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24th International Conference on Knowledge-Based and Intelligent Information & Engineering Systems

Non-invasive arterial pressure monitoring by a new pneumatic sensor and on-line analysis of pulse waveforms for a modern medical home care systems

Viacheslav Antsiperov\textsuperscript{a,b,*}, Gennadii Mansurov\textsuperscript{a}, Michael Danilychev\textsuperscript{a}

\textsuperscript{a}Kotelnikov Institute of Radioengineering and Electronics (IRE) of RAS, Mokhovaya 11/7, Moscow 125009, Russian Federation
\textsuperscript{b}Moscow Institute of Physics and Technology (MIPT), 9 Institutskiy per., Dolgoprudny 141701, Russian Federation

Abstract

The development of the third-generation devices for medical home care systems is in the center of discussion. The results of developing non-invasive arterial pressure monitoring channel on the basis of the unique pneumatic sensor are discussed in detail. In particular, the main principles of operation, design features and testing results of a pneumatic sensor are considered. Namely, the issues of the stable air flow regime in the sensor’s working chamber are discussed. It is shown that the miniature size of the sensor and the possibility of its precise positioning directly in the measurement zone on small (< 1 mm) areas of the skin elastic surfaces result in improved quality of pulse wave shape recovery, the parameters continuity measured and the disturbances reduction. Measurement examples for some human superficial arteries are given. The possibility of continuous measurement of the actual value of blood pressure for radial and temporal arteries is confirmed.

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Peer-review under responsibility of the scientific committee of the KES International.

Keywords: medical home care systems, third generation devices; non-invasive blood pressure monitoring, pulse waveforms; pneumatic sensor;

1. Introduction

The coronary heart disease and stroke are the most important healthcare problems in middle- and high-income countries. Over the past 15 years according to WHO [1] these diseases remain the leading causes of death in the world. In low-income countries cardiovascular diseases follow immediately the so-called “group I” diseases, including various infectious diseases, maternal mortality during pregnancy and childbirth, food poisoning, etc. Cardiovascular and cerebrovascular disorders, referred to in the official statistics as circulatory diseases, represent the most common death causes in the Russian Federation (47% of deaths) [2]. Today the importance of these problems has increased in

* Corresponding author. Tel.: +7-916-036-0216.
E-mail address: antciperov@cplire.ru
connection with the latest evidence on correlation between cerebrovascular, cardiovascular diseases, and poor outcome in patients with Coronavirus Disease 2019 (COVID-19) pneumonia [3].

In the diagnosis and treatment of circulatory diseases the most reliable information about the state of the cardiovascular system is usually obtained, inter alia, by analysing arterial blood pressure (ABP) in accessible parts of the human body. An invasive method of measuring blood pressure is the most accurate and reliable. However, due to the increased risk of injuries and strict professional requirements for staff, this method is used only when there is an urgent need to conduct just this kind of research, usually in ambulatory environment, under the supervision of qualified medical personnel. So, the invasive method obviously does not allow continuous monitoring of the patient’s condition in his daily home activities. The development of adequate and easy-to-use non-invasive ABP measurement technologies and incorporating them into smart analysing systems is therefore recognized as an important area of development for medical home care support.

The traditional model of health management, focused on hospitals and doctors, is increasingly demonstrating its limitations, and is less and less able to cope with the growing number of patients and diseases. The solution to this problem is a new model of health management within the framework of home care medicine, which pays more attention to patient self-assessment. It emphasizes real-time self-monitoring of patients, immediate feedback from health data and timely medical intervention. The advent of implantable / wearable smart sensors and devices, the development of smart homes and web-based smart health information platforms leads at least to a partial solution to the problem [4]. Wearable / implantable devices of the third generation can combine advanced sensors, microprocessors and wireless modules for continuous intelligent detection and monitoring of various physiological parameters of patients, while reducing energy consumption, increasing comfort and allowing combining data with health information from other channels. The advent of smartphones, smart watches, etc. provides new tools for this kind of monitoring. Attempts to integrate biosensors into smart phones should be considered as a promising way in this direction.

