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REVIEW

Cuffless blood pressure monitors: Principles, standards and approval for medical use

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SUMMARY Cuffless blood pressure (BP) monitors are noninvasive devices that measure systolic and diastolic BP without an inflatable cuff. They are easy to use, safe, and relatively accurate for resting-state BP measurement. Although commercially available from online retailers, BP monitors must be approved or certificated by medical regulatory bodies for clinical use. Cuffless BP monitoring devices also need to be approved; however, only the Institute of Electrical and Electronics Engineers (IEEE) certify these devices. In this paper, the principles of cuffless BP monitors are described, and the current situation regarding BP monitor standards and approval for medical use is discussed.

key words: cuffless blood pressure monitor, non-invasive blood pressure monitor, regulation, standard, medical approval.

1. Introduction

Blood pressure (BP) is one of the most important physiological parameters for maintaining good health. Thus, daily BP monitoring is recommended. In 2017, the American College of Cardiology and the American Heart Association introduced new definitions of normal BP, ($< 120/80$ mmHg) and hypertension ($> 130/80$ mmHg) [1]. Several cohort studies have recommended that BP be monitored either using ambulatory blood pressure monitoring (ABPM) or home-based BP monitoring devices. The cuff-based sphygmomanometer is a noninvasive blood pressure (NIBP) monitor commonly used both in the home healthcare and clinical setting. However, cuff-based sphygmomanometers can be difficult to handle because the cuff must be positioned at the same level as the heart. Also, cuff inflation during the night can disturb sleep, and long-term monitoring may be difficult. Cuffless BP monitors have recently been introduced to monitor BP without a cuff. These monitors were developed in accordance with mechanical and optical principles. The technical performance of cuffless BP monitors has been evaluated using several methods, including machine learning, deep learning, and neural

networks. Medical devices have to be approved by regulatory authorities. In particular, the use of mercury in BP monitoring devices should be approved only based on clinical evidence of safety. At present, there is insufficient evidence to support the clinical use of cuffless BP monitors.

In this paper, the principles of the cuffless BP monitor are presented and current standards and regulations are reviewed.

2. Principles of cuffless BP monitors

The basic principles of cuffless BP monitors can mainly be classified as mechanical or optical. Although the impedance cardiogram (ICG) and ballistocardiogram (BCG) are promising methods, they currently have no practical applications. Cuffless NIBP devices operate according to three principles: pulse transit time (PTT), the pulse contour, and the acceleration pulse. Cuffless NIBP monitors are designed to measure trends in BP, beat-to-beat rhythms, and waveforms.

2.1 PTT-based estimation

PTT-based BP devices are based either on photoplethysmography (PPG) and electrocardiography (ECG; R wave), or on two PPGs, as shown in Figure 1. An alternative approach to continuous NIBP measurement is based on changes in pulse wave velocity (PWV), which is the velocity of a pressure pulse propagating along the arterial wall. This can be calculated from the PTT, i.e., the time between two pulse waves propagating from two separate arterial sites during the same cardiac cycle, as shown in Figure 1.

The pulse arrival time (PAT), i.e., the interval between the ECG R-wave and the starting point of the photoplethysmographic wave (sum of PPT and the pre-ejection period [PEP]), is gaining in popularity as a method for tracking BP because it is easy to estimate [2-8]. PAT calculations were summarized in several review articles [6,8]. PAT and PTT are different, in that PAT includes PEP, which is the time between electrical depolarization of the left ventricle (QRS on the

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ECG) and the beginning of ventricular ejection; this represents the period of left ventricular contraction during which the cardiac valves are closed. If BP increases, the duration of PEP sometimes increases as well, even though it is usually expected to shorten; thus, the PAT does not exactly reflect BP changes. However, several studies consider PAT equivalent to PTT. Devices based on PAT and PTT can be used as BP monitors.

