

STN	Nositel'né 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

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)

This European Standard was approved by CENELEC on 2024-02-13. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.



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

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- latest date by which the national standards conflicting with the (dow) 2027-02-13 document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 63203-402-3:2024 was approved by CENELEC as a European Standard without any modification.

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

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

**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**





THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2024 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, ...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch

Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC - webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, ...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 500 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 25 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.



IEC 63203-402-3

Edition 1.0 2024-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

**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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 31.020

ISBN 978-2-8322-7962-5

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

CONTENTS

FOREWORD	3
INTRODUCTION	5
1 Scope	6
2 Normative references	6
3 Terms, definitions and abbreviated terms	6
3.1 Terms and definitions	6
3.2 Abbreviated terms	7
4 Test methods and procedures	7
4.1 General	7
4.2 Other considerations	7
4.3 Setup and configuration	8
4.3.1 PPG simulator test	8
4.3.2 Comparative test with a reference ECG device	8
4.4 Participant considerations	9
4.4.1 General considerations	9
4.4.2 Skin tones	9
4.4.3 BMI range	10
4.4.4 Gender balance	10
4.4.5 Skin influences	10
4.4.6 Age	10
4.4.7 Clothing and shoes	10
4.5 Comparative test protocols	10
4.5.1 Test environment	10
4.5.2 Test preparation	10
4.5.3 Test protocols	11
5 Accuracy	13
5.1 HRMD accuracy for PPG simulator test	13
5.2 Heart rate accuracy for comparative test with a reference ECG device	13
6 Test report	14
6.1 General	14
6.2 PPG simulator test results	14
6.3 HRMD properties	14
6.4 Reference device (chest type ECG)	14
6.5 Descriptions of participant characteristics	14
6.6 Test conditions	15
6.7 Detailed description of each test protocol	15
6.8 Test results	15
Annex A (informative) Example of PAR-Q	16
Bibliography	17
Figure 1 – PPG simulator circuit and setup	8
Figure 2 – Example of PPG to be tested and reference ECG devices	9

INTERNATIONAL ELECTROTECHNICAL COMMISSION

WEARABLE ELECTRONIC DEVICES AND TECHNOLOGIES –

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <https://patents.iec.ch>. IEC shall not be held responsible for identifying any or all such patent rights.

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.

koniec náhľadu – text d'alej pokračuje v platenej verzii STN