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MEDICAL AND BIOLOGICAL MEASUREMENTS

PROBLEMS OF ENSURING THE UNIFORMITY OF BLOOD PRESSURE MEASUREMENTS

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The problems of ensuring the unity of non-invasive blood pressure measurements are considered. It is shown that the artery and surrounding tissues of the body serve as a means of comparing the values of blood pressure and air pressure in the cuff, and that the metrological traceability of measurement results to pressure standards only partially determines the reliability of these results. The potential possibilities of the surface pulse wave method in comparison with the Korotkov tone method are estimated.
Keywords: *blood pressure measurement, unity of measurements, reliability of measurement results, Korotkov tone method, surface pulse waves, oscillometric measurement method, auscultatory method, quasi-auscultatory method, means of comparison of physical quantities.*

Introduction. The Secretary of the International Committee of Weights and Measures (CIPM) R. Kaarls at the XXIII General Conference on Weights and Measures (November 2007) in a report addressed to the directors of national metrological institutes, among other recommendations, notes that "In the field of healthcare reliable measurements are needed in all areas, starting with guaranteed accurate diagnostics, ..." [1]. In the Russian Federation, Federal Law No. 102-FZ dated June 28, 2008, "On Ensuring the Uniformity of Measurements," was adopted. In this law, activities in the field of healthcare are included in the scope of state regulation of ensuring the uniformity of measurements, and the need for establishing mandatory metrological requirements for such measurements is also prescribed. The relevant requirements are established by Order of the Ministry of Health No. 81-n dated 02.21.2014, "On approval of the List of measurements relating to the field of state regulation to ensure the uniformity of measurements performed in the course of activities in the field of healthcare, and the mandatory metrological requirements for them, including measurement accuracy indicators." Paragraph 4.1 (c) of GOST 8.000-2015, "State system for ensuring the uniformity of measurements. The main provisions" states that "The objectives of state regulation to ensure the uniformity of measurements are ... to meet the needs of citizens, society and the state in obtaining objective, reliable and comparable measurement results used to protect the life and health of citizens."

Methods for measuring blood pressure: objectivity, comparability and reliability of the results. Blood pressure continuously varies in the range from the lower (diastolic) P_d to the upper (systolic) P_s values in accordance with the heart rate. This dependence is represented in the form of an arterial pulse pressure curve $P_{BP}(t)$ obtained by measuring blood pressure using a transducer of pressure into an electrical signal. In this case, a direct (invasive) measurement method is implemented in which the transducer is connected directly to the internal cavity of the artery. This method is usually used in surgical operations. All other methods of measuring blood pressure that are not related to penetration into the artery are called non-invasive and, as a rule, consist in measuring the systolic and diastolic blood pressure values.

Non-invasive methods officially recognized by the medical community are based on comparing the blood pressure inside the artery $P_{BP}(t)$ with a reference value – the air pressure P_c in the compression cuff, which acts on the artery walls from the outside through the body tissue. At the same time, the conditions for direct comparison of internal and external

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pressure on the artery wall are observed, and thereby the objectivity of the measurement results is ensured, and their comparability is achieved through the use of units included in the International System of Units.

When measuring blood pressure using a compression cuff, the measuring instrument and the human body together form a certain common measuring system in which living tissue of the human body under the cuff acts as a means of comparing the physical pressure values. They respond to a change in the cross section of the artery and form a response signal, which can be used to judge the ratio of blood pressure in the artery and air in the cuff. The reaction of body tissues obeys the laws of physics, but largely depends on the physiological characteristics of a particular person. This is manifested in the ambiguity of the response of the human body to the equality of the compared pressure values and affects the reliability of the measurement result, expressed in methodological error. The methodological error substantially depends on the measurement method used.

Currently, three methods of measuring blood pressure are used in medical practice: the Korotkov tone method (auscultatory); oscillometric method; method of surface pulse waves (quasi-auscultatory). The listed methods are named according to the type of response signals of the human body, which arise as a result of physical processes occurring inside the body tissues during the interaction of internal and external pressures, namely tones, oscillations and surface pulse waves.

However, objectivity and comparability of the measurement results alone do not guarantee their reliability, which is determined by the measurement error of the real values of P_d, P_s obtained by recognizing two values of air pressure in the cuff P_c, presumably corresponding to these real values. Thus, when using the Korotkov tone method, it is assumed that tones accompany moments of instantaneous equality of the values of arterial and external pressures during systole periods on the pulse curve. Other methods of measuring blood pressure, for example, the oscillometric method, are based only on an empirical calculation of the expected values of P_d and P_s according to some empirical formulas that are based on a statistical analysis of many diagrams of pulsations of air pressure in the cuff, comparable with the value of this pressure. The results of blood pressure measurements obtained by the oscillometric method are probabilistic in nature, since they are the mathematical expectation of the measured value with unpredictable dispersion.