The authors of this work also recently participated in one of the projects on integrating an arterial blood pressure (ABP) monitoring channel – one of the most traditional diagnostic channels for assessing the condition of patients – into the wearable medical system for astronauts [5]. Despite the apparent simplicity of the problem statement, it turned out, however, that the technological solution to the problem is far from trivial. The fact is that traditional methods of non-invasive measurement of blood pressure are based on providing back pressure in the external cuff or applicator, which presses on the artery to balance the additional pressure caused by elastic wall tension [6]. As an example, we will mention the Penaz blood pressure control method, which uses the principle of volume compensation for the dynamic unloading of vascular walls [7]. A common disadvantage of traditional methods for measuring blood pressure is that the compression of the artery causes blood stasis, and it is necessary to periodically relax the cuff, violating the continues control of pressure. In addition, the recording of pulse wave signal is interrupted – it becomes impossible to analyze the change in the pulse waveform from beat-to-beat during numerous consecutive cardiac cycles with dynamically changing load and in different parts of the human body. To solve these problems, we have developed a special smart pneumatic pressure measuring sensor that meets all the requirements for home care medicine devices. The results of using the developed ABP monitoring and pulse waveform analysis system are presented below.

2. Sensor concept and design

The new applanation method of continuous blood pressure monitoring is based on the local pressure compensation technique (Fig.1). The method became possible due to developing a technique for compensatory pressure measurement on a very small (less than \(1 \text{mm}^2\)) surfaces [8].

Basically, local compensation in pressure measurement amidst barely accessible gas / fluid volumes is both intuitive and provable concept. If one makes the elastic casing locally flat via the external impact, the external pressure in plane zone will be equal to the internal pressure due to the absence of normal component of tension. The principle was implemented in the applanation tonometry method used for measuring intraocular pressure [9]. Using this principle, we developed an applanation tonometer that provides local pressure compensation by the open working chamber appearing between the rigid flat shield and the elastic surface of the skin. The significant advantage of using air instead of liquid as the working agent of the sensor lies in the fact, that excess air can be easily discharged into the atmosphere without reversing supply lines. Fig.1 illustrates how the tonometer works.
If at a moment \( P_{ch} \) (pressure in the chamber) is lower than \( P_{art} \) (arterial pressure), the tissue and skin above the artery press against the sensor air outlet, thereby shutting it. \( P_{ch} \) is growing fast due to continuous air supply from the high-pressure receiver through the screw throttle. When it reaches \( P_{art} \), the outlet opens, and the excess air is discharged into the area underneath the sensor flat surface pressed against the skin. If the air inflow to the chamber is designed correctly (by determining \( P_{rec} \) and throttle screw position), laminar airflow will keep the skin surface flat and almost enclosed, maintaining the balance \( P_{ch} = P_{art} \) (even upon variable blood pressure). In other words, the pneumatic sensor performs local pressure compensation like a safety valve with continuous compressed air inflow from the receiver through the flow limiting throttle. For conventional valves of this kind, the pressure relief is a short-term act, an emergency event during normal operation of the system. Its operation occurs when certain predetermined pressure values are exceeded. In our case, on the contrary, the pneumatic sensor operates continuously, automatically adjusting to the threshold level determined by the current value of the blood pressure in the studied artery. By direct measurements of the air pressure in the working chamber of the pneumatic sensor (Fig.1), it is possible to track the current dynamics of blood pressure with a time constant of about one millisecond. This is significantly less than all physiological temporary constants associated with the dynamics of blood pressure in the human body. Significantly, the pressure is measured directly, and not estimated, for example, by the normal component of the force per area of the sensing element. We succeeding in doing it after overcoming a number of problems in that direction. Among them, the task of ensuring the laminar regime of the expiration of the working agent — atmospheric air — and the task of correctly positioning the measuring sensor over the artery stood out for their significance.

