

IEEE Standard for Wearable, Cuffless Blood Pressure Measuring Devices

Amendment 1

IEEE Engineering in Medicine and Biology Society

Developed by the
Standards Committee

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Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

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

The Institute of Electrical and Electronics Engineers, Inc.
3 Park Avenue, New York, NY 10016-5997, USA

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PDF: ISBN 978-1-5044-5985-3 STD23762
Print: ISBN 978-1-5044-5986-0 STDPD23762

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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 measurements in the analysis methods.
- Clarifies the methods in the standard are applicable to static testing and to devices that may be used in dynamic conditions when additional 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.

Contents

4. Performance evaluation	9
4.1 Summary.....	9
4.2 Observer training and measurement	10
4.3 Subject selection	11
4.4 Validation procedure	13
4.5 Validation criteria	14
4.6 Data reporting.....	16
6. Device function and performance during ambulatory conditions and patient motion.....	19
6.1 Robustness to motion induced noise.....	19
6.2 Device design in relation to ambulatory conditions and motion.....	19
6.3 Performance during ambulatory and motion conditions.....	20
Annex C (informative) Posture of subject during validation test	23
Annex D (informative) Justification of sample size	24
D.1 Introduction	24
D.2 Experimental findings of estimation errors in cuffless BP measuring device	25
D.3 Sample size determination based on MAD.....	26
D.4 Effect of repeated measurements from subjects.....	29
D.5 Confounding factors and special patient conditions	30
Annex E (informative) Bibliography.....	32