EVALUATION OF SPHYGMOMANOMETERS USING AN ADVANCED OSCILLOMETRIC SIGNAL GENERATOR

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Abstract:
Reliable and accurate blood pressure measurements using sphygmomanometers are indispensable in the diagnostic and treatment of hypertension. Unfortunately, testing of performance and accuracy of automated oscillometric sphygmomanometers is complicated, lengthy and expensive. Fact that the oscillometric sphygmomanometers are majority of the blood pressure measuring devices on today's market makes the problem more pressing.

EMPIR project adOSSIG built a physiology-based advanced blood pressure simulator with a goal of improving blood pressure measurements. This paper describes results of testing of sphygmomanometers using this newly developed simulator.

Keywords: blood pressure; sphygmomanometer, simulator; oscillometry; metrology

1. INTRODUCTION

In average one in four adults in the European Union is diagnosed with hypertension [1], worldwide there are over 1 billion people affected. There are regions where prevalence of hypertension in adults is over 50 %. According to the WHO, less than 20 % of people with hypertension have the problem under control [2]. Hypertension increases the probability of stroke, heart attack and kidney diseases, causing over 20 % of all heart attacks and is responsible for 13 % of all non-accidental deaths. As it rarely shows symptoms, hence the nickname "silent killer", the key to successful treatment is early detection. Reliable and accurate blood pressure (BP) measurements taken by sphygmomanometers (SM) play an indispensable role in the prevention, diagnosis and treatment of this condition.

Historically non-invasive blood pressure measurements were usually taken by medical professional using mechanical mercury or aneroid manometer by auscultatory method. The blood pressure values were estimated directly by simultaneous reading of pressure value in the cuff on patient's limb and observation of the Korotkoff sounds by stethoscope. Although this method is considered by many the "gold standard" of blood pressure measurements, its correct utilisation requires the measurements to be performed by trained professionals and therefore it is not appropriate for automated, long-term and repetitive or home-care measurements.

With the development of electronics in recent decades, vast number of automated electronic devices for non-invasive blood pressure measurement has been introduced to the market, most of them based on oscillometric method.

1.1. Oscillometric method

Oscillometric method is based on evaluation of low amplitude pressure pulses, see Figure 1, in a cuff by means of an appropriate algorithm. However, the relationship between oscillometric pulses and systolic and diastolic blood pressure values is complex.

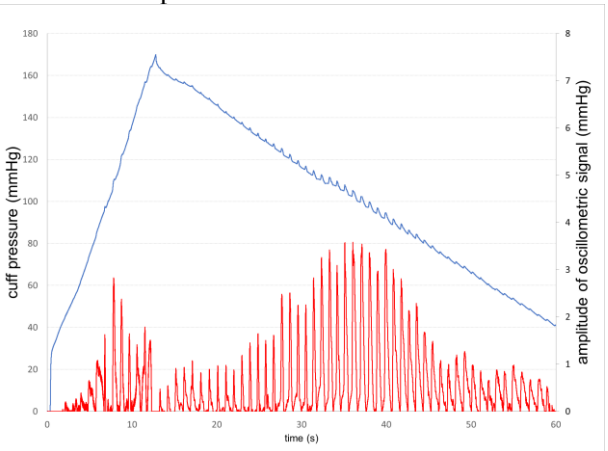

Figure 1: Cuff pressure measurement (in blue) with extracted oscillometric pulses (in red). Amplitudes of the oscillometric signal in this case are less than 4 % of the cuff pressure values.

The algorithms used to estimate BP values are based on empirical data, gained from clinical studies

by each manufacturer separately. There is no standard procedure or algorithm and proprietary internal software of automated SMs is not disclosed. Although commonly used, oscillometric sphygmomanometers are known to occasionally indicate inaccurate values due to algorithmic and software issues which is detrimental for patients with cardiac and circulatory problems, for which the accurate measurement of blood pressure is critical.

1.2. Traceability and accuracy of blood pressure measurements

The basic traceability principle applied in most fields of metrology is relatively simple; a measuring instrument or standard is compared against another standard of better accuracy. This creates a traceability chain between the top-level national standards and devices in the field. This approach works well for mechanical (aneroid or mercury column) sphygmomanometers where standard pressure calibration accompanied by several simple functional checks is sufficient [3]. However, when it comes to modern automated sphygmomanometers, the situation is different. Such a calibration only tests the ability of the pressure sensor to display the pressure correctly, other components of the device are not checked for accuracy at all, e.g. internal software, which is responsible for calculating the blood pressure values.

