Wearable electronic devices and technologies - Part 402-3: Performance measurement of fitness wearables - Test methods for the determination of the accuracy of heart rate

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NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 63203-402-3:2024 sisaldab Euroopa standardi EN IEC 63203-402-3:2024 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 63203-402-3:2024 consists of the English text of the European standard EN IEC 63203-402-3:2024.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
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ICS 31.020

EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN IEC 63203-402-3

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English Version

Wearable electronic devices and technologies - Part 402-3: Performance measurement of fitness wearables - Test methods for the determination of the accuracy of heart rate (IEC 63203-402-3:2024)

Technologies et dispositifs électroniques prêts-à-porter - Partie 402-3: Mesurage de l'aptitude à la fonction des dispositifs prêts-à-porter pour les activités de mise en forme - Méthodes d'essai pour déterminer l'exactitude des mesures de la fréquence cardiaque (IEC 63203-402-3:2024)

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European foreword

The text of document 124/247/FDIS, future edition 1 of IEC 63203-402-3, prepared by IEC/TC 124 "Wearable electronic devices and technologies" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 63203-402-3:2024.

The following dates are fixed:

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IEC 63203-402-3

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INTERNATIONAL STANDARD

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Technologies et dispositifs électroniques prêts-à-porter – Partie 402-3: Mesurage de l'aptitude à la fonction des dispositifs prêts-à-porter pour les activités de mise en forme – Méthodes d'essai pour déterminer l'exactitude des mesures de la fréquence cardiaque

IEC 63203-402-3:2024-01(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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WEARABLE ELECTRONIC DEVICES AND TECHNOLOGIES –

Part 402-3: Performance measurement of fitness wearables – Test methods for the determination of the accuracy of heart rate

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IEC 63203-402-3 has been prepared by IEC technical committee 124: Wearable electronic devices and technologies. It is an International Standard.

The text of this International Standard is based on the following documents:

Draft	Report on voting
124/247/FDIS	124/259/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

A list of all parts in the IEC 63203 series, published under the general title *Wearable electronic devices and technologies*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
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INTRODUCTION

The intent of this document is to evaluate the accuracy of wearables that measure heart rate with a photoplethysmogram (PPG) sensor.

Heart rate is a widely used physiological variable that non-invasively assesses the cardiac autonomic nervous system by measuring changes in the cardiac rhythm through time. Heart rate can be measured from an electrocardiographic signal (ECG). However, the use of physiological signals other than ECG to extract heart rate information is common. The term “pulse rate” has been used in literature to reference heart rate obtained through PPG.

Researchers have been using PPG to extract as much information as possible given its widespread use in clinical and everyday activities. PPG is a simple, non-invasive, optical measurement technique used for the detection of blood volume changes in peripheral tissue. Pulse rate has been treated as a synonym to heart rate and these two terms are often used interchangeably by manufacturers in describing device features to consumers. However, it is possible that the relationship or differences between heart rate and pulse rate will not be clear based on intent. Because some countries and manufacturers can use the term pulse rate rather than heart rate, the reader is encouraged to clarify preferential term, if the term is being used as a synonym, and testing expectations.

Heart rate measures the rate of contractions or heartbeats whereas pulse rate measures changes in blood pressure. For an unhealthy person, these two factors could be different. The reader is reminded that according to 4.4.1 of this document, test participants are asked to fill out the Physical Activity Readiness Questionnaire (PAR-Q) to determine their eligibility for the comparative test. Anyone deemed unhealthy per the PAR-Q will be disqualified from testing.

WEARABLE ELECTRONIC DEVICES AND TECHNOLOGIES –

Part 402-3: Performance measurement of fitness wearables – Test methods for the determination of the accuracy of heart rate

1 Scope

This part of IEC 63203 specifies terms, a measurement protocol, and a test to evaluate the accuracy of wearables that measure heart rate with a photoplethysmogram (PPG) sensor. While this document can be used to measure a variety of different devices claiming to report heart rate, care will be taken when testing in countries that differentiate between heart rate and pulse rate. This measurement protocol is not intended to evaluate medical devices associated with the IEC 60601 series or ISO 80601 series.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

3.1.1
heart rate
HR
speed of the heartbeat measured by the number of contractions of the heart per unit time (typically per minute), or frequency of contractions of the ventricles

3.1.2
body mass index
BMI
person’s weight divided by their height in meters squared

Note 1 to entry: It is expressed in kilograms per square meter.

3.1.3
heart rate monitoring device
HRMD
device that captures pulsation signals and calculates the pulse rate at regular intervals

Note 1 to entry: HRMD is used in this document for PPG wearable devices under test only.

3.1.4
plethysmograph
device which produces a plethysmogram