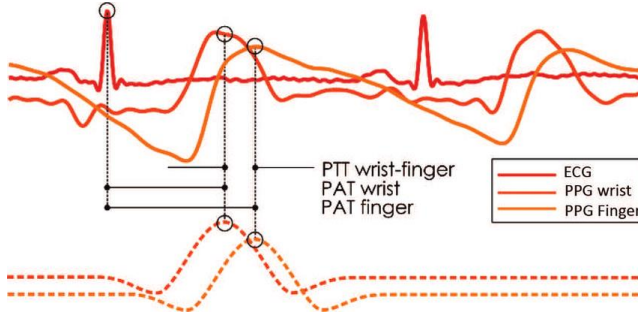


Figure 1. Estimation of BP based on the PTT, which is calculated based on the PPG waveform and ECG R wave (reproduced from [4] [open access]).

PTT, including PAT, depends on the elasticity of blood vessels, calculated based on the Moens-Korteweg equation [2] and the distance L between two PPG detectors.

$$PTT = L / \sqrt{\frac{Eh}{2r\rho}} \quad (1)$$

where ρ is the blood density, r is the inner radius of the vessel, h is the vessel wall thickness, and E is the elastic modulus of the vascular wall. In this equation, the elasticity parameter E is defined as:

$$E = E_0 e^{\alpha P} \quad (2)$$

where α is a constant, E_0 is the zero-pressure modulus of the vessel wall, and P is the BP within the vessel. Based on the two equations, the BP can be computed from PTT assuming all other parameters are held constant.

$$BP = \frac{1}{\alpha} \left[\ln \frac{2r\rho L^2}{E_0 h} - 2 \ln PTT \right] \quad (3)$$

If the changes in wall thickness, radius, and arterial elastic modulus are too small during a short period, the first term is a constant, and changes of BP are given by:

$$\Delta BP = -\frac{2}{\alpha PTT} \Delta PTT \quad (4)$$

Thus, PTT is linearly related to the changes in BP, which in this context refers to the systolic BP (SBP). Diastolic BP (DBP) is mostly obtained from SBP, substituted from the pulse pressure (PP). PP is assumed to be linearly related to changes in SBP.

$$DBP = SBP - PP \quad (5)$$

The PAT is determined relatively easily using ECG. It is more difficult to obtain a reliable PTT value, because of the complexity of vascular vessels. However, if PPT is measured over a long distance, then the signal is more reliable such that more accurate results can be obtained.

2.2 Pulse contour method

The pulse contour and acceleration methods represent alternatives for estimating BP. Pulse demodulation analysis (PDA) was developed to evaluate the arterial pressure pulse. It uses ballistocardiography and invasive central artery manometers to track mechanical events, such as heart contractions and pressure pulse reflections, in the central and peripheral arteries. Studies have confirmed two major reflection sites in the central arteries.

Figure 2 shows the pressure waveform obtained by applying the pulse contour method. The downward travelling primary pressure pulse (#1) gives rise to upward travelling pulses #2 and #3, which originate from the renal and iliac reflection sites, respectively, on which pulse #1 impinges. The amplitude ratio of the first reflection pulse (P2) to the primary systolic pulse (P1) can be used to track changes in central beat-to-beat SBP. The time difference between the arrival of P1 and the second reflection pulse (P3) is referred to as T1–3, and corresponds to changes in arterial PP. The BP was estimated from the pulse peaks and parameters included in the PDA model [9-13].

For PDA, lumped parameter models of the cardiovascular system are commonly employed to simulate the arterial BP waveform and wave propagation, with resistor impedance and capacitance used to fit SBP and DBP. The BP can be measured not only by a pressure sensor, but also by reference to PPG waveforms [14,15].

2.3 Acceleration PPG: second derivative

analysis

The second derivative of the PPG (SDPPG) signal was analyzed based on the amplitudes of waves a–e, which arose in the systolic phase of the heart cycle (Fig. 2, gray line). The amplitudes of the waves were

normalized as b/a , c/a , d/a , and e/a . The SDPPG signal contains information on aortic compliance and stiffness, which is highly correlated with BP. To make use of the SDPPG signal, the BP must be analyzed numerically using a neural network and/or support vector machine [17].