The widespread practical use of the Korotkov tone method showed that it allows accurate measurement of blood pressure for medical practice. Therefore, in 1935, this method was recognized as the reference method by the World Health Organization (WHO). This served as the basis for using the Korotkov tone method in medical testing of non-invasive blood pressure measurement methods. In this case, the blood pressure measurement technique that implements the Korotkov tone method is accepted as a reference, and the difference in blood pressure values obtained while measuring using the reference and the tested measurement technique is taken as the measurement error. However, the method, which is recognized as the reference method also has methodological errors that are independent of the error in measuring the air pressure in the cuff.

A large number of studies have been devoted to the study of the very phenomenon of Korotkov's tones, the results of which are most fully described in [2]. Fundamental theoretical studies of the nature of Korotkov tones are presented in publications [3–5]. The method of surface pulse waves appeared in the recent past as an invention [6], created at the VNIIIMT of the USSR Health Ministry, and was intensively developed within the walls of this institute until 1991. The results of studies of the processes occurring under the compression cuff made it possible to establish the physical totality of the causes of the surface pulse wave phenomenon [7, 8] and the phenomenon of Korotkov tones, namely the occurrence of intermittent blood flow in the artery.

Thus, the existing problems of the uniformity of blood pressure measurements consist in the fact that it is objectively impossible to assign any boundary values of the measurement error of specific blood pressure values to a specific measuring tool only by tracking the metrological characteristics of the manometer measuring the air pressure in the cuff to the corresponding standards of overpressure units, since the accuracy of measuring the air pressure in the cuff only partially affects the reliability of the measurement results.

Auscultatory and quasi-auscultatory methods for measuring blood pressure. When quantitatively comparing one physical quantity (blood pressure) with another physical quantity (air pressure in the cuff), a means of comparison is needed that signals the equality of the compared quantities or their ratio according to the "more or less" principle. In this case, the comparison of the measured $P_{BP}(t)$ and the reference $P_c(t)$ of pressure occurs inside the human body in the absence of any artificial device installed at the comparison site. In this case, the measured physical quantity pulsates with the frequency of the heart, and the reference value changes with the rate of change of air pressure in the cuff. Therefore, their current values

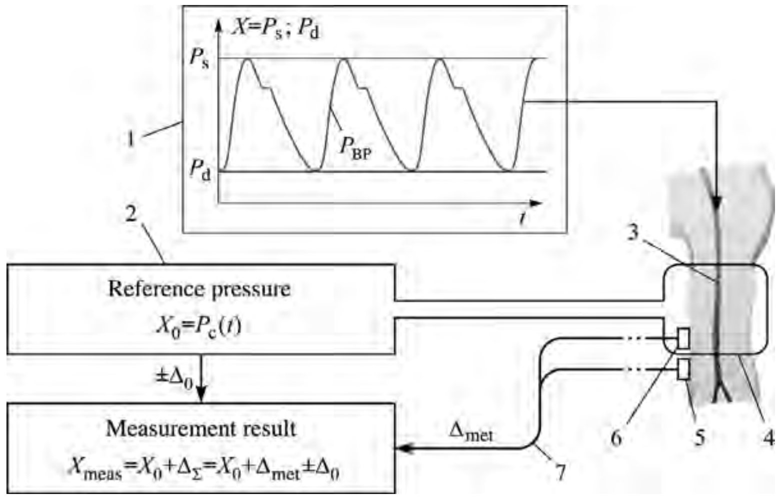

Fig. 1. A scheme for measuring blood pressure by instant comparison of its values with the reference pressure value: *1*, *2*) sources of blood pressure and reference pressure, respectively; *3*) means of comparison (artery); *4*) compression cuff; *5*) phonendoscope (microphone); *6*) detector of surface pulse wave; *7*) feedback line.

can only be equal instantaneously. In addition, the comparison tool should have the properties of an instant response to this short-term event and the ability to notify the measuring system about the comparison.

As a means of comparing the values of $P_{BP}(t)$, $P_c(t)$ in the case under consideration, only the part of the artery with the surrounding body tissues under the compression cuff is used. In the case of instantaneous equality of the compared pressure values, the artery responds with sounds (Korotkov tones) when using the auscultatory method for measuring blood pressure, and in the form of surface pulse waves in the quasi-auscultatory method. In both cases, the said section of the brachial artery passes from a closed state to an open one after the blood pressure exceeds the external pressure on the artery created by the compression cuff. The measurement scheme for blood pressure $P_{BP}(t)$ by instant comparison of its values with the value of the reference pressure $P_c(t)$ is shown in Fig. 1, where the measured values X are the values P_s, P_d, and the reference pressure X_0 is the air pressure $P_c(t)$ in the cuff fixed to the shoulder. In this case, the reference pressure is measured with an absolute error of $\pm\Delta_0$.