Static tests on the artery simplified model connected to a water column of adjustable height showed that the measured values correspond to the water pressure in the model from 0 to 90 \( mmHg \) with a stable offset of about +10 \( mmHg \). As a model we used a thin-walled rubber tube — a piece of sausage-shaped air balloon of a diameter of less than 1 \( cm \) at pressures up to 90 \( mmHg \). The pressure drop on the model wall can be explained by the properties of rubber — simple elasticity, in contrast to the viscoelastic properties of living tissue.

3. Ensuring quasi-laminar air outflow

The phenomenon of disruption of the flow stationarity is well known both in aerodynamics and in the theory of aeroelasticity, as well as in many practical applications. For example, in [10] several mechanisms of instability in
and almost enclosed, maintaining the balance between the artery pressure against the sensor air outlet, thereby shutting it. Part Prec designed correctly (by determining the actual values that correspond to the water pressure in the model from 0 to 90 mmHg).

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The pressure drop on the model wall can be explained by the properties of the working medium and throttle (Fig. 1), the atmosphere. Strictly speaking, the above calculations are valid for chambers separated by thin rigid partitions and entering through the inlet. The paper [11] presents a detailed calculation of such dependences, performed under the assumption of the adiabaticity of the process with

\[
P/\rho_{atm}^k = \text{const}
\]

where \(k = 1.4\) for atmospheric air. The joint solution of the corresponding system of equations leads to the following relations for the cross-sectional areas of the channels and the flow rates under these conditions:

\[
\frac{V_{in}}{V_{out}} = \sqrt{\frac{P_{ch}}{P_{atm}}} \left[1 - \sqrt{\frac{V_{in}}{V_{out}}} \right]^{-1}
\]

and

\[
\frac{S_{in}}{S_{out}} = \left(\frac{P_{ch}}{P_{atm}}\right)^{1-\eta} \left(\frac{V_{in}}{V_{out}}\right)^{\eta} \sqrt{\frac{P_{ch}}{P_{atm}}} - \frac{V_{in}^2}{V_{out}^2}
\]

where the designation \(\eta = (k - 1)/k\) is introduced. \(S_{in}\) is the area of the inlet of the chamber defined by the control throttle (Fig. 1), \(V_{in}\) is the air flow rate generated by the pressure of the receiver \(P_{rec}\) and entering through the inlet, \(V_{out}\) is the speed of free outflow of air into the atmosphere, \(S_{out}\) is the total area of cracks in the outflow of air into the atmosphere. Strictly speaking, the above calculations are valid for chambers separated by thin rigid partitions and almost enclosed, maintaining the balance between the artery pressure against the sensor air outlet, thereby shutting it. Part Prec designed correctly (by determining the actual values that correspond to the water pressure in the model from 0 to 90 mmHg).
with holes. The thinness of the partitions means here that the length of the channels connecting the chambers can be neglected. Of course, in accurate calculations, it is necessary to consider the real values of this parameter, as well as the viscosity factor of air in the stream. Nevertheless, the obtained estimates allow us to identify the basic principles of the process and determine the actions for the design correction. The excitation of oscillations in the air stream to the atmosphere leads to instability of pressure in the whole working chamber, that was demonstrated by the experiments (Fig. 2). The suppression of vibrations of this type by simply reducing the flow velocity is unacceptable, since this value itself depends on the ratio of the pressures in the working chamber and atmosphere, and the pressure in the chamber must correspond to the value of the measured blood pressure. It became possible to achieve real stabilization of the flow by reducing the value of $S_{\text{out}}$ – i.e. the total area of the slots of the outflow of air into the atmosphere. To this end, by adjusting the inlet throttle (Fig.1), the cross-sectional area of the inlet channel $S_{\text{in}}$ was diminished, the air intake into the system was reduced, and thereby the volumetric air flow through the working chamber was reduced too. However, the limitation of the volumetric air flow rate, in turn, limits the rate of increase in pressure in the working chamber, which must with a margin exceed the maximum time derivative of pressure in a pulse wave (of the order of 0.5 mmHg/ms) to ensure real-time blood pressure measurement time. This problem was solved by significantly reducing the working volume of the chamber while increasing the pressure in the receiver (at the inlet) to a value that is only twice as large as mean pressure in the working chamber, relative to the atmospheric pressure level taken as zero. In the modified version (below in Fig. 4), the volume of the working chamber is about 1 mm³ and consists mainly of the volume of the connecting tube and the pressure sensor. Fig. 3 shows the rate of rise and fall of pressure in the working chamber when performing the control test in the “full closure – keeping at maximum – full open” mode – curve 1. Curve 2 on the same figure reflects the behaviour of the pulse wave of blood pressure in the examined artery. One can see that there is a good margin of the rate of increase in pressure in the working chamber, and the starting delay to the operating mode does not exceed 0.04-0.05 s. To estimate the cross-sectional area of the inlet throttle and the thickness of the air gap beneath the surface of the applicator, the air flow was measured in real blood pressure measurements at a pressure in the receiver of 240 mmHg. The value obtained in this case, considering possible leaks, for one working channel turned out to be less than 0.2 cm³/s. With an average pressure drop of 100 mmHg the air velocity in the hole is approximately 140 m/s. Hence, the cross-sectional area of the output stream is estimated as $0.2 \text{ cm}^3/140m = 0.0014 \text{mm}^2$, which gives an estimate of the cross-section of the input stream too. With the assumption that the outflow is only half the perimeter of the chamber opening (with a slit length of about 1 mm), the gap of the outlet slit can be estimated as 1–2 microns.

