Validation of new device with pneumatic sensor for measurement and recording of arterial blood pressure

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Abstract. This paper presents construction, operating principle and initial study of new device for measurement and recording of arterial blood pressure, created at Wrocław University of Science and Technology. This device is equipped with a pneumatic pressure sensor based on the pneumatic nozzle flapper amplifier principle. During the measurement sensor is applied to the patient’s body, where the pulse is easily palpable. After that, sensor is gradually pressed against to the artery, in order to record peak amplitude. Maximum value of this amplitude corresponds to the real blood pressure waveform. This device was validated according to “International Protocol revision 2010 for the validation of blood pressure measuring devices in adults”.

1 Introduction

Nowadays blood pressure measurement is one of the most commonly used medical examination. There is a wide range of easily purchasable commercial apparatus. According to World Health Organization, hypertension is the greatest factor leading to heart diseases and the main cause of death risk. Around 54% of strokes, 47% of infarcts and 13% of all deaths are caused by high blood pressure [2]. The high demand for measurements has resulted in the creation of various types of measuring devices.

Among blood pressure measurement apparatus one can find sphygmomanometers. They use aneroid mechanism which displays pressure value taken on the cuff of the examined person as indication of an needle of a manometer mechanism which is scaled in millimeters of mercury. They are commonly used by physicians however there are models accessible for household use. Another group are mercury apparatus. They use mercury as an agent balancing pressure on the cuff of the examined person. Reading the indication of the mercury one can precisely measure the blood pressure level. The next group are electronic digital apparatus. They are usually fully automatic, mainly utilized in households. They use oscillometric method of pressure change measurement in the cuff. There occurs few versions: a carpal version, which measure blood pressure on the radial artery and the traditional of shoulder version. There are also semi-automatic models, where some functions are performed manually, either air is pumped by means of a bulb syringe or the pressure is measured by the

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auscultation method using a classic stethoscope. To the group of electronic blood pressure apparatus also belong Hi-End class manual pressure meters. These devices use Korotkov’s auscultation method. The pressure test is carried out in the same way as in the case of manual devices but the cuff pressure measurement is done by the electronic system, which additionally provides automatic calibration and deflation rate control. The pressure value in the cuff is displayed on the electronic display.

2 Design and operation of the device

An alternative to the previously described methods of pressure measurement, additionally enriched with the possibility of registering a blood-pressure wave, may be developed at the Wroclaw University of Science and Technology device with a pneumatic nozzle-flapper amplifier sensor.

![Fig. 1. The device for the blood-pressure wave measurement and recording [4]](image)

The scheme of those device is shown in Fig.1. The sensor (1) is supplied with compressed air from the interface (2) by a flexible tube (3). The interface processes the pneumatic signal into digital form and transmits it in the form of voltage to the computer (4), which registers and analyzes the received signal [4].

During the measurement, the sensor is applied in a position, where the artery runs directly under the skin and where it is possible to place the sensor’s center directly above the central part of the artery (for example on a neck or on the wrist). After its exact position is checked, the sensor is gradually pressed by the operator against the chosen artery. At the same time, cardiac waveforms appear on the notebook screen, their amplitudes increasing at first and then decreasing. The largest peak corresponds to the blood pressure value. The devices not meant as a continuous blood pressure monitoring. The systolic and diastolic pressure is calculated directly from the characteristics of pressure-voltage transducer. The principle of pressure compensation is used [5].
The pneumatic blood pressure waveform sensor is a repeater, built using a nozzle-flapper amplifier. In this particular sensor, the flapper is a membrane made of silicon. The amplifier scheme is shown in Fig. 2. The following elements may be distinguished: a throttle (1); a power cord (2); a vent nozzle (3); a membrane acting as a flapper (4); a measurement chamber (5) and a pressure-voltage transducer (6). If the value of the measured pressure ($p_1$) acting on the membrane (4) from the outside equals the atmospheric pressure, the supply air flows freely through the throttle (1), the measuring chamber (5) and through the gap, and then freely exits. In this case, the pressure inside the sensor is equal to the pressure outside the system. When the pressure $p_1$ increases, the flapper bends towards the venting nozzle, which causes it to close. As a result, the intraventricular pressure $p_2$ begins to increase until once again the pressure equalization occurs on both sides of the membrane. This is the effect of the negative feedback applied in the system [7].

3 Experiment

To determine the accuracy of the tested device and to assess its applicability, it should be subjected to the validation procedure. Validation of the pressure measure devices in adults is based on the protocol: "International Protocol revision 2010 for the validation of blood pressure measuring devices in adults" created by the European Society of Hypertension [7]. Following the recommendations contained in the protocol, the initial validation of the tested device was carried out. During the first validation campaign, fifteen volunteers over the age of 20 were examined. Three series of measurements were carried out on each of the volunteers. In each series, two measurements were made. One with the help of a device used as a golden standard, which included a blood pressure monitor and stethoscope (ERKA Perfect-Aneroid Sphygmomanometer and Erka Precise stethoscope), and the second one with use of the tested device.
4 Results

Analyzing the obtained results for the systolic pressure, Fig. 3, it can be seen that the most errors are within the limit of 3-15% which, based on the validation protocol, allows to state that the device is of average accuracy, however the results obtained are quite precise. From which it can be concluded that the possibility of correcting the processing characteristics of the tested device should be considered, introducing a proportional coefficient with a value not much larger than one. The mean error for systolic blood pressure is 12%.

Analyzing the error distribution for diastolic pressure, Fig. 4, it can be seen that more than a half of errors do not exceed 10%, which allows to conclude that the device in the case of diastolic blood pressure measurement is much more accurate. The mean error for diastolic pressure is 10%.
5 Conclusion

Analyzing the pressure values obtained during the preliminary validation process of the tested device, it can be noticed that the device at the current preliminary stage of work does not meet the minimum requirements in terms of accuracy for devices intended for non-clinical use. Most errors range from 0 to 10%, but some of the measurements are subject to an error of up to 28%. The measurement values for which the error is the largest, do not necessarily result in inaccuracies of the device. It is possible that during the measurement the device’s sensor was imprecisely applied to the wrist artery. In the case of systolic pressure measurements, the majority of the values are understated, and in the case of diastolic pressure, the values are definitely overstated. It may mean that the device does not keep up with the dynamically changing arterial pressure parameters or is not sensitive enough. In order to improve the device, the algorithmic compensation of its static and dynamic properties should be considered. In addition, the simplification of the measurement method should be reviewed. It seems highly probable that a significant part of the errors is the result of the inadequate skill of the person performing the measurement. Future aim is to check the relation between body mass index and accuracy of the measurement.

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