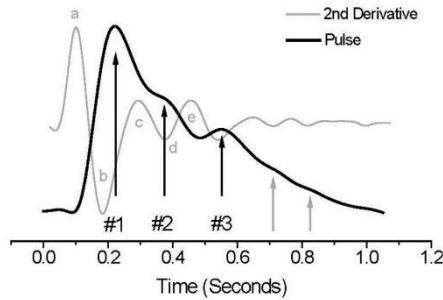


Figure 2. Real time (solid line) and second derivative (grey line) of the PPG signal obtained by the pulse contour method.

2.4 Tonometry

In applanation tonometry of the radial artery, when a radial artery is partially compressed or splinted against a bone, the pulsations are proportional to the intraarterial pressure, as shown in Fig. 3.

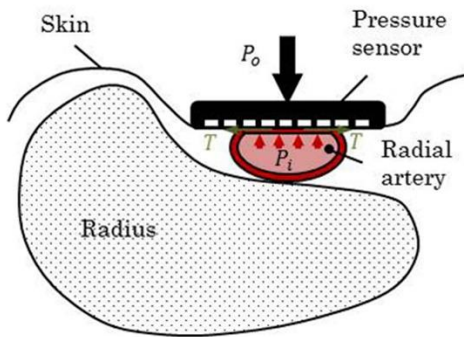


Figure 3. Principle of applanation tonometry.

However, the transducer must be positioned directly over the center of the artery; hence, the signal is highly position-sensitive. This has been dealt with by using an array of transducers placed across the artery. Although this technique was developed for beat-to-beat monitoring of the wrist BP, it requires calibration for each individual patient and is not suitable for a routine clinical setting [18-20].

2.5 Other principles

Other less well-known methods for measuring PAT and PTT include electrical bio-impedance (Bimp) [21-24], BCG [25-29], and seismocardiography (SCG) [30-33]. To use Bimp, BCG, and SCG, specialized technology are required; no commercial medical devices are available.

For Bimp, an array of wrist-worn bio-impedance

sensors are placed on the radial and ulnar arteries of the wrist to monitor the arterial pressure pulse resulting from blood volume changes at each sensor site. An impedance ring with spot electrodes is more suitable for wearable cuffless BP monitors than PPG sensors, in terms of noise reduction. An ICG sensor placed on the chest for thoracic impedance measurement via radar has also been proposed [24].

BCG can measure the response of the body to blood being ejected during the cardiac systole. Slight accelerations in the body caused by heart activity, mainly in the head-to-foot direction, and other relevant information were analyzed in a previous study. The method used therein was based on ECG and BCG, and allowed efficient monitoring of central pressure [25]. Furthermore, BP was estimated from upper-limb BCG recordings, obtained using an accelerometer embedded in a wearable armband simultaneously with finger PPG recordings [26-29]. SCG measures pericardial vibration during cardiac movement. It can monitor the PTT (with PEP excluded) and improve the conventional PTT analysis approach, but selection of the most appropriate measurement site can be difficult [30-33].

Ultrasound sensors are also used to measure BP and capture BP waveforms in relatively deep layers of arterial and venous sites [34-36]. In an NIBP sensor using ultrasound, high frequency sound waves are bounced off a blood vessel and the echo patterns received are sent to a computer to create a representation of the vessel's changing diameter. When calibrated to a patient's blood pressure, these waveforms can be used to monitor changes in blood pressure. An ultrathin, stretchable and wearable ultrasound patch sensor that enables non-invasive, continuous, and accurate monitoring of cardiovascular performance has been developed [35,36].

