ICS 31.020 SLOVENSKÁ TECHNICKÁ NORMA Máj 2024

STN	**Nositeľné elektronické zariadenia a technológie Časť 402-3: Meranie výkonnosti nositeľných zariadení používaných pri posilňovaní a udržiavaní telesnej kondície Skúšobné metódy na stanovenie presnosti merania srdcovej frekvencie**	**STN EN IEC 63203-402-3** 35 9350

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/24

Obsahuje: EN IEC 63203-402-3:2024, IEC 63203-402-3:2024

obsahuje farebné strany

138495

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 63203-402-3

February 2024

ICS 31.020

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)

Tragbare elektronische Geräte und Technologien - Teil 402-3: Leistungsmessverfahren für Fitness-Wearables - Testmethoden für die Bestimmung der Genauigkeit der Herzfrequenz (IEC 63203-402-3:2024)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 63203-402-3:2024 E

EN IEC 63203-402-3:2024 (E)

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:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2024-11-13
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2027-02-13

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In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601 (series)	NOTE	Approved as EN 60601 (series)
ISO 80601 (series)	NOTE	Approved as EN ISO 80601 (series)

IEC 63203-402-3

Edition 1.0 2024-01

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 31.020 ISBN 978-2-8322-7962-5

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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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,
- withdrawn, or
- revised.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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.