Non-invasive Recording with a New Three-channel Pneumatic Sensor

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Abstract: The paper presents the design features and test results of a new non-invasive blood pressure monitoring sensor based on the local pressure compensation principle. Real-time differential processing of three-channel pulse wave data is used to determine and maintain the optimal position of the sensor on the patient's body. The small size measuring unit with very small (1 mm^2 or less) sensor pads, when placed accurately on elastic surfaces (for example, on the skin and underlying tissues), provides high-quality pulse wave recording, continuity of measurement and minimization of external interference. The paper also gives the results of measurement for some superficial arteries of the human body. Further development version of the sensor with synchronous ECG measurement is also presented.

1 INTRODUCTION

Cardiovascular and cerebrovascular disorders, referred to in the official statistics as circulatory diseases, represent the most common death causes in the Russian Federation (55% of deaths) (Chazova et al., 2015). As part of diagnosis and treatment of those disorders, specialists use the data on the state of the circulatory system and the state of specific organs, obtained by analysing blood pressure measurement data (for accessible body parts). Though the invasive blood pressure measurement method is considered the most accurate and reliable, it is used only in a medical institution under continuous supervision of a competent and accredited medical staff. This method is not suitable in everyday life due to strict staff requirements and the risk of injury. Besides, the invasive method is not applicable for everyday health examination, monitoring of hemodynamics and the state of the cardiovascular system in real-time.

Most modern non-invasive blood pressure measurement methods are based on counter-pressure handling in the cuff or pad applied to this artery (usually to the whole limb). The purpose of these manipulations is to maximally balance the excess pressure held by the elastic walls of the artery (Settels, 2015). For instance, the Penaz blood pressure monitoring method employs the volumetric compensation principle, which implies the dynamic unloading of vascular walls (Peňáz, 1973). Speaking of the bottlenecks of those methods – the limb gripping causes blood stagnation and a physician should periodically relax the cuff, which violates continuous monitoring and disturbs the wave pattern. Furthermore, it is quite difficult to arrange the continuous recording of pulse wave signals during numerous consecutive cardiac cycles under dynamically changing load and at various parts on the human body. From a technical point of view, transmitting and processing the recorded signals by developed or existing software cause no difficulties. However, what remains to be a problem is capturing high-quality blood pressure signals with no artifacts at various points on the human body.

2 SENSOR CONCEPT / DESIGN

To address the above problem, a new continuous blood pressure monitoring method was developed based on the local pressure compensation technique (Figure 1). The method became viable thanks to the local compensation principle for pressure measurement on small (1 mm^2 and less) surfaces,

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worked out earlier by the authors (Antsiperov et al., 2017).

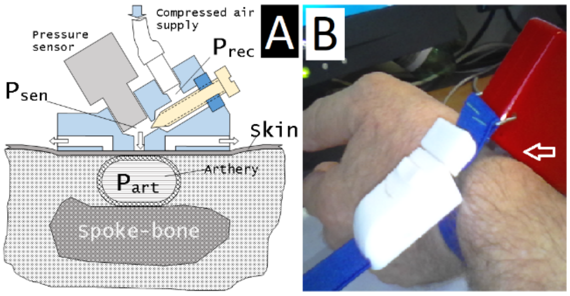

Figure 1: Blood pressure measurement through local pressure compensation. P_{rec} is compressed air receiver pressure, P_{art} is pressure in the artery, P_{sen} is that in the sensor chamber (A); and measuring assembly applied to the patient's wrist (B).

Basically, local compensation in pressure measurement amidst barely accessible gas/fluid volumes is an intuitive concept. If it is possible to make the surface enclosing the volume of an elastic covering locally flat via the external impact, external pressure will equalize internal pressure due to the absence of normal tension. The principle was implemented in the applanation tonometry method used for measuring intraocular pressure (Goldmann et al., 1975). After several years of hard work, the authors found the solution and developed an applanation tonometer that provides local pressure compensation and has an open chamber between the tile flat surface and the elastic surface of the skin. With that, the chamber volume is quite small (about 1mm^3) and mostly consists of the connection tube hole and pressure sensor hollow. Using air as the working agent of the sensor, we get an advantage over the analogues sensor filled with liquid. Excess air can be easily discharged into the atmosphere without reversing charge ducts. Figure 1 illustrates how the tonometer works. If at a specific moment P_{sen} (pressure in the measurement unit) is lower than P_{art} (arterial pressure), the tissue and skin above the artery press against the sensor air duct, thereby shutting it. P_{sen} is growing fast due to continuous air supply from the high-pressure receiver through the screw throttle. When it reaches P_{art}, the duct 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 $P_{sen} \approx P_{art}$ (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. Significantly, the pressure is measured directly, and not calculated, for example, by the normal component of the force per area of the sensing element. Static tests on the artery simplified the 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 was 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.