The concerns on accuracy of automated sphygmomanometers led to development of several test protocols for clinical validation of sphygmomanometers, e.g. [4]-[6]. In EU, clinical validation is also a necessary step in introducing any new device to market, as the Regulation (EU) 2017/745 on medical devices requires for SM (and other medical devices with measuring function as well) to prove sufficient accuracy, precision and stability for their intended purpose. Clinical validation is performed on representative group of human test subjects by means of comparison of reference measurements (usually auscultatory or invasive intra-arterial measurements) and the tested sphygmomanometer. Test protocols define required demographics and health state of human test subjects, e.g., age limitations, distribution by gender and blood pressure values (normotensive, hypertensive and hypotensive) and requirements for SM to pass the validation (e.g., average error of measurement equal or less than ±5.0 mmHg and standard deviation (SD) of 8.0 mmHg or less [6]). Due to the required number of test subjects (at least 85 participants and 255 measurements in [6]) and other requirements for clinical validation, the evaluations of sphygmomanometers are time consuming and costly.

1.3. Blood pressure simulators

Clinical validations are so far the only possibility how to evaluate in-depth the accuracy of SM. In recent decades, mainly to reduce costs and difficulties of development and testing SMs, special devices called patient or blood-pressure simulators began to appear on the market.

These devices mimic the real-life oscillometric signals and allow testing in manner similar to standard blood pressure measurement. However, these simulators generate signals only similar to the physiological ones and they use proprietary algorithms to generate these signals as well. Due to their limitations, they are currently only recommended for evaluating the repeatability and stability of SM, investigation on influence of environmental conditions of SMs, but not the accuracy of measurement [10].

To avoid these limitations new types of simulators are being designed and built – simulators capable of reproducing real physiological blood pressure signals [7],[8]. EMPIR funded project adOSSIG – “Developing an infrastructure for improved and harmonised metrological checks of blood-pressure measurements in Europe” aims to improve the reliability and accuracy of blood pressure measurements by developing an advanced oscillometric signal generator (aOSG).

The project goal is to build and evaluate an oscillometric signal generator, capable of generating oscillometric blood pressure pulses indistinguishable from real physiological human signals. The overall aim of the adOSSIG project is “to develop sustainable metrological research capabilities to provide traceability for blood pressure measurement in Europe”. This includes the development of the aOSG itself, investigation of possible role of this device as an absolute blood pressure standard to carry out in-depth checks of the performance of SM, development of test procedures for the simulator and development of dynamic pressure traceability for the aOSG itself, accompanied by implementation of smart specialisation concept for blood pressure measurements [9].

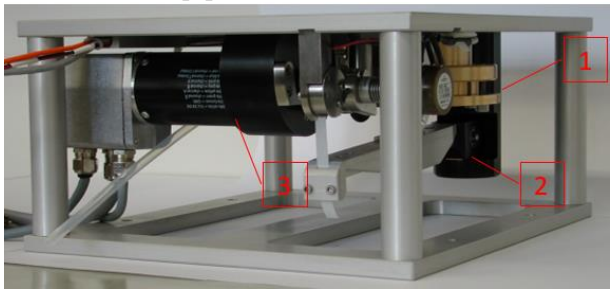

Figure 2: Main mechanical components of the aOSG. Oscillometric pulses are generated in chamber (1) by movement of a diaphragm connected to lever (2) and step-motor (3).

1.4. Experimental sphygmomanometer evaluation

In this paper, the comparison of performance results of 11 commercially available sphygmomanometers tested by aOSG is presented.

2. SPHYGMOMANOMETER EVALUATION

The aOSG has been developed and tested by German metrology institute PTB early in the project. The key component of the simulator is an extensive database of real-life oscillometric signals that was made available to the project participants by the Newcastle University. The database was created previously as part of another research and it consists of more than 1300 oscillometric waveforms from approximately 600 people, each waveform with paired reference auscultatory blood pressure measurements.

Additional testing of the aOSG was performed by the University of Ljubljana [10], where functionality was evaluated using a clinically validated SM and a commercially available blood pressure simulator for a comparison.

Further testing, focused on applicability of developed test procedures for sphygmomanometer testing was conducted by CMI. The testing was done as part of a consumer test for Czech newspaper Mladá fronta DNES [11] and consisted of simulated clinical trial using the aOSG to test 11 recently bought oscillometric sphygmomanometers.

2.1. Test procedure

85 oscillometric signals representing 85 people fulfilling the criteria of ISO 81060-2 were randomly selected from the database. None of the selected waveforms was recorded on person with cardiovascular disease (e.g., arrythmia etc.) or diabetes. These signals represented 42 women and 43 men with age from 16 to 79 years, average of 52 years. Average blood pressure of all "test subjects" was 139 mmHg / 83 mmHg. Values of the systolic blood pressure (SBP) among the subjects varied from 80 mmHg to 208 mmHg, while the diastolic blood pressure (DBP) among the subjects varied from 40 mmHg to 132 mmHg.

Testing was done in two stages: In the first stage, each of the sphygmomanometers was tested with all 85 oscillometric waveforms. Average error and standard deviation were calculated for each of the tested SMs.

