Home Blood Pressure Monitors For 21st Century

Jiri Jilek
Carditech
Culver City
California
USA
jjilek30@gmail.com

Milan Stork
Department of Electronics and Information Technology/RICE
University of West Bohemia
Plzen, Czech Republic
stork@fel.zcu.cz

***Abstract* — Home blood pressure monitors will play increasingly important role in 21st century healthcare. Improvements in their accuracy and reliability will be necessary. In this paper we described their function and suggested several improvements. The improvements include static accuracy check, a public database of cuff pulse waves, utilization of cuff pulse waves for several hemodynamic variables, and wider cuff for wrist monitors.**

Keywords* — *blood pressure, home monitor, cuff pressure, cuff pulse waves

I. Introduction

High blood pressure (hypertension) is a world-wide health problem. Measurement of blood pressure (BP) is the most frequently performed health test. It belongs to the family of vital signs. BP measurement is increasingly performed in the home. Home BP monitoring provides useful information to the physician and to the patient [1]. Most recommended home monitors on the market are automatic, with an arm cuff. Wrist home monitors are also popular, but are usually not recommended by experts. The advantage of wrist monitors is small size, low power consumption, and they can usually be used even on very obese people. The disadvantage is that the wrist must be kept at the level of the heart during measurement. When the cuff is not at heart level the BP reading can be artificially higher (cuff below heart) or lower (cuff above heart). Fig. 1 shows a home arm monitor and a wrist monitor.

Fig. 1. Arm and wrist home BP monitors

Milan Stork was supported by Department of Electronics and Information Technology/RICE, University of West Bohemia, Plzen, Czech Republic and by the Ministry of Education, Youth and Sports of the Czech Republic under the project OP VVV Electrical Engineering Technologies with High-Level of Embedded Intelligence, CZ.02.1.01/0.0/0.0/18_069/0009855 and by the Internal Grant Agency of University of West Bohemia in Plzen, the project SGS-2018-001.

In recent years, several wearable and cuff-less BP devices have been introduced. They use cuff-less methods or very small cuffs. These devices have not been recommended for home BP monitoring.

Originally, home BP monitors (HBPM) were used for screening and their accuracy was not closely examined. More recently, home monitors have been increasingly used for diagnostics and hypertension management. Accuracy and reliability of HBPMs have been questioned [2].

Most HBPMs have memory storage that holds BP and heart rate values that can be recalled. More recent monitors come with blue tooth feature that allows transmission of monitor data to a smart phone equipped with an appropriate app. BP data can then be sent via Internet to a healthcare facility. These procedures are a part of the larger scheme called telemonitoring and telemedicine [3].

In this paper we concentrated on home monitor functions, their accuracy, reliability, and on their future improvements.

II. Methods

Basic method of HBPM measurement is similar to the method of a professional (clinic or hospital) monitor. Such monitor consists of an arm cuff connected vie air tube to a pressure transducer. Arm monitors have a detachable cuff and wrist monitors have a wrist cuff with monitor body attached directly to the cuff (see Fig. 1). The output of the transducer is digitized and processed by a microprocessor. A fully automatic monitor has an air pump that inflates the cuff and an air valve that deflates the cuff. The microprocessor controls the functions.

Block diagram in Fig. 2 shows the essential components of a HBPM. The cuff is a part of the pneumatic circuit that consists of an air pump, an air valve, and a digital control for cuff inflation (air pump) and air valve that deflates the cuff. The analog to digital converter serves as an interface to digital processor and display of BP values. A HBPM is usually equipped with several buttons that turn the monitor on and off, start/stop the test, and control the display of stored BP values.

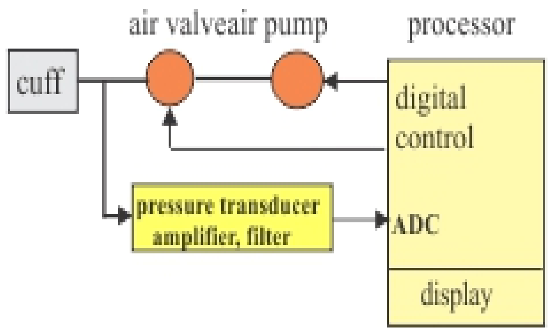

Fig. 2. - block diagram of basic components of an automatic BP monitor

2022 International Conference on Applied Electronics (AE) | 978-1-6654-9482-3/22/$31.00 ©2022 IEEE | DOI: 10.1109/AE54730.2022.9919887

III. CUFF-PULSE PROCESSING AND EVALUATION

Digital processing of cuff pressure (CP) and cuff pulse waves (CPW) is an essential part of an automatic BP monitor. Fig. 3 shows the descending curve of CP (upper trace) and the amplified CPWs (lower trace).