Inexpensive piezoresistive sensors by Honeywell International Inc., used as primary pressure converters, are mounted close to sensing pads to minimize working volumes. Preamplified signals are fed to analog inputs of embedded MCU (we use STM32L151), which performs all low-level tasks, including the micro compressor steering, data acquisition, processing and communication with the host computer (or smartphone).

3 POSITIONING PROBLEM

Beneficial as it may be the local pressure compensation method entails new problems concerning positioning the sensor. As the sensing area of contact (duct outlet) is much smaller than the artery cross-section, P_{sen} matches P_{art} (Figure 1) only if the area of contact is located exactly above the artery axis. Figure 2 shows in detail the uneven distribution of pressure along the contact line of the sensor in the transverse direction. As is seen, if the sensor is moved left or right from the symmetry axis, the observed value of pressure decreases while the ratio of various curve elements distorts (Figure 2). A detailed study showed that if the sensor is positioned exactly above the artery axis, the pressure signal has the largest amplitude, and local extrema points themselves turn out to be sharper. For positions symmetrically located against the artery, pulse wave charts are almost identical though they may have certain distinctions. Those distinctions are most explicit at the diastole stage (Figure 3).

In the sensor tests the pressure appeared to be 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.

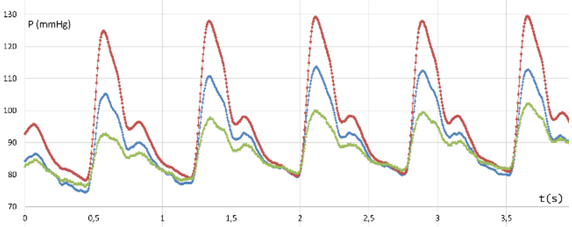

Figure 2: Different shapes of pulse wave signal depending on the sensor pad position: ● — pad is located accurately above the artery axis, ■. ♦ — pad is moved left and right from the center of the radial artery, respectively.

This leads to two important conclusions relating to positioning the sensor. 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 practically realize the "targeting" method similar to the lateral signals equalizing approach used in radar technique. According to that, the authors designed a blood pressure monitoring sensor whose main part is the measuring block with three separate chambers. Each chamber has its own independent measuring output. During the operation, the channel nozzles are positioned in a row transversely against the artery. With that, the dimensions of the area of contact must be designed to ensure that all the three nozzles are located above the subject artery during the operation. Figure 3 gives the sketch of the sensor and the result of concurrent three-channel pulse wave measurement (the sensor located above the radial artery).

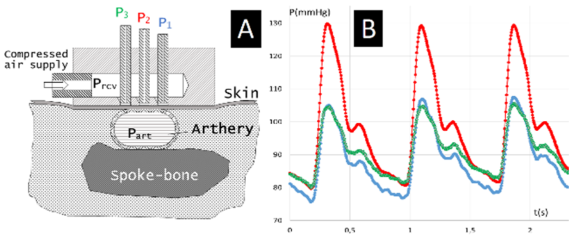

Figure 3: Three-chamber sensor enabling local-compensation blood pressure measurement (A); and synchronous three-channel pulse wave chart (B).

The comprehensive specification of the sensor is provided in the patent (Mansurov et al., 2018). In terms of the proposed design, the main task of side channels is to ensure proper positioning of the central measurement pad. With the correct position of the measuring unit, the calibrated signals on the side channels (Figure 3) 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, that its signal will be a non-distorted copy of arterial pressure (Antsiperov et al., 2018).

The methodology of measuring blood pressure by the three-chamber pneumatic sensor is tightly related 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 that place so that measuring chambers are positioned in a row transversely against the artery (Figures 2 and 3). Then, manually moving the sensor along this direction (transversely against the artery), the physician should find a position in which signals of side channels are as equal as possible. After that, the measurement unit is pressed against the skin so that the contact area under the central pad became flat, but without the artery occlusion (applanation principle). For the radial artery case, the criterion of the best position was experimentally determined. According to it, the signal amplitude of the central channel must be about twice as high as the equalized amplitudes of the side channels.

