P1708a

Submitter Email: c.carey@ieee.org
Type of Project: Amendment to IEEE Standard 1708-2014
PAR Request Date: 04-May-2018
PAR Approval Date: 14-Jun-2018
PAR Expiration Date: 31-Dec-2022
Status: PAR for an Amendment to an existing IEEE Standard
Root Project: 1708-2014

1.1 Project Number: P1708a
1.2 Type of Document: Standard
1.3 Life Cycle: Full Use

2.1 Title: Standard for Wearable Cuffless Blood Pressure Measuring Devices

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3.1 Working Group: Wearable Cuffless Blood Pressure Monitors (EMB/Stds Com/WC-BPM)
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3.2 Sponsoring Society and Committee: IEEE Engineering in Medicine and Biology Society/Standards Committee (EMB/Stds Com)
Contact Information for Sponsor Chair
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Contact Information for Standards Representative
None

4.1 Type of Ballot: Individual
4.2 Expected Date of submission of draft to the IEEE-SA for Initial Sponsor Ballot: 08/2018
4.3 Projected Completion Date for Submittal to RevCom
Note: Usual minimum time between initial sponsor ballot and submission to Revcom is 6 months.: 12/2018

5.1 Approximate number of people expected to be actively involved in the development of this project: 30
5.2.a. Scope of the complete standard: The intent of this standard is to establish objective performance evaluation of wearable, cuffless blood pressure (BP) measuring devices. 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 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 does 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.

5.2.b. Scope of the project: The intent of this amendment is to (1) clarify further the subject selection of sample size of 45 in the clinical study, (2) look into the results of the validation study with respect to the patient's body position and activity level for their applicability to ambulatory patients, and (3) address the issue of motion artifact.

5.3 Is the completion of this standard dependent upon the completion of another standard: No
5.4 Purpose: There is currently no defined, independent standard for wearable cuffless BP measurement devices, which have drawn growing interest in recent years. 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 wearable devices. 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.

5.5 Need for the Project: It is imperative to establish a standard especially for the cuff-less wearable BP measuring devices. The reasons for this urgent need are as follows: (1) based on many studies, it is found that the existing standards for validating the conventional BP devices do not agree with each other in all circumstances; (2) the standards set up for conventional devices fall short of accurate evaluation for the newly developed wearable BP measurement devices, since the new devices use completely different measurement techniques from those of the conventional cuff-based ones. These techniques enable the new devices to be noninvasive, miniature in size, low-power consumption, cost-effective, durable and have the potential ability to measure the beat-to-beat BP continuously; (3) in existing technology, the BP record obtained by an observer using stethoscope and mercury sphygmomanometer simultaneously is used as the reference for the calibration of cuffless BP devices. However, observers themselves are vulnerable to errors, although they are well trained professionally. Besides, training is expensive and time consuming. Therefore, there is a clear need for a new standard based on automated technology.

5.6 Stakeholders for the Standard: The stakeholders will be the wearable BP devices manufacturers, potential purchasers and users including hospitals, health care professionals, and patients suffering from hypertension, especially those who need daily BP detection or monitoring.

Intellectual Property
6.1.a. Is the Sponsor aware of any copyright permissions needed for this project?: No
6.1.b. Is the Sponsor aware of possible registration activity related to this project?: No

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7.1 Are there other standards or projects with a similar scope?: No
7.2 Joint Development
Is it the intent to develop this document jointly with another organization?: No

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8.1 Additional Explanatory Notes: The standard was approved in 2014. Since then new information from research in this emerging technology area have been reported in literature and conferences as well as experience from users. A revision of the standard to make it more robust requires new input and more participation from various stakeholders such as academia, industry and government. An updated standard will benefit the users.

[5.2.b] Post publication of IEEE 1708-2014, the Sponsor and on behalf of the WG submitted the standard for consideration as an FDA-recognized consensus standard. Early last year we received the FDA reply letter stating 3 specific areas for the Standard to address. FDA further stated that, "If/when the standard is revised, we can review it at that time for recognition upon request."