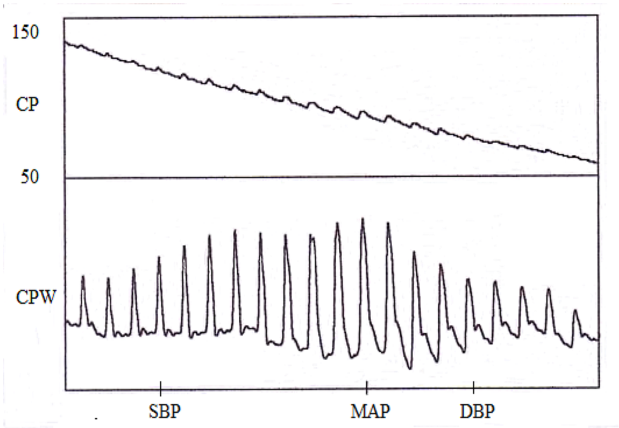

Fig. 3. - cuff pressure (CP) and cuff pulse waves (CPW) during gradual cuff deflation.

Air pressure in the cuff, modulated by arterial pulsations under the cuff (upper trace of Fig. 3), is converted to electrical signal by a pressure transducer. CPWs are obtained by their separation from the CP by filtering and amplification. CP values are retained as a reference to the waves.

Fig. 3 shows CP and CPWs recorded from a 62 years old male. CPWs were recorded during a gradual CP deflation procedure. Monitor pump inflates the cuff with the air valve closed, and the deflation procedure begins with CP above systolic blood pressure (SBP). Cuff pulse waves are present at CPs above SBP and their amplitudes increase until they reach the point of mean arterial pressure (MAP) and then the amplitudes decrease past the point of diastolic blood pressure (DBP) until the procedure is terminated. The CPWs are detected even when the artery under the cuff is completely occluded at CPs above the point of SBP. The proximal edge of the fully inflated cuff is exposed to the pulsations of the proximal segment of the artery. There are no easily discernible points of SBP and DBP by means of CPW amplitudes. This is viewed as a shortcoming of the cuff-pulse (oscillometric) method for BP determination Increasing number of monitors use slow cuff inflation and the cuff pulse waves are processed during the inflation. The cuff inflation is terminated when CP exceeds the value of SBP.

CPW and CP values are used to algorithmically determine the pressures. Published algorithmic methods for the determination of SBP and DBP present differing approaches. Geddes makes certain empirical assumptions about algorithmic determination. His proposed algorithm is based on the ratio of waveform amplitudes. According to Geddes [4], SBP corresponds to the point of 50% of maximum amplitude (MAP); for DBP, the ratio is 80%. Another proposed ratio algorithm uses the point of SBP at 40% of maximum amplitude and 75% of max. amplitude for DBP. Other algorithms for the determination of blood pressure are based on the change of slope in the waveform amplitude envelope. An article describing the function of a BP device [5] claims that the device determines SBP as the point of the initial increase of the cuff pulsations. Another author [6] puts SBP on the minimal ascending slope of the amplitude envelope and DBP on the maximum slope of the descending envelope.

The above algorithmic approaches result in differing SBP and DBP values. Furthermore, the approaches do not offer physiological explanation for their assertions. The only commonly recognized and physiologically verified variable is the MAP. Common to the published algorithms is that they use amplitudes of cuff pulsations. Little attention has been paid to the contours of these pulsations. Algorithms used in commercial BP monitors (professional and home monitors) are generally considered intellectual property and are kept secret. Home BP monitors probably use some versions of the algorithms described above but the exact nature of these algorithms is not publicly known. This makes verification of accuracy difficult.