3. Standardization and clinical approval of the cuffless blood pressure monitor

3.1 The International Standards Organization (ISO)

The ISO is an international agency that regulates industrial and medical devices. The main aim of regulation is to ensure the high accuracy, validity, and safety of devices. ISO 81060-1:2007 and ISO 81060-2:2018, 09 have been published as standards for BP devices. Also, the ISO in cooperation with the IEC partly uses IEC 60601-1:2005, and IEC 60601-2-30:20. ISO 81060-2:2018 pertains to cuff-based sphygmomanometers. Recently, the ISO Technical Committee (TC) 121/Subcommittee (SC) 3/ Joint Working Group (JWG) 7, which is concerned with NIBP monitors, discussed continuous BP monitors and proposed the following standard: "ISO DIS 81060-3: Noninvasive sphygmomanometers - Part 3: Clinical investigation of continuous automated measurement type". Most national ISO committees approved this proposed standard, but the Comité Européen de

Normalisation (CEN) did not. The standard pertains mainly to continuous automated BP monitors, as exemplified by the Finapres (Finapres Medical Systems, Enschede, The Netherlands), CNAP (CNSystems, Graz, Austria) and Nexfin (Edwards Lifesciences, Draper, UT, USA) devices. These devices use a voltage clamp method based on a continuous PPG waveform and passive control. ISO JWG 7 is scheduled to discuss the cuffless NIBP monitor in April 2021 following publication of ISO 81060-3.

3.2 The Institute of Electrical and Electronics Engineers (IEEE)

The IEEE Standards Association (SA) has long been concerned with wearable BP monitors. In 2014, the 1708-2104 IEEE standard for wearable cuffless BP measuring devices was approved by the IEEE SA. The standard is applicable to all types of wearable BP measurement devices, including wearable and unobtrusive BP devices having different modes of operation (e.g., short- vs. long-term measurement, discrete vs. continuous readings, beat-to-beat BP, BP variability measurement, etc.). The content of the 1708-2104 IEEE standard is in accordance with that of ISO 81060-2:2009. However, the static accuracy is $\pm 5 \pm 8$ mmHg of 45 subjects instead of 85 subjects. For the purposes of the US Food and Drug Administration (FDA), an amendment was proposed for the standard, published in October 2019 as IEEE 1708A1-2019. The main amendments of the revision were that the numbers of subjects are 45 to 85, and that two clauses should be included concerning the estimation of noise reduction, and measurement site during rest. The IEEE submitted a combined IEEE 1708-2014 and 1708A-2019 to the FDA to request the recognized consensus standards. The FDA database provides an up-to-date list of voluntary standards, for which a supplier can make a declaration of conformity. The FDA partly recognizes IEEE standards for wearable cuffless BP monitoring devices excluding the following items [37]. No recognized clauses for observed measurements, which is in conflict with the ISO 81060-2 definition of special patient populations, detailed requirement for testing BP change, accuracy of dynamic changes in BP levels with no statistical justification for the proposed criteria, and risk management of wireless technologies used for communication. The IEEE standard association working group (P1708) will try to revise the comments mentioned.

3.3 The FDA

The FDA is responsible for protecting public health in the US by ensuring the safety and efficacy of human and veterinary drugs, biological products, and medical devices. The FDA operates in association with other regulatory bodies, such as the Association for the Advancement of Medical Instrumentation (AAMI), the

American National Standards Institute (ANSI), the IEEE, and the ISO, and adheres to international standards.

Based on ISO 81060-2, the FDA approved the commercially available BP monitors shown in Figure 4 and Table 1. However, the clinical utility of these devices is difficult to evaluate, although evidence of the clinical efficacy of the Caretaker device (Caretaker Medical LLC, Charlottesville, VA, USA) has been provided. Cuffless BP monitors could be used on a large scale to assess cardiovascular function during the ongoing Covid-19 pandemic, but to date there have been no reports of its use in this capacity.