The Korotkov tone detector is a phonendoscope of a mechanical blood pressure monitor (tonometer) or a microphone of an automatic blood pressure monitor (tonometer). Special detectors are used to register surface pulse waves. Korotkov's tones or the output signals of the surface pulse wave detector notify the doctor or receiver about the comparison of the measured and reference pressure. In this way, feedback takes place between the comparison tool and the reference pressure meter, which allows attributing only two measured values of the reference pressure to the measured values P_s, P_d taking into account the measurement errors (see Fig. 1). When a phonendoscope is used, the feedback *7* is implemented by the person making the measurements. The real process of comparing blood pressure with air pressure in the cuff is illustrated in Fig. 2, which shows the functions of the pressure of air in the cuff $P_c(t)$ and blood pressure (pulse curve $P_{BP}(t)$). The air pressure in the cuff during the measurement of blood pressure decreases linearly with velocity v_P:

$$P_c(t) = P_{c0} - v_P t;$$

$$P_{c0} = P_c(0),$$

where P_{c0} is the initial air pressure in the cuff.

For a zero countdown, we take the start of the decrease in air pressure in the cuff. Initially, $P_c > P_s$, the part of the artery under the cuff is completely pinched, and distal of the cuff there is no blood flow in the artery. As the air pressure in the cuff decreases, the curve $P_c(t)$ at time t_{sc} reaches the value of P_s. After that, the first entry of blood into the arterial circulatory system leads the function $P_{BP}(t)$ to exceed the function $P_c(t)$ and, as a result, to the start of the movement of the first portion of blood through the artery (see Fig. 2, time t_{sibf} of the start of intermittent blood flow). Intermittent blood flow is formed as

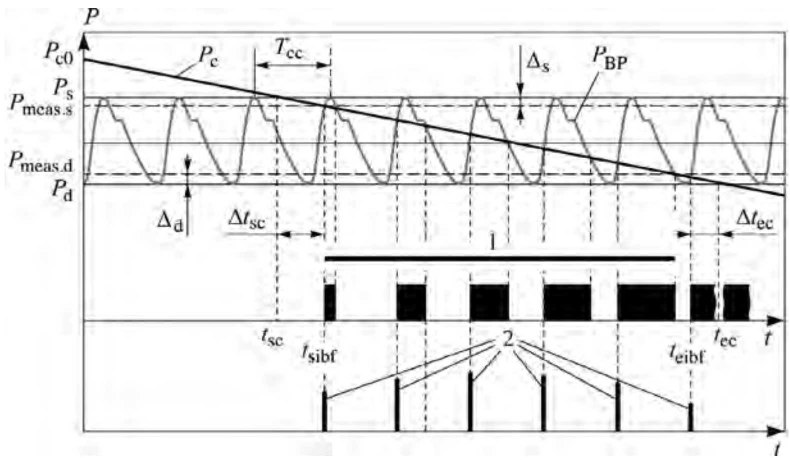

Fig. 2. The process of comparing blood pressure with the pressure air in the cuff: *1*) intermittent blood flow; *2*) Korotkov tones or surface pulse waves; T_{cc} – duration of cardiac cycle; t_{sc} – start time of comparison; t_{ec} – end time of comparison; t_{sibf} – start time of intermittent blood flow; t_{eibf} – end time of intermittent blood flow; Δt_{sc} – delay in starting comparison; Δt_{ec} – advance of the end of comparison

follows. As soon as blood pressure at the beginning of the next cardiac cycle T_{cc} becomes less than reference pressure, the artery closes and blood flow stops until the next portion of blood enters into the arterial system. Further, within the range of pulse pressure P_s–P_d, separate portions of blood sequentially pass through the artery under the cuff simultaneously with the work of the heart, forming intermittent blood flow [7]. Moreover, the passage under the cuff of each portion of blood creates the conditions for the appearance of the next Korotkov tone and the next surface pulse wave, which indicate the next instant comparison of the functions $P_{BP}(t)$ and $P_c(t)$. The last comparison cycle is carried out at time t_{eibf} of the end of intermittent blood flow, after which the curve $P_c(t)$ at the time t_{ec} of the end of comparison, it goes out of the pressure range P_s–P_d, and intermittent blood flow becomes steady.