The problem of positioning the sensor on the radial artery was addressed via designing a monolithic three-chamber sensor that reflected the problem specifics. Three chambers are made in a rigid flat surface (1.8 mm increment) along the line perpendicular to the artery axis projection on the sensor plane. The chambers are independently fed by the air from the receiver through individual air throttles. This way the pressure on the sensor surface can be measured concurrently and independently at three points (0.8 mm in diameter). To estimate the thickness of the air cushion underneath the plane surface, the current air consumption rate was measured and amounted to ~ 0.5 cm^3/s (with accounting possible leaks). By the average pressure difference of 100 mm Hg, the discharge flow speed in the hole is about 140 m/s. The flow cross-section thereby totaled 500/140,000 = 0.0036 mm^2 or 0.0012 mm^2 for each camera. Assuming that air is discharged within the half of the chamber hole perimeter (cleft length is ~ 1 mm), the cleft width should be ~ 1 μm.

The sensor of this type can be used for measuring parameters of radial and other arteries (carotid, temporal, etc.). However, such a sensor positioning algorithm enabling adequate quantitative blood pressure measurement is developed and empirically confirmed only for positioning the sensor on the radial artery.

4 PRIMARY TESTING

The experiments accompanied every stage of hardware and software development. Some of the recent results we found to be interesting are presented below. The comparison of the results shows that every artery is subject to individual specifics of pulse wave parameters recorded at a certain point on the human body. Those specifics affect the methodology of practical measurements and further data interpretation. Generally, the procedure of measuring, interpreting, and using such data requires coordinated efforts of equipment developers and cardiologists, as well as measurement statistics for every artery.

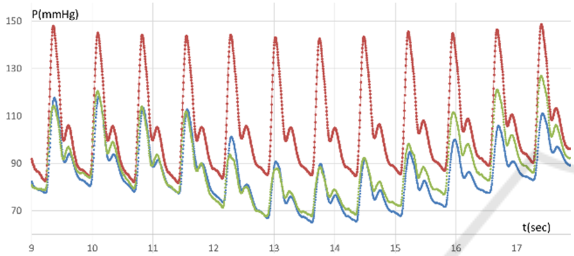

Figure 4: Radial artery pulse wave, optimal position, slight variations of press force ● – central channel signal (right above the radial artery axis), ■, ♦ – side channels signals.

The experiments on measuring the pressure on various surface arteries showed that the arteries located over rigid tissue (bone) enable to register the pulse wave shape and current blood pressure. Besides the radial artery (Figure 4), we managed to measure pressure only on the temporal artery (below in text). With that, the positioning of the present sensor on it turned out to be a difficult procedure, probably due to the mobility and small diameter of the artery. Unfortunately, as for the carotid artery, we can still register the pulse wave pattern (Figure 5), but the shape of the pulse wave does not give us the appropriate information about the aorta state and the cerebral circulation activity.

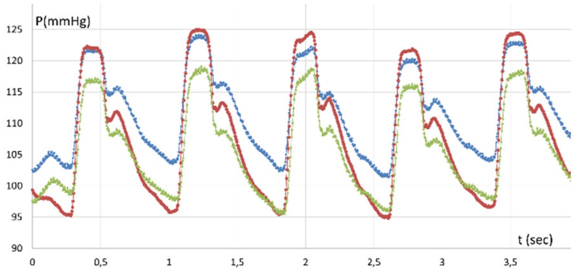

Figure 5: Carotid artery pulse wave: ● – central channel signal, ■, ♦ – side channel signals.

The charts presented in Figure 5 demonstrate that the carotid artery's cross-section (which is significantly larger than that of the radial artery) and the lack of rigid tissues underneath has explicit impact on the central vs side signal ratio. It seems necessary to study the correlation and find an optimal artery diameter/channel interval ratio for every artery type.

The pulse wave pattern and quantitative parameters change under various external and internal processes. For instance, this phenomenon is reflected in the radial artery pulse wave charts for the quiescent state with consecutive deep inhaling and exhaling (Figure 6) and holding breath when inhaled (Figure 7). Let us consider those situations.

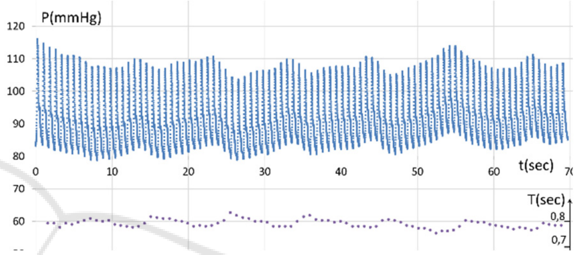

Figure 6: Pulse wave (upper curve) and variability of heartbeat intervals (bottom point row, right scale), quiescent, deep breathing.