IV. RESULTS

HBPMs usually have a display that shows values of SBP, DBP, and heart rate, sometimes called pulse rate. Most home monitors also display time and date of the test. BP test result values are stored in a memory and they can be recalled in a sequential manner. Some newer monitors also feature blue tooth that allows transmission of stored BP values to a smart phone or a computer. Some home monitor manufacturers have apps for phones that allow various presentations of multiple BP values, usually in the form of trend graphs. Individuals with hypertension can share the smart phone BP data with their physicians. Some newer home monitors have arrhythmia detection, usually atrial fibrillation (AF). Some monitors are capable of determining BP values in the presence of arrhythmia. Older versions of BP monitors usually display error message. Error messages are usually displayed when the monitor cannot detect pulses in the cuff, when there is excessive leak in the pneumatic circuit, presence of movement artifacts, or tremor. Movement artifacts and tremor detection is not always guaranteed and the resulting BP values can be erroneously low or high.

V. DISCUSSION

Professional monitors allow testing for static accuracy, but home monitors generally have no provisions for accuracy checking. Because there are no reliable instruments for testing the dynamic accuracy of BP monitors, performance testing protocols for device validations have been developed [7]. Validation protocols of BP monitors usually use manual BP determination (auscultation) as the reference BP values..

Validation protocols require recruitment of large number of volunteers with varied blood pressures, ages, and arm circumferences. These requirements inevitably make validation studies expensive. Validations are supposed to be performed for each new software update, but this is rarely done. Replications of validation studies are nonexistent. Most HBPMs on the market today have not been validated [8] and their accuracy is not known. This presents a problem because home monitors are increasingly used for diagnostics and for management of hypertension.

Another problem with HBPMs is lack of maintenance. While professional BP monitors used in clinical setting are periodically maintained and tested with testers available on the market, home monitors are not maintained and tested for accuracy. Home monitors do not facilitate test features like static pressure test and leakage.

VI. SOME PROSPECTIVE IMPROVEMENTS TO HOME BP MONITORS

We propose the following solutions to the shortcomings of HBPMs:

A. Static pressure and pneumatic circuit leak test

This can be facilitated with a software routine that turns the monitor into a passive static pressure monitor. A calibrated pressure gauge (aneroid or electronic) and a manual inflation bulb are inserted into the monitor pneumatic circuit and the pressure gauge reading is compared with the monitor display reading. This test verifies accuracy of monitor pressure transducer. The required pressure accuracy according to the Association for Advancement of Medical Instrumentation standard [9] is 1%. The pneumatic circuit leak test involves inflating the cuff to a predetermined pressure and taking a pressure reading after a 60 second interval. The pressure drop should not exceed 4 mmHg.

B. Public database of raw data from a BP cuff

We propose a solution that potentially remedies several problems with validations discussed above. It applies equally to professional and home monitors. The solution is based on a data acquisition and storage system. We described such system previously [10]. The system components are: notebook computer, hardware module, and detachable cuff. The hardware module consists of a pneumatic circuit similar to the circuit in Fig. 2, electronic processing circuit and ADC, and a notebook computer connected to the hardware module via USB port. Data acquisition procedure is similar to a BP test. Example of acquired CP and CPWs data is shown in Fig. 3. When data acquisition procedure is finished, reference SBP and DBP values are determined by auscultation (manual method), which is still the "gold standard" for noninvasive BP measurement. The acquired raw data and reference BP values are then stored in files and annotation is added. The stored digital data files can then be used to test software algorithms or to study cuff-pulse waveforms. The data acquisition procedures can be used on a wide range of subjects to form a database.

Benefits of open access database of raw data from BP cuff:

- The database has to be developed only once. The developed and publicly available database can then be used by any interested party. The data can be processed at much higher speed than real time.
- The database can be expanded to include special groups (pregnancy, arrhythmias), different cuffs (wrist cuffs, special designs), and other applications.
- The database can eventually replace the inefficient and expensive validations as performed today.
- The database can include much larger populations than required by validation protocols used today. This will increase accuracy of BP devices validated with the database.
- Developers of new BP devices will have the advantage of not having to develop their own proprietary databases, as the past and present manufacturers had to do.
- Existing BP device manufacturers/developers will be able use the database to improve or test their existing software.
- The database can serve as a knowledge base that is lacking today.
- It is conceivable that the database applications will lead to a standardized BP device performance.