Korotkov tones and surface pulse waves are the measured information from which the systolic and diastolic pressure values are determined, having attributed to them with some total error Δ_Σ the measured values $P_{s.meas}$ and $P_{d.meas}$ of air pressure in the cuff that existed at the moments of the formation of the first and last Korotkov tones or the first and last surface pulse wave, respectively. The error Δ_Σ is the difference between the measurement result X_{meas} and the reference value X_0 and is determined by the sum of the absolute errors of the measurement method Δ_{met} and the error $\pm\Delta_0$ of measurement of the reference value of the air pressure in the cuff:

$$\Delta_\Sigma = \Delta_{met} + \Delta_0.$$

In this case, the measurement result is

$$X_{meas} = X_0 + \Delta_\Sigma = X_0 \pm \Delta_0 + \Delta_{met}.$$

The decrease in the error Δ_0 to a level of less than 1 mmHg can be achieved by using a pressure gauge or transmitter required for this accuracy class. Therefore, the main problem of ensuring the uniformity of blood pressure measurements is to reduce the methodological error. The transition of an artery from a closed to an open state occurs periodically once during each cardiac cycle, which leads to discreteness of measurement information and generates systematic absolute measurement errors of systolic and diastolic pressures, respectively:

$$\Delta_s = -v_P \Delta t_{sc}; \quad (1)$$

$$\Delta_d = v_P \Delta t_{ec}. \quad (2)$$

The parameters Δt_{sc} (delayed start of comparison) and Δt_{ec} (advance of the end of comparison) have equally random probability within the cardiac cycle of duration T_{cc}. Therefore, the maximum values of the errors Δ_s, Δ_d are the same and are determined by replacing Δt_{sc}, Δt_{ec} in formulas (1), (2) with the duration T_{cc}. The indicated errors are proportional to the velocity v_P, therefore, their values can be reduced to any required minimum by decreasing the velocity v_P with the guaranteed occurrence of Korotkov tones and surface pulse waves after each completed comparison of the reference and measured pressures. However, according to the results of recent theoretical and experimental studies, the appearance of Korotkov tones is due to the threshold intensity of the blood flow front at the time of passage of a portion of blood [5]. In this regard, if the comparison results in an equality of the compared pressures, the Korotkov tone may not arise if the intensity of the blood flow front has not reached the threshold value. Thus, additional errors $\Delta_{\text{s.phys}}$ and $\Delta_{\text{d.phys}}$ are quite probable because of the missed moment of equality of the values of $P_{\text{BP}}(t)$ and $P_{\text{c}}(t)$ when measuring the values of P_{s}, P_{d}. These errors are determined by the physiological characteristics of a particular person and do not depend on the rate of decrease in air pressure in the cuff.

In the case of listening to Korotkov tones using a phonendoscope, errors of the indicated unaccounted equality arise due to the inexperience of the operator performing the measurements, as well as due to the low technical characteristics of the phonendoscope as a transducer of oscillations of the body surface into sound pressure affecting the hearing organs. Korotkov tones have characteristic features that allow the operator to recognize these tones against the background of other sounds. Therefore, the results of automatic measurement of blood pressure using the Korotkov tone method are less reliable than the results obtained by the operator.

In the monograph [2], the effect of the intrinsic elasticity of the artery walls on the process of blood pressure measurement by the Korotkov tones method was considered. In [9], the results of an experimental measurement of the intrinsic elasticity of the walls of the human ulnar arteries are presented. In this case, the critical value P_{cr} of external pressure (overcoming the elasticity of the artery walls) at which the artery closes is experimentally determined. If we consider an artery as a thin-walled tube with flexible walls, then for its compression by the external pressure of the body P_{ext}, it is necessary to observe the inequality $P_{\text{ext}} > P_{\text{cr}}$. According to [2, 9] for the human ulnar artery, $P_{\text{cr}} \leq 1$–2 mmHg. This value can be taken as the error Δ_{w} of the changes in the shape of the artery walls, which should be accounted for with a negative sign.

Thus, the total measurement errors of systolic P_{s} and diastolic P_{d} pressures by auscultatory and quasi-auscultatory methods are determined by the expressions

$$\Delta_{\Sigma\text{s}} = \pm\Delta_0 + \Delta_{\text{s}} + \Delta_{\text{s.phys}} + \Delta_{\text{w}};$$

$$\Delta_{\Sigma\text{d}} = \pm\Delta_0 + \Delta_{\text{d}} + \Delta_{\text{d.phys}} + \Delta_{\text{w}}.$$

