

SLOVENSKI STANDARD oSIST prEN IEC 63203-402-3:2022

01-december-2022

Nosljive elektronske naprave in tehnologije - 402-3. del: Metoda merjenja zmogljivosti nosljivih izdelkov - Serija 2: Točnost ugotavljanja srčnega utripa

Wearable electronic devices and technologies - Part 402-3: Performance measurement method of wearables - Series 2: Accuracy of Heart Rate Determination

iTeh STANDARD PREVIEW (standards iteh ai)

Technologies et dispositifs électroniques prêts-à-porter - Partie 402-3: Méthode de mesure de l'aptitude à la fonction des technologies et dispositifs électroniques prêts-à-porter - Série 2: Exactitude des mesures de la fréquence cardiaque

62df282423/osist-pren-iec-63203-402-3-2022

Ta slovenski standard je istoveten z: prEN IEC 63203-402-3:2022

<u>ICS:</u>

31.080.99Drugi polprevodniški elementi Other semiconductor devices59.080.80Inteligentne tekstilijeSmart textiles

oSIST prEN IEC 63203-402-3:2022 en

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>oSIST prEN IEC 63203-402-3:2022</u> https://standards.iteh.ai/catalog/standards/sist/fd6099ce-41f7-471d-bf54b962df282423/osist-pren-iec-63203-402-3-2022



124/196/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: IEC 63203-402-3 ED1 DATE OF CIRCULATION: C

CLOSING DATE FOR VOTING: 2023-01-06

SUPERSEDES DOCUMENTS:

2022-10-14

124/167/CD, 124/193/CC

IEC TC 124 : WEARABLE ELECTRONIC DEVICES AND TECHNOLOGIES				
SECRETARIAT:	SECRETARY:			
Korea, Republic of	Mr Jae Yeong Park			
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD:			
	Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.			
FUNCTIONS CONCERNED: TEM STANDA	QUALITY ASSURANCE			
SUBMITTED FOR CENELEC PARALLEL VOTING	NOT SUBMITTED FOR CENELEC PARALLEL VOTING			
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.	<u>3203-402-3:2022</u> ards/sist/fd6099ce-41f7-471d-bf54- 1-iec-63203-402-3-2022			

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Wearable electronic devices and technologies - Part 402-3: Performance measurement method of wearables - Series 2: Accuracy of Heart Rate Determination

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

Copyright © **2022 International Electrotechnical Commission, IEC**. All rights reserved. It is permitted to download this electronic file, to make a copy and to print out the content for the sole purpose of preparing National Committee positions. You may not copy or "mirror" the file or printed version of the document, or any part of it, for any other purpose without permission in writing from IEC.

