IEEE STANDARDS ASSOCIATION

IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices

Amendment 1

IEEE Engineering in Medicine and Biology Society

Developed by the
Standards Committee

IEEE
3 Park Avenue
New York, NY 10016-5997
USA

IEEE Std 1708a™-2019
(Amendment to
IEEE Std 1708™-2014)

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Approved 13 June 2019

IEEE SA Standards Board

Abstract: Clarifying and furthering the subject selection of the sample size in the clinical study; looking 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 addressing the issues of motion artifact is covered in the amendment.

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

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Introduction

This introduction is not part of IEEE Std 1708a-2019, IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices—Amendment 1.

This amendment addresses the following:

- Clarifies and increases the subject selection of the sample size in the clinical study.
- Looks into the results of the validation study with respect to the patients body position and activity level for their applicability to ambulatory patients.
- Addresses the issue of motion artifact.
- Provides rationale and support for the sample size included in the standard and include information to account for potential correlations in repeated measurments in the analysis methods.
- Clarifies the methods in the standard are applicable to static testing and for devices that may be used in dynamic conditions when addional testing may be necessary.
- Incorporates performance reporting for patient-specific parameters (e.g., age, height, and weight) when used in the calculation of blood pressure by wearable, cuffless blood pressure measuring devices.
- Provides clarity when additional testing may be needed.

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