Secondary pressure of bodily tissues on the artery. It is usually believed that the air pressure P_{c} in the cuff is almost completely reproduced in the body tissues in the form of the secondary pressure P_{sec} of bodily tissues, which is almost uniformly distributed along the artery along the entire width of the cuff. In [7], it was shown that the values of the secondary pressure of bodily tissues on the artery walls increase from zero values along the edges of the cuff to a maximum value in the middle of the cuff equal to the air pressure in the cuff. This fundamentally changes the prevailing ideas about the physical processes of the interaction of the external secondary pressure of bodily tissues on the artery with the blood pressure inside the artery. Figure 3 shows the distribution functions of the secondary pressure $P_{\text{sec1}}(l)$, $P_{\text{sec2}}(l)$ for two reference values of the air pressure in the cuff: $P_{\text{c1}} > P_{\text{s}}$ and $P_{\text{d}} < P_{\text{c2}} < P_{\text{s}}$, where l is the longitudinal coordinate equal to zero at the proximal (initial in the direction of blood flow) edge of the cuff and the value of l_{c} at its distal (final in the direction of blood flow) edge; $\Delta l_{\text{c.mid}}$ is the area of bodily tissues in which the value of the secondary pressure is equal to the value of air pressure in the cuff. Such a spatial distribution of the secondary pressure of bodily tissues is caused by the fact that the part of the body under the cuff is not limited by the edges of the cuff with respect to its neighboring areas, which makes it impossible to jump in pressure in the bodily tissues within these conditional boundaries. The region of pulsations of blood pressure in the range of values from diastolic P_{d} to systolic P_{s} is indicated in Fig. 3 by two dashed lines. Blood pressure $P_{\text{BP}}(t)$ is spatially limited by arterial walls *3* and acts on them from the inside from the proximal part of the artery.

Consider the processes occurring in the artery the air pressure in the cuff is P_{c1}, which creates a secondary pressure distribution $P_{\text{sec1}}(l)$ in the body tissues. As indicated above, the air pressure in the cuff P_{c1} exceeds the systolic blood pressure, and as a result in the middle part of the cuff $\Delta l_{\text{c.mid}}$ at the location of the artery, the external pressure of the body tissues on the artery $P_{\text{sec1}}(\Delta l_{\text{c.mid}})$ also exceeds the value of systolic blood pressure, and this section of the artery is pinched for all pulse pressure values. From fig. 3 it follows that the value of the function $P_{\text{sec1}}(l_{\text{d1}})$ is equal to the pressure P_{d}, and the coordinate l_{d1} itself is the proximal boundary of the place of clamping of the artery by external pressure, to the left of this border the

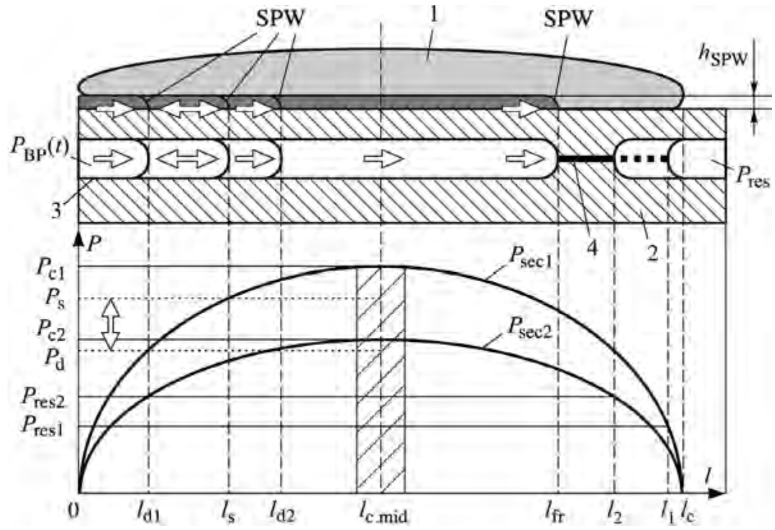

Fig. 3. Formation of surface pulse waves: *1*) compression cuff; *2*) body tissue; *3*) artery filled with blood; *4*) artery squeezed by external pressure.

artery is constantly filled with blood. As a result of periodic contractions of the heart, the blood pressure in the artery during the systole increases to the systolic value P_s, which leads to a shift of the clamping site of the artery from the coordinate l_{d1} to the coordinate l_s during the systole period and to a return back to the original position during the diastole period (see Fig. 3, arrows in the artery). The longitudinal movement of the border of the clamping site of the artery in the direction of blood flow is accompanied by its filling with blood and an increase in the cross section of the artery, which leads to the appearance of a front l_{fr} of the longitudinal movement of the clamping border and the corresponding transverse displacement of the body surface near the artery, which forms the surface pulse waves. Surface pulse waves move on the surface of the body from the coordinate l_{d1} to the coordinate l_s and vice versa with the surface pulse wave displacement amplitude h_{SPW}. As long as the air pressure in the cuff exceeds systolic pressure, the front of the pulse wave cannot cross the region of the middle of the cuff.

In the process of measuring blood pressure, the air pressure in the cuff gradually decreases and at some point in time it becomes less than the value of P_s, that is, it falls into the pressure range P_s–P_d. After that, the front of the blood flow and the pulse wave, starting from the coordinate l_{d2}, passes under the entire cuff. For a short period of time, the artery opens, passing a portion of blood. Further, during the time the function $P_c(t)$ passes the range of pulse pressure values P_s–P_d, intermittent blood flow occurs (see Fig. 2).