Figure 6 illustrates the long-term pulse wave pattern for a calm patient. Several deep inhalations and exhalations explicitly affect average pressure in the radial artery and heartbeat variations. It could be supposed that, in the quiescent state, the heartbeat rate adapts to maintain the average pressure in the aorta against the thorax pressure. Perhaps a well innervated aortic arch acts as a pressure gauge that is sensitive to pressure differences inside and outside the aorta.

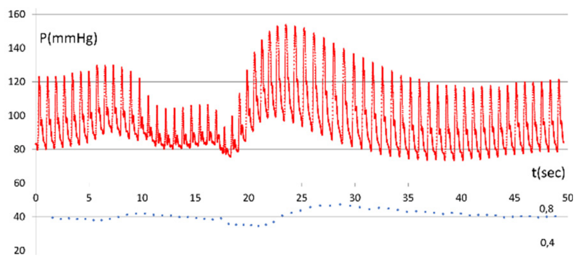

Figure 7: Radial artery pulse wave transformation (upper curve) and variability of heartbeat intervals (bottom point row, right scale) for short breath holding after inhaling.

The next figure (Figure 7) shows the pulse wave pattern for the radial artery for held breath after inhaling. Here's how we can explain the peculiar pattern of oscillations. During the very first seconds of breath holding, the lung and thorax pressure increase due to the reflective desire to exhale suppressed by the shut pharynx. The average pressure in the artery starts growing following the aortic pressure. At the 6th-7th second, the pressure starts falling. Probably due to the increasing pressure drop, insufficient venous blood enters the chest. At the 17th second of the recording after exhalation, we can see how the pressure drops briefly and then, after a smooth increase in pressure for 20-25 seconds, the initial picture of the pulse pressure wave is restored. Figure 8 illustrates the pulse wave pattern under the Valsalva maneuver. A few seconds before exhaling the aortic walls appear to be unloaded almost completely because of the pressure balance.

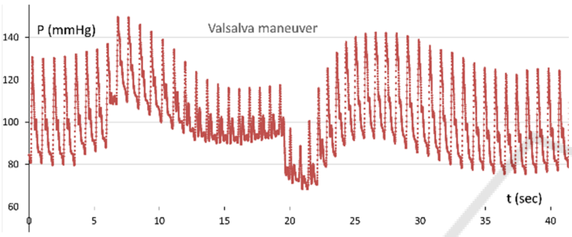

Figure 8: Radial artery pulse wave pattern under Valsalva maneuver.

Another instance of an unusual radial artery pulse wave pattern is shown in Figure 9. This signal was recorded in the patient on the second day after the injection of the EnceVir vaccine against tick-borne encephalitis. It is known that this medicine may cause reactions manifested in higher body temperature (37.1° to 38.0°C), headache, fatigue, muscle and joint pain. The reaction usually lasts for 3 days. By the end of the second day, the above symptoms faded away and the pulse wave pattern normalized.

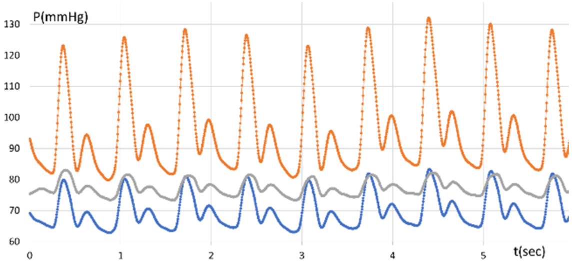

Figure 9: Radial artery pulse wave pattern transformation (central and side channels) one day after EnceVir injection.

Figure 10 illustrates the pulse wave pattern of the diseased and fatigued patient. It is seen that the regularity of the registered systolic pressure peaks remains, while the partial losses look like omissions without any disturbance of time intervals. Most probably it is arrhythmia manifested in the form of extrasystoles. However, without a synchronous ECG, it is difficult to assert it is arrhythmia.