4. Positioning problem

The need for the correct solution to the problem of positioning the sensor over the artery naturally follows from the limited size of the area, on which the locally-compensation principle is valid. Due to the fact that the contact window (channel outlet) of the sensor is substantially smaller than the size of the artery, the measured pressure $P_{\text{cam}}$ coincides with $P_{\text{arr}}$ (Fig. 1) in the case when the window is located exactly in the valid zone on the projection of the artery axis onto the sensor plane. In practice, to solve the problem of positioning the sensor on the radial artery, a monolithic three-chamber sensor design was developed (Fig. 4), considering this specificity. Three working chambers are arranged in a row with a pitch of 1.8 mm across to the projection of the axis of the artery onto the plane of the applicator. The working chambers are independently supplied with the air from the receiver through individual capillary pneumatic throttles. Thus, it becomes possible to measure the pressure on the applicator surface at three points (work areas with a diameter of 0.8 mm) simultaneously and independently.

The sensor tests showed that pressure is distributed unevenly in the direction transversal to the artery axis. That is due to the artery shape and wavering of the artery axis position upon pulsation under the sensor plate. This leads to two important conclusions related to the sensor positioning. First, the central measuring chamber must be located accurately above the artery axis projection. Second, the artery must be pressed by the sensor to underlying tissues in a way its axis does not waver upon pulsation. These observations stimulated the authors to realize in practice the "targeting" method analogous to the side lobes equalizing approach used in radar technique. Fig. 4 gives the sketch of the sensor and the result of concurrent three-channel pulse wave measurement (the sensor located above the radial artery). The authors provided technical details of the sensor design in the acquired patent [12]. In terms of the proposed design, the main objective of side channels is ensuring proper positioning of the central measurement unit. With the
correct position of the measuring unit, the calibrated signals on the side channels (Fig.4) coincide or slightly differ from each other. It can be neglected that artery walls under side channels cannot be fully unloaded, so the pulsation response in those channels is significantly distorted. It is only important that upon the equality of those signals, the central chamber is positioned accurately above the artery axis ("targeted") — in such a position, its signal will be a non-distorted copy of arterial pressure [13].

The methodology of measuring blood pressure by the three-chamber pneumatic sensor is closely tied to the described design features. At the first stage, just before the measurement, the location of the artery is determined by palpation. Then the sensor is applied onto the place found, so that the measuring chambers are positioned in a row transversely against the artery (Fig.4). Then, manually moving the sensor along this direction (transversely against the artery), the physician must find a position in which signals of side channels are as equal as possible. After that, the measurement unit is pressed against the arm so that the contact area between the central area and the artery wall becomes flat, but the occlusion must be avoided (i.e. applanation principle). For the radial artery case, the criterion of
Fig. 5. Radial artery pulse wave, optimal position, slight variations of press force 2 – central channel signal (right above the radial artery), 1 and 3 – side channels.

the best position was experimentally determined. According to it, the signal amplitude of the central channel must be about twice as high as equalized amplitudes of side channels.