The output of the values of the function $P_c(t)$ beyond the lower boundary of the P_s–P_d range leads to the constant filling of the artery section closed by the cuff with blood and the restoration of steady blood flow.

To complete the picture of what is happening, we should consider the processes that occur distal to the cuff. During the initial filling of the cuff with air, all blood vessels under the cuff from venous to arterial are alternately squeezed by the secondary pressure of body tissues and form a part of the circulatory system that is completely isolated from the rest of it. The pressure in this part of the circulatory system is averaged to a certain residual value P_{res1}. The coordinate of the initial distal border of the clamping site l_1 is determined by the equality of the values of the function $P_{sec1}(l)$ and pressure P_{res1}. During intermittent blood flow, an additional part of the blood enters the isolated part of the circulatory system, while the pressure slightly increases to the value of P_{res2}, and the distal border of the clamping site moves to the left to the coordinate l_2.

Selection of surface pulse waves and features of the quasi-auscultatory method. To register surface pulse waves, a special detector is needed that selectively responds only to this type of response of body tissues to the existence of intermittent blood flow. Displacement signals resulting from oscillations of the air pressure in the cuff and as a result of contraction of the body muscles under the compression cuff are considered as interference signals. The optimal solution to the problems of surface pulse wave selection against the background of the above interference is described in publications [10, 11]. The essence of the problem lies in the allocation of surface pulse waves against the background of interference (oscillations of air

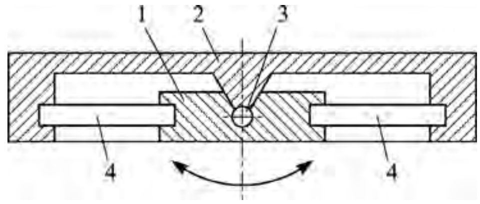

Fig. 4. Surface pulse wave detector: *1*) sensing element; *2*) detector housing; *3*) hinge axis; *4*) transducer of the angle of rotation of the sensing element into an electrical signal.

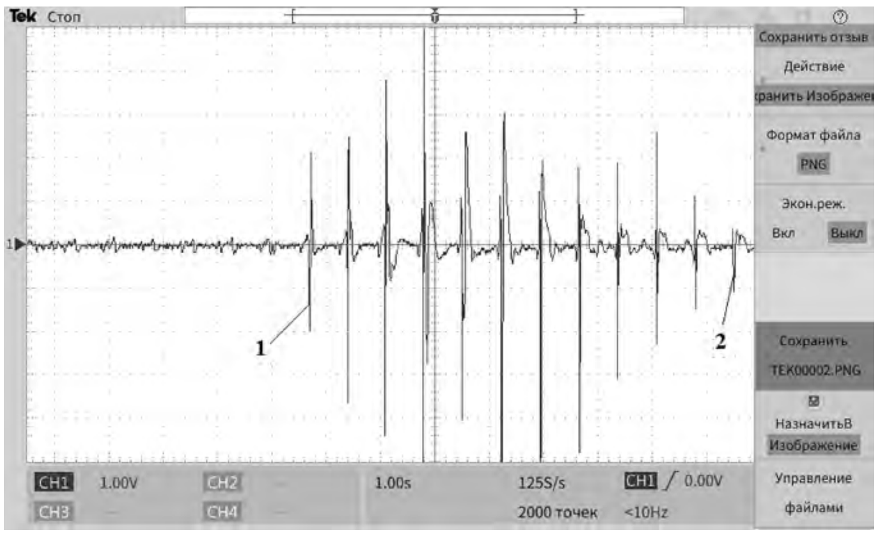

Fig. 5. Oscillogram of real output signals of the surface pulse wave detector; *1*, *2*) first and last signals, respectively.

pressure in the cuff) and contraction of muscle tissue under the cuff, under the influence of which the body surface under the cuff also shifts. In this work, the problem is solved by using a surface pulse wave detector of a special design (Fig. 4). As a sensitive element, a plate *1* is used, which has one degree of freedom of movement – freedom of rotation relative to the housing *2* around its own symmetry axis *3*. Such a constructive solution allows the plate to swing under the action of a wave running under it. In this case, a simple press on the entire surface of the plate does not lead to its rotation. When the plate is rotated, two piezoelectric transducers *4* bend in opposite directions, while their electrical signals are summed. Displacement of the plate parallel to itself leads to the bending of the piezoelectric transducers in the same direction, while their electrical signals are mutually subtracted. Thus, the surface pulse wave detector converts into an electric signal only the value of the angle of rotation of the sensitive plate, which is mathematically proportional to the derivative of the surface pulse wave envelope.

