线约1cm处，其轴线垂直于所述动脉。本发明还涉及一种通过所述血压计记录的特定痕迹测量全身动脉血压的方法，以及测量心脏和中心动脉功能参数的方法。