4 FOREWORD	1 2 3			CONTENTS	
5 1 Scope 5 6 2 Normative references 5 7 3 Terms and definitions 5 8 3.1 heart rate 5 9 3.2 body mass index 5 10 3.4 plethysmograph 5 11 3.4 plethysmograph 5 12 3.5 photoplethysmogram 5 13 4 plethysmogram 5 14 General 6 14 1 General 6 14 1 General 6 15 4.7 Detter considerations 6 16 4.2 Other considerations 6 16 4.3 Setup and configuration 6 16 4.3.1 PPG simulator test 6 16 4.3.2 Comparative test with a reference ECG device 7 17 4.4 Participant considerations 8 21 4.4.1 General considerations 8 22 4.4.3 BMI Range 9 24 4	3	F	OREWO)RD	3
6 2 Normative references 5 7 3 Terms and definitions 5 8 3.1 heart rate 5 9 3.2 body mass index 5 11 3.4 plethysmograph 5 12 3.5 photoplethysmogram 5 13 4 present methods and procedures 6 14 1 General 6 15 4.2 Other considerations 6 16 4.2 Other considerations 6 15 4.2 Other considerations 6 16 4.3 Setup and configuration 6 17 4.4 Participant considerations 8 20 4.4.1 General considerations 8 21 4.4.1 General considerations 8 22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 24 4.5 Comparative test protocols 9 26 4.5.1 Test provo	5	1	Scope	e	5
7 3 Terms and definitions 5 8 3.1 heart rate 5 9 3.2 body mass index 5 10 3.3 heart rate monitoring device 5 11 3.4 plethysmograph 5 12 3.5 photoplethysmogram 5 13 4 Test methods and procedures 6 14 4.1 General 6 15 4.2 Other considerations 6 16 4.2 Other considerations 6 16 4.3 Setup and configuration 6 16 4.3 Setup and considerations 8 17 4.3.1 PPG simulator test 6 18 4.3.2 Comparative test with a reference ECG device 7 19 4.4.1 General considerations 8 20 4.4.3 BMI Range 8 21 4.4.3 BMI Range 8 22 4.4.3 BMI Range 9 23 4.4.4 Gender balance 9 24 4.5 Comparative test p	6	2	Norma	ative references	5
8 3.1 heart rate 5 9 3.2 body mass index 5 10 3.3 heart rate monitoring device 5 11 3.4 plethysmograph 5 12 3.5 photoplethysmogram 5 13 4 Test methods and procedures 6 14 4.1 General 6 15 4.2 Other considerations 6 16 4.3 Setup and configuration 6 16 4.3 Comparative test with a reference ECG device 7 19 4.4 Participant considerations 8 21 4.4.1 General considerations 8 21 4.4.2 Skin Tones 8 21 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 25 4.6 M Age 9 26 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 20 4.5.3 Test protocols 10 215 Accuracy 12	7	3	Terms	s and definitions	5
0 3.2 body mass index 5 10 3.3 heart rate monitoring device 5 11 3.4 plethysmograph 5 12 3.5 photoplethysmogram 5 13 4 Test methods and procedures 6 14 1.1 General 6 15 4.1 General 6 16 4.2 Other considerations 6 17 4.3.1 PPG simulator test 6 18 4.3.2 Comparative test with a reference ECG device 7 19 4.4 Participant considerations 8 20 4.4.1 General considerations 8 21 4.4.2 Skin Tones 8 22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 25 4.6 M Age	, 8	Ũ	3 1 he	e una deminiere	5
0 3.3 heart rate monitoring device 5 11 3.4 plethysmograph 5 12 3.5 photoplethysmograph 5 13 4 Test methods and procedures 6 14 4.1 General 6 14 4.1 General 6 14 4.1 General 6 15 4.2 Other considerations 6 16 4.2 Other considerations 6 17 4.3.1 PPG simulator test 6 18 4.3.2 Comparative test with a reference ECG device 7 19 4.4 Participant considerations 8 21 4.4.2 Skin Tones 8 22 4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.5 Skin influences 9 25 4.6 Mage 9 26 4.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.3	a		3.2 hor	di rate	5
3.4 plethysmograph 5 3.5 photoplethysmogram 5 3.4 Test methods and procedures 6 4.1 General 6 4.2 Other considerations 6 4.3 Setup and configuration 6 4.3 Setup and configuration 6 4.3 Setup and configuration 6 4.4 Participant considerations 6 4.4 Participant considerations 8 4.4.1 General considerations 8 4.4.2 Skin Tones 8 2.4.3 BMI Range 8 2.4.4.3 BMI Range 8 2.4.4.5 Skin influences 9 4.4.5 Skin influences 9 4.4.6 Im Age 9 4.4.7 Clothing and shoes 9 4.5.1 Test environment 9 9 4.5.2 Test preparation 9 9 4.5.3 Test protocols 10 10 5 Accuracy 12 12 5.1 HRMD accuracy 12 13 Annex A (informative) Example of PAR-Q questionnaire 15 8 Bibliography 16 7 Figure 1 – A PPG simulator cir	10		3.3 hea	ay mass mass and a second s	5