Figure 5 shows the waveform of the actual output signals of the surface pulse wave detector obtained by measuring blood pressure. Signal *1* indicates that the air pressure in the cuff exceeds the level of systolic pressure P_s, and signal *2* indicates the maximum approximation of the air pressure in the cuff to the diastolic pressure P_d and the restoration of normal blood flow in the artery.

The quasi-auscultatory method of measuring blood pressure, like the auscultatory one, is based on the occurrence and subsequent termination of intermittent blood flow and is in fact a development of the auscultatory method [8], which allows replacing Korotkov tones with surface pulse wave detector signals in cases where this can reduce the error and increase the reliability of measurement results. Only the quasi-auscultatory method is resistant to vibrations, as well as to movements of the arm with the compression cuff [12] and therefore, in the process of testing, it was possible to measure blood pressure in pediatrics.

Oscillometric measurement method. When measuring blood pressure by the oscillometric method, the measurement information uses oscillations of the air pressure in the cuff arising in the process of comparing the measured and reference values. The scheme for measuring blood pressure by the oscillometric method is shown in Fig. 6. The causes of

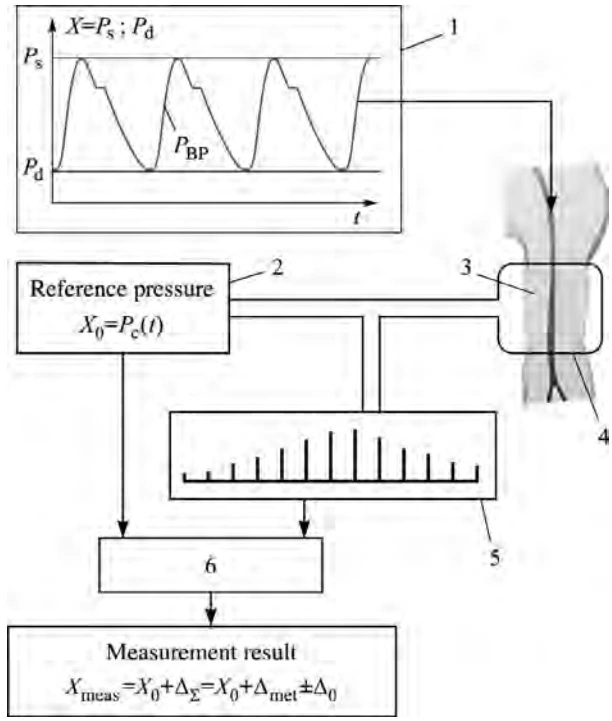

Fig. 6. A scheme for measuring blood pressure by the oscillometric method: *1*, *2*) sources of blood pressure and reference pressure, respectively; *3*) means of comparison (brachial artery); *4*) compression cuff; *5*) oscillation selection unit; *6*) controller.

oscillations of the air pressure in the cuff are given in [13]. In the case under consideration, when the shoulder cuff is used, oscillations arise as a result of cyclical changes in the volume of shoulder tissue squeezed by the cuff due to pulsations of the volume of blood vessels of this part of the shoulder. In this case, the body tissues themselves, located under the cuff, perform the function of means for comparing the pressures $P_{BP}(t)$ and $P_c(t)$. A cuff with a volume V_c and body tissues under the cuff with a volume V_t occupy a certain total volume

$$V_\Sigma = V_c + V_t. \quad (3)$$

Part of the volume V_t is made up of arterial vessels, the total volume of which pulsates with the heart rate, leading to pulsations ΔV_t of this volume. For ease of consideration of the processes, we take the volume of the brachial artery as the total volume of arterial vessels, as shown in Fig. 6. In this case, with a constant total volume V_Σ, the cuff volume should also pulsate with an amplitude ΔV_c, but with a negative sign:

$$V_\Sigma = (V_t + \Delta V_t) + (V_c - \Delta V_c). \quad (4)$$

From the expression (4) follows the equality

$$\Delta V_t = -\Delta V_c.$$

From the equation of state of an ideal gas

$$P_c V_c / T = \text{const},$$

in which the absolute temperature T of the air in the cuff can also be considered constant during the measurement of blood pressure, follow the equalities

$$P_c V_c = (P_c + \Delta P_c)(V_c - \Delta V_c);$$

$$\Delta P_c = P_c[\Delta V_c/(V_c - \Delta V_c)].$$

TABLE 1. Reliability, %, of Measurement Results According to the BHS 93 Protocol for Various Confidence Intervals

Accuracy class	Confidence interval, mmHg, not exceeding		
	5	10	15
A	60	85	95
B	50	75	90
C	40	65	85