The sensor of this type can be used for measuring parameters of radial and other touch examination-accessible arteries (carotid, temporal, ulnar, brachial, femoral, popliteal, etc.). However, such a sensor positioning algorithm allowing adequate quantitative blood pressure measurement is developed and empirically proven only for manual positioning of the sensor on the radial artery.

5. Primary testing

The comparison of the results obtained shows that any artery has characteristic features of the pulse wave parameters recorded at a certain place on the human body. These features affect the methodology of practical measurements and the subsequent interpretation of the data. The experiments on measuring pressure on various superficial arteries showed that for the case of arteries under which hard tissues (bone) are located, it is possible to register both the pulse wave shape and the current value of the blood pressure (Fig. 5).

In addition to the radial artery (Fig. 5), in our experiments we managed to measure the pressure in absolute units only for the temporal artery. At the same time, positioning the existent sensor on it turned out to be a difficult procedure, obviously, due to the mobility and small diameter of the artery. For the case of the carotid artery, it is possible to register the shape of the pulse wave (Fig. 6) with an unconfirmed error in the absolute pressure values. But even in this case, the shape of the pulse wave enables certain evidence on the condition of the heart and the explored artery.

In general, a change in the shape and quantitative indicators of the pulse wave occurs with a wide variety of external and internal processes. For example, this fact is reflected in our graphs of the pulse wave of pressure on the radial artery for the case of a calm state with successive deep breaths and exhalations, as well as for breath holding on inspiration (Fig. 7, 8). Fig. 7 shows the shape of the pulse pressure wave (curve 1) over a sufficiently long-time interval when the patient is at rest. Several deep breaths and exhalations have a noticeable effect on the average pressure in the radial artery, and on heart rate variations (row of points 2). It can be assumed that at rest, the heart rate is adjusted in such a way as to stabilize the average pressure in the aorta relative to the pressure in the chest cavity. In this case, the well innervated aortic arch is quite suitable for the role of a kind of “pressure gauge”, sensitive to the pressure difference in the aorta and outside it. Fig 8 presents the recording of a pulse wave of pressure on the radial artery when the patient is holding his breath for a short time after inhalation.
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The unusual form of oscillations in this figure can be explained as follows. In the first seconds of the delay, the pressure in the lungs, as well as in the chest cavity, begins to increase due to the reflex tendency to exhalation, restrained by a closed nasopharynx. The average pressure in the artery (coherent to aorta pressure) grows. At the
The results of the study lead to the following conclusions:

- The sensors designed allow real-time continuous blood pressure measurement on several surface arteries, displaying the pulse wave within a single cycle and in long-time intervals.
- The experiments on measuring pressure on various surface arteries showed that arteries located over the rigid tissues (bones) allow easy registering the pulse wave shape and current blood pressure. This was proved for the radial and temporal arteries.
- The sensors allow not only measuring systolic/diastolic pressure but also monitoring their current values and dynamics associated with respiration and the processes of autonomic regulation.

6. Conclusions
The sensors developed can be easily expanded on the board of the same microprocessor by additional data channels, for example, synchronous ECG channel. Such enhancement of the amount of measured data would allow the monitoring of parameters of pulse wave transit along surface arteries significant for several diseases.

In a view of results obtained the developed sensors are substantially the third generation devices that can be easily enhanced by power microprocessors and wireless modules for continuous intelligent detection and monitoring of various physiological parameters. The real possibility of reducing their energy consumption, increasing comfort and allowing combining data with health information from other channels makes the sensors described, as we hope, potentially very perspective candidates for medical home care systems.

Acknowledgements

The authors are grateful to the Russian Foundation for Basic Research (RFBR), grant N 18-29-02108 mk for the financial support of this work.

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