12 3.5 photoplethysmogram 5 13 4 Test methods and procedures 6 14 4.1 General 6 15 4.2 Other considerations 6 16 4.3 Setup and configuration 6 17 4.3.1 PPG simulator test 6 18 4.3.2 Comparative test with a reference ECG device 7 19 4.4 Participant considerations 8 20 4.4.1 General considerations 8 21 4.4.2 Skin Tones 8 22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 25 4.4.6 Im Age 9 26 4.4.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 30 4.5.3 Test protocols 10 31 5 Accuracy 12 32 5.1 HRMD accuracy 12 33 5 Annex A (informative) Example of PAR-Q questionn	11		3.4 ple	ethvsmograph	5
13 4 Test methods and procedures 6 14 4.1 General 6 15 4.2 Other considerations 6 16 4.3 Setup and configuration 6 16 4.3 Setup and configuration 6 16 4.3 Setup and configuration 6 17 4.3.1 PPG simulator test 6 18 4.3.2 Comparative test with a reference ECG device 7 14 Participant considerations 8 8 20 4.4.1 General considerations 8 21 4.4.2 Skin Tones 8 22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.5 Skin influences 9 24 4.5 Comparative test protocols 9 24 4.5 Comparative test protocols 9 25 Comparative test protocols 9 9 26 4.5.1 Test protocols 10 27 4.5.2	12		3.5 ph	otoplethysmogram	5
14 4.1 General	13	4	Test r	methods and procedures	6
15 4.2 Other considerations 6 16 4.3 Setup and configuration 6 17 4.3.1 PPG simulator test 6 18 4.3.2 Comparative test with a reference ECG device 7 19 4.4 Participant considerations 8 20 4.4.1 General considerations 8 21 4.4.2 Skin Tones 8 22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 24 4.4.5 Skin influences 9 25 4.4.6 Age 9 26 4.4.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 29 4.5.3 Test protocols 10 31 5 Accuracy 12 31 5.2 Heart rate accuracy <t< td=""><td>14</td><td></td><td>4.1</td><td>General</td><td>6</td></t<>	14		4.1	General	6
16 4.3 Setup and configuration 6 17 4.3.1 PPG simulator test 6 18 4.3.2 Comparative test with a reference ECG device 7 19 4.4 Participant considerations 8 20 4.4.1 General considerations 8 21 4.4.2 Skin Tones 8 23 4.4.3 BMI Range 8 24 4.4.5 Skin influences 9 24 4.4.5 Skin influences 9 24 4.4.7 Clothing and shoes 9 25 4.4.6 Age. 9 26 4.4.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test proparation 9 30 4.5.3 Test protocols 10 31 5 Accuracy 12 31 5.2 Heart rate accuracy 12 31 5.2 Heart rate accuracy	15		4.2	Other considerations	6
17 4.3.1 PPG simulator test 6 18 4.3.2 Comparative test with a reference ECG device 7 19 4.4 Participant considerations 8 20 4.4.1 General considerations 8 21 4.4.2 Skin Tones 8 22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 24 4.4.5 Skin influences 9 25 4.4.6 Age 9 26 4.4.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 30 4.5.3 Test protocols 10 31 5 Accuracy 12 32 5.1 HRMD accuracy 12 33 5.2 Heart rate accuracy 12 34 6 Test report 13	16		4.3	Setup and configuration	6
18 4.3.2 Comparative test with a reference ECG device 7 19 4.4 Participant considerations 8 20 4.4.1 General considerations 8 21 4.4.2 Skin Tones 8 22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 24 4.6 Age 9 24 4.6 Age 9 25 4.6 Age 9 26 4.5.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 30 4.5.3 Test protocols 10 31 5 Accuracy 12 32 5.1 HRMD accuracy 12 33 5.2 Heart rate accuracy 12 34 6 Test report 13 35	17		4.3.1	1 PPG simulator test	6
19 4.4 Participant considerations 8 20 4.4.1 General considerations 8 21 4.4.2 Skin Tones 8 22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 24 4.4.5 Skin influences 9 25 4.4.6 Influences 9 26 4.4.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 30 4.5.3 Test protocols 10 31 5 Accuracy 12 32 5.1 HRMD accuracy 12 33 Annex A (informative) Example of PAR-Q questionnaire 13 34 Annex A (informative) Example of PAR-Q questionnaire 15 36 Bibliography 16 17 37 Figure 1 – A PPG simulator cir	18		4.3.2	2 Comparative test with a reference ECG device	7
20 4.4.1 General considerations 8 21 4.4.2 Skin Tones 8 22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 24 4.4.5 Skin influences 9 25 4.4.6 Age 9 26 4.4.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 30 4.5.3 Test protocols 10 31 5 Accuracy 12 32 5.1 HRMD accuracy 12 33 5.2 Heart rate accuracy 12 34 6 Test report 13 35 Annex A (informative) Example of PAR-Q questionnaire 15 36 Bibliography 16 17 37 Figure 1 – A PPG simulator circuit and setup 7 <	19		4.4	Participant considerations	8