Considering the inequality $\Delta V_c \ll V_c$, the following expression is valid:

$$\Delta P_c = P_c \Delta V_c / V_c. \tag{5}$$

Formula (5) explains the cause of air oscillations in the cuff, but it does not physically take into account that the volume V_t of body tissues (see expression (3)) is not closed at the ends at the edges of the cuff. Thus, the distribution of the secondary pressure of body tissues on the artery can be considered similar to that shown in Fig. 3, and real pulsations of the air pressure in the cuff pass three different phases of the ratios of external and arterial pressures in succession: $P_c(t) > P_s$; $P_s > P_c(t) > P_d$; $P_c(t) < P_d$ [7]. The cross-section of the artery according to Fig. 3 pulsates in the proximal part of the cuff at $P_c(t) > P_s$, over the entire width of the cuff at $P_s > P_c(t) > P_d$ and continues to pulsate at $P_c(t) < P_d$ due to elastic pulsations of the diameter of the artery along the entire width of the cuff. The given ratios of the quantities $P_c(t)$, P_s, P_d confirm the existence of air oscillations in the cuff at any non-zero air pressure in it. Pressure oscillations are separated from the static air pressure signals and sent to one input of the controller *6* (see Fig. 6). The signal reflecting the value of the reference air pressure in the cuff is sent to the second input of the controller. The controller according to a given program empirically calculates the "measured" values of P_s, P_d and displays them on the display of the device. In this case, the measurement error of these blood pressure values is completely determined by empirical formulas or controller software. Since the oscillations themselves are in no way connected with the moments of instantaneous equality of the compared pressure values, the measurement information in the form of oscillations of the air pressure in the cuff is insufficient for any calculation. Therefore, empirical laws are included in the calculation program. These laws are a statistical generalization of sets of oscillation diagrams of people without medical pathologies of the cardiovascular system. Therefore, the results of blood pressure measurements by the oscillometric method do not reflect specific values of blood pressure, but at the same time correlate with them within the limits of statistical error.

The insufficient reliability of the results of oscillometric measurements of blood pressure is reflected in the Order of the Ministry of Health of the Russian Federation No. 4 dated January 24, 2003, "On measures to improve the organization of medical care for patients with arterial hypertension in the Russian Federation" as follows: "The main non-invasive method for measuring blood pressure is the N. S. Korotkov auscultatory method. Measurement of blood pressure using other methods (primarily oscillometric) and using automatic devices in 5–15% of cases gives blood pressure values that are stably and significantly different from those obtained by the Korotkov method."

The automatic method of measuring blood pressure has become widespread in the world; in several countries, national standards have been developed for clinical verification of the accuracy of automatic blood pressure meters, for example, the protocols of the British Hypertension Society BHS 93 described in [12]. In accordance with these Protocols, automatic blood pressure meters are divided into three classes A, B, C by accuracy and confidence intervals of deviations of the readings of the tested device from blood pressure values measured by the Korotkov tone method are established. In this case, the readings and measurements by the Korotkov tone method should occur simultaneously. The test results are entered in a table where the relative (expressed as a percentage) number of measurement results falling within a given confidence interval is indicated, which factually numerically determines the reliability of the obtained measurement results.

According to Table 1, the use of oscillometric blood pressure meters of even the highest class A implies that the results obtained with a probability of up to 5% may differ from the actual values of blood pressure by at least 15 mmHg. After medical verification of oscillometric blood pressure meters, it is advisable to enter this information into the operating instructions for the utilization of automatic measurement instruments.

Conclusion. The metrological traceability of blood pressure measurement results only partially determines the reliability of blood pressure measurement, since only the air pressure in the compression cuff can be accurately measured, which does not affect the correspondence of the measured values of this pressure to real blood pressure values. When comparing blood arterial pressure with the air pressure in the cuff, body tissues act as a means of comparison, generating signals of equality of the compared values, and the generated signals do not always unambiguously arise at the moments of this equality. The reliability of the measurement results largely depends on the method used to compare the measured values with the reference air pressure in the cuff, which encourages the improvement of these methods by studying the physics of the phenomena occurring under the compressor cuff.

The Korotkov method, which is the reference method, has not been studied much in terms of its metrological properties, however, recent studies of this method and the physics of processes occurring in the human body under the cuff can lead to an increase in the reliability of blood pressure measurements, including by automatic measurement instruments. The possibilities of the quasi-auscultatory (quasi-Korotkov) method of measuring blood pressure look promising in terms of reducing the error of measurement results, possible use in automatic devices, measurement of blood pressure during physical activity, and measurement of blood pressure of children. In addition, the quasi-auscultatory method of measuring blood pressure can be used in space, aviation and sports medicine, as it allows to monitor blood pressure at times of real stress of the human body.

The oscillometric measurement method has not yet been sufficiently studied in terms of the physics of the processes occurring under the cuff during the formation of oscillations of the air pressure in the cuff during the phase of comparing this pressure with systolic and diastolic pressures. It is possible that a further study of the physics of these processes will make it possible to discover a unique, but not correlative, relationship between the indicated quantities.

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