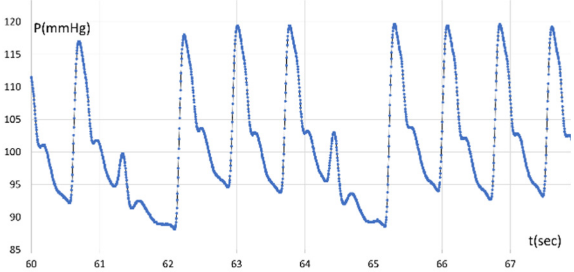

Figure 10: Pulse wave pattern disturbances (possibly arrhythmia).

Therefore, this experiment drove us to develop the synchronous ECG channel and integrate it into the device. Since the high-resolution ECG is not required to locate R-peaks, we designed a simplified single-channel cardio-signal amplifier.

5 ECG CHANNEL-INTEGRATED CIRCUIT

In the simplified cardio-signal amplifier we developed an original scheme for connecting ECG electrodes. It enables the equipment to operate without a neutral electrode and without a conductive gel. In this case, the suppression of interference is carried out at the circuitry level and then using digital signal processing (filtering). The purpose of modifying the initial design was the desire to find out the relationship between the pulse wave dynamics and the rhythmic activity of the heart. Figure 11 illustrates the radial artery pulse wave pattern (blue curve) recorded synchronously with the ECG (red curve). Introducing the ECG channel to the circuit enables watching the cardiac contraction signal (input signal) pattern and the pattern of the resulting pulse wave (output signal) at one of the possible measurement locations (e.g. wrist, Figure 11). Based on the analysis of the relationship between the signals at the input and output of the cardiovascular system, a few its time-frequency characteristics can be estimated using methods known in radio physics.

Using the subject pneumatic sensor with an ECG channel enables non-invasive measurement of the pulse wave transit time. This value, jointly with non-invasive systolic pressure monitoring and continuous analysis of the pulse wave dynamics, can be used to estimate the current state of the cardiovascular system and diagnosing clinical and subclinical atherosclerosis.

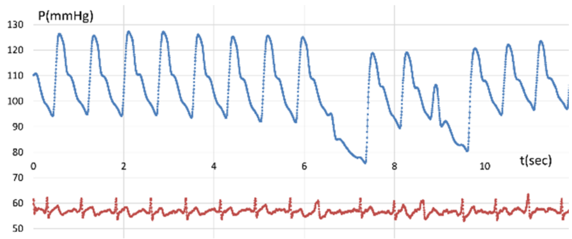

Figure 11: Pulse wave pattern disturbances (extrasystoles) and synchronously recorded ECG.

As mentioned above, in our experiments we managed to measure actual pressure (in mmHg) in the temporal artery (likewise the radial artery). It was quite difficult to ensure proper positioning in that case (probably due to high motility and small diameter). Figure 12 illustrates the results of synchronous pulse wave measurement and ECG.

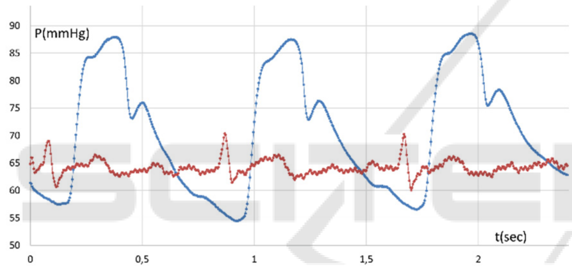

Figure 12: Temporal artery pulse wave pattern and synchronously recorded ECG.

It goes without saying that the complex technology of acquiring and interpreting combined data described in this section has much room for further improvement. However, there is feasibility in the significant growth of the comprehensiveness and reliability of the suggested approach in early heart and vessel disease diagnosis compared to earlier methods not employing pressure wave measurement with ECG timing.

6 CONCLUSIONS

The research results in the following conclusions:

1. The device designed enables real-time continuous blood pressure measurement on several surface arteries, displaying the pulse wave within a single cycle and in long-time intervals.
2. The experiments on measuring pressure of various surface arteries showed that arteries located over rigid tissues (bones) allow to register the pulse wave shape and current blood pressure. This was proved for the radial and temporal arteries.
3. The device enables not only systolic/diastolic pressure metering but also monitoring current value as well as durable variations of arterial pressure associated with respiration and the processes of autonomic regulation.
4. Implementing the synchronous ECG channel increased the amount of measurement data and enabled monitoring of parameters of pulse wave transit along surface arteries significant for several diseases.
5. In general, the research of the optimal methods for measuring, interpreting, and using discussed data demands the cooperation of cardiologists and equipment developers, as well as the software developers.

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