21 4.4.2 Skin Tones 8 22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 25 4.4.6 Age. 9 26 4.4.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 30 4.5.3 Test protocols 10 31 5 Accuracy 12 32 5.1 HRMD accuracy 12 33 5.2 Heart rate accuracy 12 34 6 Test report 13 35 Annex A (informative) Example of PAR-Q questionnaire 15 36 Bibliography 16 37 Figure 1 – A PPG simulator circuit and setup 7 38 Figure 2 – Wearing both a PPG and a chest type ECG wearable devices 8 41 42 41 42 </td <td>20</td> <td></td> <td>4.4.1</td> <td>1 General considerations</td> <td>8</td>	20		4.4.1	1 General considerations	8
22 4.4.3 BMI Range 8 23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 25 4.4.6 Age 9 26 4.4.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 29 4.5.3 Test protocols 10 30 4.5.3 Test protocols 10 31 5 Accuracy 12 32 5.1 HRMD accuracy 12 33 5.2 Heart rate accuracy 12 34 6 Test report 13 35 Annex A (informative) Example of PAR-Q questionnaire 15 36 Bibliography 16 37 Figure 1 – A PPG simulator circuit and setup 7 38 Figure 2 – Wearing both a PPG and a chest type ECG wearable devices 8 41 42 4 4 </td <td>21</td> <td></td> <td>4.4.2</td> <td>2 Skin Tones</td> <td>8</td>	21		4.4.2	2 Skin Tones	8
23 4.4.4 Gender balance 9 24 4.4.5 Skin influences 9 25 4.4.6 Mage 9 26 4.4.7 Clothing and shoes 9 27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 30 4.5.3 Test protocols 10 31 5 Accuracy 12 32 5.1 HRMD accuracy 12 33 5.2 Heart rate accuracy 12 34 6 Test report 13 35 Annex A (informative) Example of PAR-Q questionnaire 15 36 Bibliography 16 37 Figure 1 – A PPG simulator circuit and setup 7 38 Figure 2 – Wearing both a PPG and a chest type ECG wearable devices 8 41 42 41	22		4.4.3	BMI Range	8
24 4.4.5 Skin influences AST. nr.EN.HEC.61203.402.12022 9 25 4.4.6 http Age.minitation.initiation/standards/standard	23		4.4.4	4 Gender balance	9
25 4.4.6 http Agedards.itch.ai/catalog/standards/standar	24		4.4.5	5 Skin influence <u>s SIST. pr.F.N.IEC. 63203-402-3-2022</u>	9
264.4.7Clothing and shoes9274.5Comparative test protocols9284.5.1Test environment9294.5.2Test preparation9304.5.3Test protocols10315Accuracy12325.1HRMD accuracy12335.2Heart rate accuracy12346Test report1335Annex A (informative)Example of PAR-Q questionnaire1536Bibliography1637Figure 1 – A PPG simulator circuit and setup738Figure 2 – Wearing both a PPG and a chest type ECG wearable devices8404142	25		4.4.6	³ http Age and ards, iteh, ai/catalog/standards/sist/fd6099cc-41f7-471d-bf54	9
27 4.5 Comparative test protocols 9 28 4.5.1 Test environment 9 29 4.5.2 Test preparation 9 30 4.5.3 Test protocols 10 31 5 Accuracy 12 32 5.1 HRMD accuracy 12 32 5.1 HRMD accuracy 12 33 5.2 Heart rate accuracy 12 34 6 Test report 13 35 Annex A (informative) Example of PAR-Q questionnaire 15 36 Bibliography 16 7 37 Figure 1 – A PPG simulator circuit and setup 7 38 Figure 2 – Wearing both a PPG and a chest type ECG wearable devices 8 40 41 42	26		4.4.7	7 Clothing and shoes 23/051st-pren-iec-63203-402-3-2022	9
28 4.5.1 Test environment	27		4.5	Comparative test protocols	9
29 4.5.2 Test preparation .9 30 4.5.3 Test protocols .10 31 5 Accuracy .12 32 5.1 HRMD accuracy .12 33 5.2 Heart rate accuracy .12 34 6 Test report .13 35 Annex A (informative) Example of PAR-Q questionnaire .15 36 Bibliography .16 37	28		4.5.1	I Test environment	9
30 4.5.3 Test protocols	29		4.5.2	2 Test preparation	9
31 5 Accuracy	30	_	4.5.3	3 Test protocols	10
32 5.1 HRMD accuracy 12 33 5.2 Heart rate accuracy 12 34 6 Test report 13 35 Annex A (informative) Example of PAR-Q questionnaire 15 36 Bibliography 16 37 7 Figure 1 – A PPG simulator circuit and setup 7 38 Figure 2 – Wearing both a PPG and a chest type ECG wearable devices 8 40 41 42	31	5	Accur	racy	12
33 5.2 Heart rate accuracy 12 34 6 Test report 13 35 Annex A (informative) Example of PAR-Q questionnaire 15 36 Bibliography 16 37 Figure 1 – A PPG simulator circuit and setup 7 38 Figure 2 – Wearing both a PPG and a chest type ECG wearable devices 8 40 41 42	32		5.1	HRMD accuracy	12
 6 Test report	33		5.2	Heart rate accuracy	
 Annex A (informative) Example of PAR-Q questionnaire	34	6	l est r	report	13
 Bibliography	35	A	nnex A ((informative) Example of PAR-Q questionnaire	15
 Figure 1 – A PPG simulator circuit and setup	36	Bi	ibliograp	phy	16
 Figure 1 – A PPG simulator circuit and setup	37				
 Figure 2 – Wearing both a PPG and a chest type ECG wearable devices	38	Fi	gure 1 -	 A PPG simulator circuit and setup 	7
40 41 42	39	Fi	gure 2 -	 Wearing both a PPG and a chest type ECG wearable devices 	8
41	40				
42	41				
	42				