In the second stage, repeated measurements were performed with 3 oscillometric waveforms representing a normal blood pressure (i.e., 126 mmHg / 84 mmHg); waveform with maximum average deviation from the first stage at SBP (i.e., simulated BP 177 mmHg / 100 mmHg) and similarly, waveform with maximum average deviation from first stage at DBP (i.e., 185 mmHg / 132 mmHg). Ten repeated measurements were performed with each waveform with all tested devices. The goal of the second stage was to assess repeatability of the measurement of the tested SMs. In both stages sphygmomanometers were tested with their respective cuffs wrapped around a rigid cylinder simulating a limb, simulator was connected by means of a T-piece, see Figure 3. Calibration and adjustment of the aOSG was performed with each simulator-cuff assembly to minimise the influence of difference in internal volume of cuff's bladder.

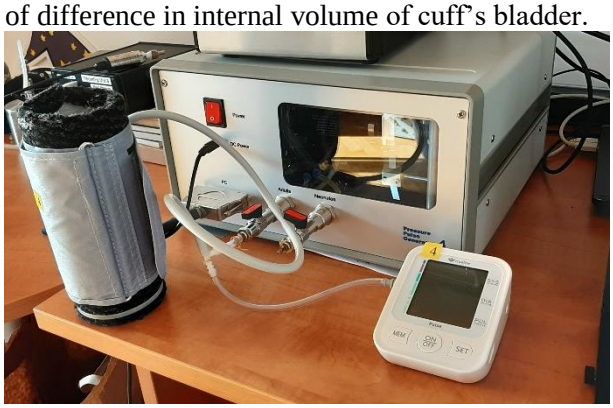

Figure 3: Example of test setup, sphygmomanometer connected to the aOSG.

2.2. Results

The test results are summarised in Tables 1 - 4.

Although only 4 of the tested devices met in the first stage criteria of ISO 81060-2, i.e., average error not greater than ±5.0 mmHg and standard deviation not greater that 8.0 mmHg, the majority of results are close to these requirements. The average errors of the tested devices may (mis)lead to conclusion that *all* the BP measurements of these SMs are accurate to certain degree. Certainly, there are signals where all tested SMs measured the simulated BP with very good agreement.

On the other hand, a non-negligible part of the results is burdened with significant errors. It is worth mentioning that the measurements in the second stage of testing, where the selected signals represented BP values 177 / 100 mmHg and 185 / 132 mmHg respectively, were burdened by significant underestimations of blood pressure values. In the case of signal representing the BP 177 / 100 mmHg, the SBP was in average underestimated by 28.9 mmHg and the DBP by 9.8 mmHg. In the case of signal representing the BP 185 / 132 mmHg, there was an average underestimation of 13.9 mmHg in SBP and 28.4 mmHg in DBP. There were also signals where the tested SMs calculated one of the BP values accurately to certain degree while the other BP value was calculated with a significant deviation. An example of this is represented by the waveform of BP 109 / 86 mmHg, where the average SBP error

was only -1.9 mmHg, while the mean DBP error was -19.3 mmHg.

We can speculate, if by choosing different signals the results of the first stage will be significantly different. Nevertheless, the first stage of the testing proved, that independently on the manufacturer, there are certain oscillometric signals where all tested devices provide erroneous readings.

Second stage of the measurement proved very good repeatability of the measurements of the tested devices, although with large systematic errors.

The results partially confirm frequently claimed statement, that the oscillometric method tends to measure blood pressure close to "normal" blood pressure values with acceptable errors, and the further the systolic or diastolic blood pressure value is from the "normal" value, the higher is the chance, that the sphygmomanometer reading will be incorrect.

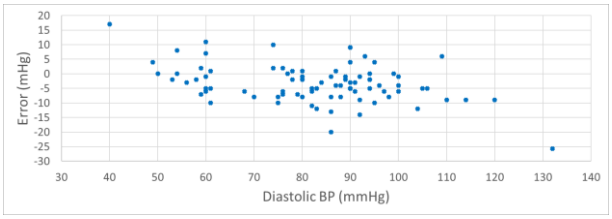

Figure 4: Example of results of the SM testing, Hartmann. Veroval at DBP.

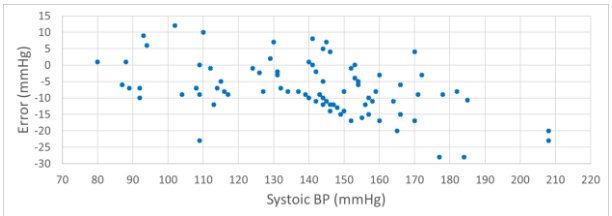

Figure 5: Example of results of the SM testing, Hartmann Veroval at SBP.

