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IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices

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IEEE Std 1708™-2014

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IEEE-SA Standards Board

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Abstract: IEEE Std 1708™ establishes a normative definition of wearable cuffless blood pressure (BP) measuring devices and the objective performance evaluation of this kind of device. The standard is independent of the form of the device or the vehicle to which the device is attached or in which it is embedded. The standard is applicable to all types of wearable BP measurement devices including epidermal and unobtrusive BP devices that have different modes of operation (e.g., to measure short-term, long-term, snapshot, continuous, beat(s)-to-beat(s) BP, or BP variability). This standard is, however, limited to evaluation of devices that do not use a cuff during measurement and do not cover evaluation of all sphygmomanometers that are used with an occluding or inflatable cuff for the indirect determination of BP on the upper arm or wrist. This standard provides guidelines for manufacturers to qualify and validate their products, potential purchasers or users to evaluate and select prospective products, and health care professionals to understand the manufacturing practices on wearable BP devices.

Keywords: blood pressure measuring devices, cuffless, epidermal, hypertension, IEEE 1708™, performance evaluation, unobtrusive, wearable

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Participants

At the time this IEEE standard was completed, the Wearable Cuffless Blood Pressure Monitors Working Group had the following membership:

Yuan-Ting Zhang, *Chair*
Carole Carey, *Vice Chair*

Todd Cooper
Guy Dumont
Young Huh
S. Johnson
Emil Jovanov
Yongming Kim
Ikka Korhonen
J. Liu
Nigel Lovell
S. Luo
Ratko Magjarević
Jens Muehlsteff
K. S. Park
C. Poon
E. Solane
Kenji Sunagawa
H. L. Tai
Toshiyo Tamura
Z. H. Wang
Z. Y. Wu
I. R. F. Yan
Kenichi Yumakoshi

The following members of the individual balloting committee voted on this standard. Balloters may have voted for approval, disapproval, or abstention.

Arthur Astrin
Christopher Biernacki
Lyle Bullock
Keith Chow
Todd Cooper
Sourav Dutta
Kenneth Fuchs
Randall Groves
Voicu Groza
Kai Hassing
Werner Hoelzl
Noriyuki Ikeuchi
Atsushi Ito
Piotr Karocki
JongMuk Lee
Vincent Lipsio
Greg Luri
Iulian Profir
Sergio Rapuano
Bartien Sayogo
Veselin Skendzic
Kapil Sood
Walter Struppler
Chandrasekaran Subramaniam
John Vergis
Oren Yuen
Yuanting Zhang
Daidi Zhong

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Richard H. Hulett, *Past Chair*
Konstantinos Karachalios, *Secretary*

Peter Balma
Farooq Bari
Ted Burse
Clint Chaplin
Stephen Dukes
Jean-Philippe Faure
Gary Hoffman
Michael Janezic
Jeffrey Katz
Joseph L. Koepfinger*
David J. Law
Hung Ling
Oleg Logvinov
Ted Olsen
Glenn Parsons
Ron Petersen
Adrian Stephens
Peter Sutherland
Yatin Trivedi
Phil Winston
Don Wright
Yu Yuan

*Member Emeritus

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Introduction

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Hypertension is an important public-health challenge worldwide [B12]. In 2000, the estimated global number of adults with hypertension was 972 million, 26.4% of the adult population [B12]. Hypertension is important not only because of its high frequency but also because it is a major modifiable risk factor for cardiovascular and kidney disease [B12]. It was reported by WHO report 2002 [B2] that about 62% of strokes and 49% of heart attacks are caused by hypertension; 7.1 million die from hypertension, which is about 13% of the global fatality in total [B35].

Despite the risk people with hypertension may face, lack of awareness makes the situation difficult to control. The Joint National Committee 7th report (JNC 7) [B5] stated that the percentage of persons in whom hypertension is properly controlled (BP < 140 mmHG/90 mmHg) is limited; more than 30% of the hypertensive populations are still unaware of their condition and are therefore not receiving treatment.

BP measured in a clinical setting by a trained physician using the auscultative technique with the mercury column has been used as the standard parameter for clinical diagnosis for over 100 years [B25]. It is, however, becoming increasingly clear that this reading is often inadequate or even misleading to represent a patient's true BP status [B25]. On the other hand, ambulatory BP measurement (ABPM) and home (or self) BP measurement (HBPM) are shown to be superior to clinic BP measurement (CBPM) in predicting cardiovascular mortality [B6]. Comparing to CBPM, ABPM, and HBPM have the following advantages [B5], [B10], and [B16]: (1) eliminate the white-coat effect; (2) helpful to the assessment of clinic effects, drug effects, and work influence on BP; (3) better predict cardiovascular events and mortality; and (4) cost effective.

Therefore, in 2008, the American Heart Association (AHA), American Society of Hypertension (ASH), and Preventive Cardiovascular Nurses Association (PCNA) published a joint scientific statement that recommended using HBPM and further stated that HBPM should become a routine component of BP measurement in the majority of patients with known or suspected hypertension [B25].