C. Utilization of cuff pulse waves for estimation of hemodynamic variables

Blood pressure belongs in a family of hemodynamic variables: these variables are stroke volume, cardiac output, peripheral resistance, and arterial compliance. Hemodynamics can be used in management of resistant hypertension. It appears possible to determine some hemodynamic variables from cuff-pulse waveforms and BP values [11]. Cuff pulse waves acquired at CP equal or below DBP level are similar to CPWs obtained by other methods. Commercial instrument Sphygmocor Xcel (Atcor Medical, Sydney, Australia) uses CPWs acquired from a brachial cuff at CP 10 mmHg below DBP level. The CPWs are used to noninvasively estimate central blood pressure [12]. BP monitors can be easily modified to facilitate acquisition and processing of cuff pulse waves for hemodynamics.

D. Accuracy improvement of wrist BP monitors.

Wrist monitors usually have a narrow cuff (about 6 cm wide) permanently attached to the monitor. This results in under-cuffing for many individuals with wrist circumference larger than 15 cm. Under-cuffing results in erroneously elevated BP readings [13]. Another potential problem with wrist monitors is that the cuff needs to be held at the heart level. Cuff at levels below heart level can results in higher BP reading. For the above reasons, wrist HBPMs are generally not recommended by experts. Wider cuff and a built-in position sensor that allows a test only when the cuff is at heart level can improve accuracy of wrist BP monitors.

VII. CONCLUSION

Static pressure check and pneumatic circuit leak check can be facilitated. Dynamic accuracy of HBPMs can be increased by means of a publicly available database of cuff pulse waves and reference BP values. Functions of HBPMs can be expanded to include some hemodynamic variables. Wrist cuff monitor accuracy can be improved by wider wrist cuff and a position sensor. Some improvements can be implemented immediately (static accuracy, wider wrist cuff) and other improvements will require more extensive research and development effort. Cuff-less and wearable BP devices are mostly in experimental stages of development and more future work is necessary.

REFERENCES

[1] Stergiou G. S, Kario K, Kollias K, McManus RJ, Ohkubo T, Parati G, Yutaka I. Home blood pressure monitoring in the 21st century. J Clin Hypertens; 20: 1116-1121.

[2] Ruzicka M, Hiremath S. Accuracy - a limiting factor of home blood pressure monitors ? Am J Hypertens. 2017; 30: 661-664.

[3] Parati G, Dolan E, McManus RJ, Omboni S. Home blood pressure telemonitoring in the 21st century. J Clin Hypertens 2018;20: 1128-1132.

[4] Geddes, L.A. Characterization of the oscillometric method for measuring indirect blood pressure. Ann Biomed Eng 1982, Vol. 10, pp 271-280.

[5] Borow KM, Newburger JW. Noninvasive estimation of central aortic pressure using the oscillometric method for analyzing systemic artery

pulsatile blood flow; comparative study of indirect systolic, diastolic and mean brachial artery pressure with simultaneous direct ascending aortic pressure measurement. Am Heart J. 1982;103:879.

[6] Ng KG. Blood pressure measurement. Med Electron, Feb1999:61-64.

[7] [Stergiou GS, Alpert BS, Mieke S, Wang J, O'Brien E. Validation protocols for blood pressure measuring devices in the 21st century. J Clin Hypertens 2018; 20: 1096-1099.

[8] Picone DS, Desphande RA, Schultz MG, Fonseca R, Campbell N, Delles C. Olsen MH, Schutte AE, Stergiou G, Padwal R, Sharman JE.Nonvalidated Home Blood Pressure Devices Dominate the Online Marketplace in Australia.Hypertension 2020;75:1593-1599.

[9] Association for the Advancement of Medical Instrumentation: The national standard for electronic automated sphygmomanometers. Arlington, VA, USA, 1993.

[10] Jilek J, Stork M. Development of a Public Database of Raw Data from a Blood Pressure Cuff. AE2018 International Conference, Plzen, Czech Republic.

[11] Jilek J, Stork M. Estimation of hemodynamics from arm blood pressure cuff waveforms. Int Conf Proc AE2013, Plzen, Czech Republic.

[12] Butlin M, Qasem A, Avolio AP. Estimation of central aortic pressure derived from brachial cuff volume displacement waveform. 2012 Int Conf IEEE, San Diego,CA,USA

[13] Jilek J and Stork M. Cuff width alters the amplitude envelope of wrist cuff pressure pulse waveforms, Physiol Meas 2010;31(7):43-49.