Table 1. FDA-approved cuffless blood pressure monitors

Product name	ViSi Mobile sensor [38]	Caretaker [39]	Biobeat BB613W P [40]	BPro [41]
Company	Sotera Wireless	Caretaker Medical LLC	Biobeat Technologies Ltd.	Med Tach Inc.
FDA 510(k)	K112478 Mar. 22, 2012	K163255 April 21, 2017	K190792 Aug. 22, 2019	K173028 June 12, 2018
CE mark			2797	
Measurement principle	ECG + PPG	Pulse contour-based method Pressure sensor	Pulse contour-based method PPG	Tonometry
Calibration	Oscillometric	Cuff-based Nexfin (Edwards Life Sciences) Voltage clamp Continuous BP		Cuff-based
Measurement site	Finger	Finger	Wrist	Wrist
Measurement contents	SBP, DBP HR, pulse waveform	SBP, DBP HR, pulse waveform	SBP, DBP HR	SBP, DBP HR, pulse waveform
Duration	Continuous monitoring			
Communication	Bluetooth			
Validation	ISO 81060-2			
Reference		[9,13,42]	[43]	[44,45]



Figure 4. FDA-approved cuffless BP monitors. (a) ViSi, (b) Caretaker, (c) Biobeat, and (d) BPro.

3.4 The Pharmaceuticals and Medical Devices Agency (PMDA)

BP monitors should ideally be cuff-based according to Japanese Standard JIST1115. Several manufacturers have attempted to obtain class II certification by third parties, but none has been successful. The main purpose of cuffless BP devices is for screening and health check-ups, so clinical approval is mandatory.

3.5 Trends in medical device approval in Japan

Medical devices not intended to aid physicians in making a diagnosis still require medical approval. A new trend in device approval has emerged in Japan. On July 20, 2020, the Ministry of Health and Welfare added two new items to the Japanese Medical Device Nomenclature (JMDN), as shown in Table 2. On September 4, 2020, the Apple Watch, which has ECG and heart rate monitoring capabilities, was approved by the PMDA. The definition of “device” now includes “the information obtained from general-purpose digital apparatus such as portable watch, specially Apple watch can be used to analyze ECG waveform and to support the detection of diagnosis or find irregular heart rhythm notifications”. Here, the terms “general digital apparatus” and “support” are especially interesting. The Apple Watch can be purchased through the Apple Store, as opposed to from medical equipment specialists providing maintenance and management services.

The FDA approved Apple Electrocardiograph software for over-the-counter purchase following a de novo classification request. To obtain this classification, medical devices must demonstrate safety and efficacy with respect to the intended use.

Table 2. Japanese Medical Device Nomenclature (JMDN) newly introduced on July 20, 2020

Name	Home-use ECG	Home-use heart rate monitor
Device class	II	
Code	47699002	58884002
Global Harmonization Task Force (GHTF)	10	
Medical equipment requiring specialist maintenance and management	No	
Quality Management System (QMS)	Yes	
Classification	P01 diagnostic program	
Review category	General medical devices¥14 (program)	
Description	General purpose apparatus: ECG waveform is collected and processed to predict disease in conjunction with software. A recording system is included with the software.	General-purpose apparatus: heart rate data are collected and processed to predict irregular heart rhythms in conjunction with software. A recording system is included with the software.

4. The market for cuffless BP monitors and their clinical utility

Cuffless BP monitors are actively being sought. The clinical use of cuffless BP monitors has been described [46], but has not been approved by the PMDA or the Ministry of Health, Labor and Welfare of Japan. Third-party certification has been obtained only for the Somnotouch NIBP monitor (Somnomedics, Randersacker, Germany) [47]. Several inexpensive smart watches with embedded BP monitors are commercially available from online retailers. Based on personal communications, inexpensive smart watches do not meet the accuracy and validation requirements of cuff-based sphygmomanometers.

To be approved by regulatory authorities, clinical utility, safety, and accuracy must be demonstrated. No clinical protocol for cuffless BP monitors has been established, but this is important for clinical application.

5. Conclusion

The principles of cuffless BP monitors, which show promise for healthcare applications, were described. However, more detailed and precise evaluation of these devices is needed to confirm their clinical efficacy.

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