Current devices employed for ABPM and HBPM are usually developed based on the oscillometric method, which has to be used with an inflatable cuff during measurement. Those systems have several drawbacks which hinder their popularizing in the broad masses. One of the major problems is the employment of an inflatable cuff during the measurement. Patients find the cuff pressure is intolerable, particularly those with very high BP and who need frequently repeated readings; petechiae of the upper arm and bruising under the inflating cuff may occur; sleep disturbance is fairly common.

Moreover, to have an accurate measurement, an appropriate cuff size must be selected according to the upper-arm circumference of users [B7]. Applying a cuff that is inappropriately small or large against the upper-arm circumference will contribute a substantially false elevation or reduction to the BP readings [B7]. Educating practitioners about appropriate sized cuffs for out-of-office BP measurement is necessary [B7] but increases the workload of the nurses.

Last but not least, the readings by conventional devices may be insufficient indicators for hypertension. Since only intermittent measurements of single snapshot readings are provided, current devices are incapable of recording the time varying BP or capturing the dynamic state of the cardiovascular system throughout the day [B15]. In addition, study of pathogenesis of hypertension reveals that the systolic hypertension is dependent on a series of changes in the vasculature, the most important of which is increased central arterial stiffness [B8]. Those signals are diffused by the relative imprecision in the techniques utilized by current devices [B8].

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In the past few years, there was an emerging interest in developing non-invasive BP measuring devices without an occluding cuff. Leading investigators in this field suggest that BP can be estimated indirectly from pulse transit time (PTT), which is a time period taken for the pulse wave to travel along the artery and arrive at the periphery, or parameters such as pulse arrival time (PAT), pulse wave velocity (PWV), pre-ejection period (PEP), etc., or their combinations. Models that relate BP, PTT, and other physiological parameters have been developed based on biological and mechanical properties of the cardiovascular system, e.g., elastic modulus, dimensions and stiffness of the intervening vessels. Based on these models, systems that use electrocardiographic, photoplethysmographic, and/or phonocardiographic sensors have been proposed for the cuffless and continuous measurement of BP [B15], [B8], [B4], [B28], [B27], and [B18].

Cuffless BP measuring devices successfully release the users from the cuffs and are therefore more suitable to be implemented into the HBPM or ABPM systems, where frequent measurements are usually needed. When they are designed as wearable devices, e.g., a shirt [B40] or watch [B26] and [B29], or integrated with furniture at home, e.g., a chair [B36] or bed [B9] for unobtrusive BP monitoring, or epidermal BP devices based on flexible-stretchable-printable electronics, the long-term and out-of-office monitoring becomes more comfortable and thus more attractive to the patients.

In addition, those devices have the great advantage of being not only capable of providing a snapshot of BP, but also potentially being usable for continuous BP monitoring. This special feature makes them superior to CBPM for the prompt identification of cardiovascular risk. Also, since signals (e.g., arterial stiffness) are implemented into the estimation model, the cuffless devices are potentially more capable of providing informative indication of the patient's health condition.

Nevertheless, since the physiology coefficients employed for BP estimation are subject-dependent, calibration is crucial to ensure the accuracy of the cuffless devices. A major challenge is to find a simple and accurate way to calibrate the device individually or estimate BP directly without a calibration procedure.

To date, there is no defined and independent standard for wearable cuffless devices. Existing standards for evaluating sphygmomanometers are intended only for devices that are used with an occluding cuff and, therefore, do not cover all aspects needed for the emerging cuffless devices. As a result, validating approaches of the cuffless techniques or devices vary largely from study to study.

Since cuffless approaches have become important in hypertension research in recent years, a section of this standard is devoted to the assessment process. It is crucial for the clinicians and engineers to join efforts in establishing an evaluation standard. Although existing standards for evaluating sphygmomanometers were developed for devices with an occluding or inflatable cuff, parts of them are still applicable to the evaluation of cuffless devices. The experiences of these current standards need to be carefully appreciated during the development of the new standard.

In typical settings of wearable cuffless devices, biosignals such as biopotentials and body motion signals are acquired by wearable sensors attached to a patient's body (or epidermal sensors on the skin) and sent to a nearby intermediate terminal for processing and/or relaying to a remote terminal. The wearable sensors may be equipped with a sensor of optical transmitter and detector, accelerometer, pulse meter, thermometer, pressure sensor, and galvanic skin reflex (GSR) electrodes to monitor the user's health conditions and/or movements. The signals collected from the sensors may also communicate with the personal server, which in turn connects to a mobile gateway for further signal processing and storage. Cellular communication capability may be added to expand service coverage to outdoors. Wireless body area networks (BSN) have great potential to be implemented into the settings.

For compatibility and convenience, the standard is organized to cover all of the following aspects: 1) device accuracy, 2) wearable sensors, 3) network with communication protocols if used, 4) electrical safety, and 5) stability.

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