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

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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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Amendment 1

NOTE—The editing instructions contained in this amendment define how to merge the material contained therein into the existing base standard and its amendments to form the comprehensive standard.

The editing instructions are shown in ***bold italic***. Four editing instructions are used: change, delete, insert, and replace. ***Change*** is used to make corrections in existing text or tables. The editing instruction specifies the location of the change and describes what is being changed by using ~~strikethrough~~ (to remove old material) and underscore (to add new material). ***Delete*** removes existing material. ***Insert*** adds new material without disturbing the existing material. Insertions may require renumbering. If so, renumbering instructions are given in the editing instruction. ***Replace*** is used to make changes in figures or equations by removing the existing figure or equation and replacing it with a new one. Editing instructions, change markings, and this NOTE will not be carried over into future editions because the changes will be incorporated into the base standard.

Cross references that refer to clauses, tables, equations, or figures not covered by this amendment are highlighted in green.[1]

4. Performance evaluation

4.1 Summary

Change item b) as follows:

b) Subject selection. Twenty subjects are recruited at Phase 1of the assessment, and devices passing the criteria of this phase will proceed to Phase 2, where an additional ~~25~~ 65 subjects are recruited. The characteristic of recruited subjects should follow the requirement stated in this standard. Correlation between errors in measurements from the same subject is considered after Phase 1 to determine if additional subjects (more than 65) may be needed in Phase 2, see 4.5.3.

Replace Figure 1 with new Figure 1 as follows:

[1] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

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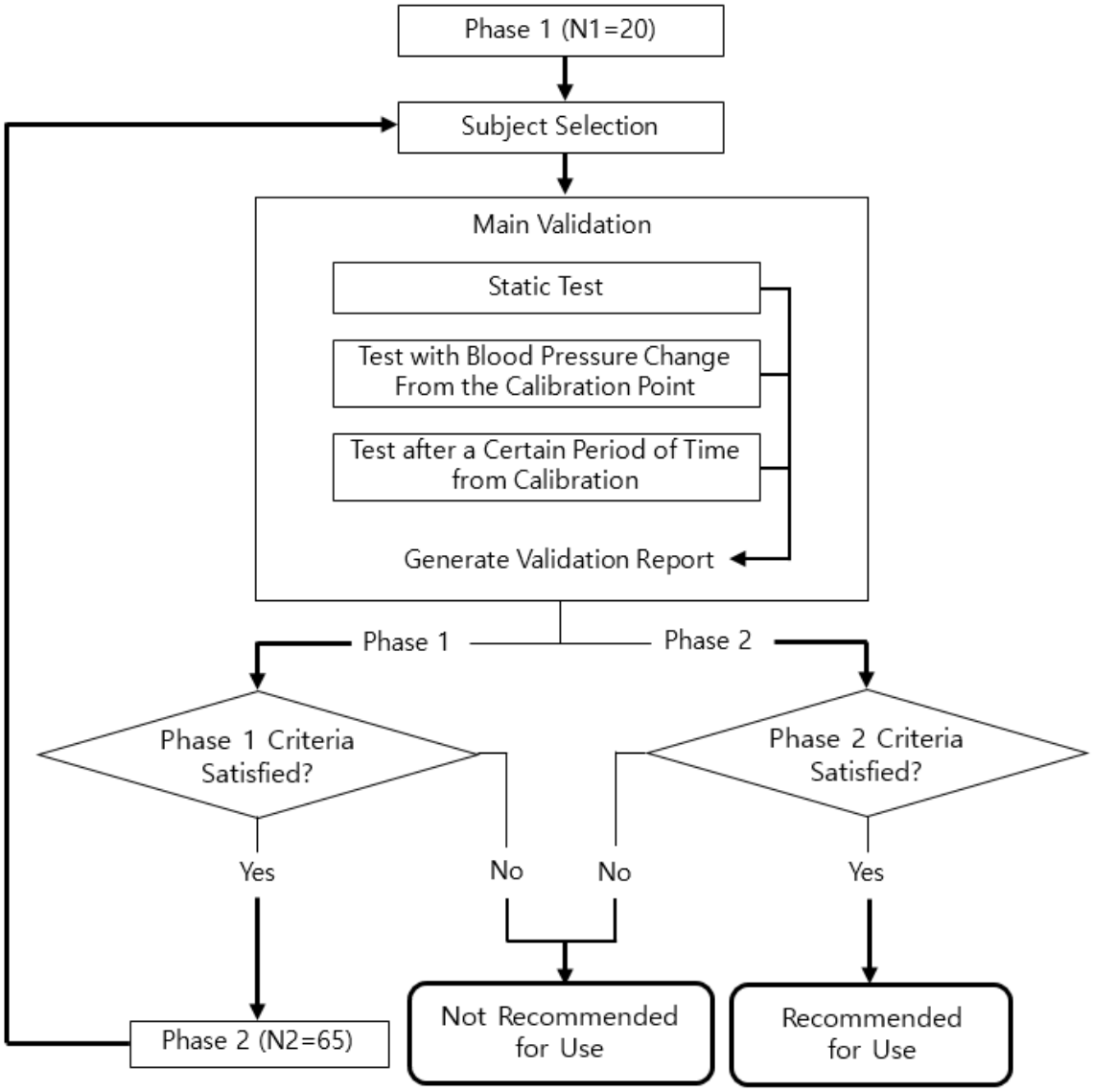

Figure 1—Summarized validation procedure

4.2 Observer training and measurement

4.2.2 Observer measurement

Change fourth paragraph as follows:

During the validation procedure in 4.4, BP readings from the test device and the ~~observer~~ reference device should be collected either simultaneously or sequentially according to the concrete conditions described in 4.2.2.1 and 4.2.2.2. At least 30 s should be allowed after observer measurement to avoid venous congestion. When reference and test device measurements are conducted sequentially (see 4.2.2.2), no more than 60 s should be allowed after observer measurement or variability may be increased.

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