Table 1: Results of the first stage of testing. Figures in bold mean passing the criteria of ISO 81060-2

	1	2	3	4	5	6	7	8	9	10	11a	11b
Device	Hartmann Veroval	Silvercrest	Truelife Pulse	Geratherm smart	.Soehnle Systo mon.	Microlife BP10	Depan	Esperanza	OMRON M7	SENCOR SBP690	Braun ExactFit 3	Braun, large cuff
Avg. error (mmHg)	-5.2	-5.3	**-4.2**	-5.3	-5.2	**-2.1**	**-0.7**	-8.4	**-3.5**	-3.1	-5.2	-7.0
SD (mmHg)	7.6	7.7	**7.5**	8.1	7.8	**7.7**	**7.1**	10.3	**7.5**	8.6	7.7	7.5

Table 2: Results of the second stage of testing, results of repeated measurement with waveform representing normal BP (126 mmHg / 84 mmHg)

	1	2	3	4	5	6	7	8	9	10	11a	11b
Device	Hartmann Veroval	Silvercrest	Truelife Pulse	Geratherm smart	Soehnle Systo mon.	Microlife BP10	Depan	Esperanza	OMRON M7	SENCOR SBP690	Braun ExactFit 3	Braun, large cuff
Avg. error at SBP (mmHg)	-2.4	2.3	0.7	0.8	4.9	7.1	6.5	-9.6	-3.4	0.2	0.8	-0.3
SD (mmHg)	0.5	0.6	2.2	1.7	0.5	1.1	1.7	1.3	0.5	1.2	0.6	0.5
Avg. error at DBP (mmHg)	-3.0	-4.1	-1.5	-6.0	-5.0	-1.8	0.2	-2.7	0.7	2.6	-4.0	-4.9
SD (mmHg)	0.6	0.3	0.8	0.6	0.0	1.2	1.2	1.1	0.6	1.1	0.8	0.5

Table 3: Results of the second stage of testing, results of repeated measurement with waveform with maximum average deviation at SBP during the first stage, (BP 177 mmHg / 100 mmHg)

	1	2	3	4	5	6	7	8	9	10	11a	11b
Device	Hartmann Veroval	Silvercrest	Truelife Pulse	Geratherm smart	Soehnle Systo mon.	Microlife BP10	Depan	Esperanza	OMRON M7	SENCOR SBP690	Braun ExactFit 3	Braun, large cuff
Avg. error at SBP (mmHg)	-28.0	-28.0	-30.6	-29.9	-29.5	-29.4	-19.9	-30.7	-30.2	-31.8	-28.7	-30.0
SD (mmHg)	0.0	1.4	1.7	1.1	0.7	1.0	2.4	4.1	0.9	1.1	0.9	0.4

Avg. error at DBP (mmHg)	-1.0	-11.4	-10.4	-13.2	-12.9	-10.3	-10.6	-9.9	-8.7	-5.1	-11.8	-12.4
SD (mmHg)	0.0	0.7	1.6	0.7	1.0	1.0	1.5	1.7	0.5	0.7	0.6	0.7

Table 4: Results of the second stage of testing, results of repeated measurement with waveform with maximum average deviation at DBP during the first stage, (BP 185 mmHg / 132 mmHg)

Device	1 Hartmann Veroval	2 Silvercrest	3 Truelife Pulse	4 Geratherm smart	5 Soehnle Systo mon.	6 Microlife BP10	7 Depan	8 Esperanza	9 OMRON M7	10 SENCOR SBP690	11a Braun ExactFit 3	11b Braun, large cuff
Avg. error at SBP (mmHg)	-10.7	-18.6	-10.5	-21.0	-20.0	-7.2	-6.3	-15.9	-6.8	-12.6	-18.2	-19.4
SD (mmHg)	0.6	0.7	2.2	1.1	0.4	0.7	1.0	9.3	0.7	0.5	0.7	0.7
Avg. error at DBP (mmHg)	-25.7	-30.6	-24.6	-32.0	-30.8	-24.3	-27.4	-30.5	-25.5	-25.0	-31.5	-32.4
SD (mmHg)	1.0	1.1	0.7	0.4	0.7	0.6	2.2	2.8	0.9	0.4	0.8	0.5

3. SUMMARY

EMPIR project adOSSIG has one of the goals to build a physiology-based advanced blood pressure simulator. This paper describes the tests of applicability of the built device in a sphygmomanometer testing.

An advanced oscillometric signal generator, capable of generating real-life physiological signals, is envisaged as reliable supplement for clinical validation of non-invasive oscillometric sphygmomanometers. The main difference to commercial simulator is the large embedded database of real-life oscillometric signals and its technical capability to accurately and reliable reproduce these signals.

Using this device is a foundation for time- and financially undemanding in-depth testing of sphygmomanometers.

4. ACKNOWLEDGEMENT

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