43

124/196/CDV

3

44 INTERN	INTERNATIONAL ELECTROTECHNICAL COMMISSION						
45							
46							
47 WEARABL	E ELECTRONIC DE	VICES AND TECH	NOLOGIES				
48	- <i>-</i>	.					
49 Part 402-3: 1	Performance measu	irement method of	wearables –				
	S 2. Accuracy of h	eart Rate Determin	ation				
52	FORE	WORD					
531) The International Electro54all national electrotech55international co-operatio56this end and in addition57Technical Reports, Put58Publication(s)"). Their pr59in the subject dealt wi60governmental organization61with the International Co62agreement between the formational control	technical Commission (IEC) is nical committees (IEC Nati n on all questions concerning to other activities, IEC pub blicly Available Specification eparation is entrusted to tech th may participate in this p ons liaising with the IEC also organization for Standardizati wo organizations.	s a worldwide organization fo onal Committees). The obj standardization in the electr lishes International Standard is (PAS) and Guides (her- nical committees; any IEC N- preparatory work. Internation participate in this preparation (ISO) in accordance wit	r standardization comprising ect of IEC is to promote ical and electronic fields. To ls, Technical Specifications, eafter referred to as "IEC ational Committee interested hal, governmental and non- on. IEC collaborates closely h conditions determined by				
 63 2) The formal decisions or a 64 consensus of opinion o 65 interested IEC National 0 	agreements of IEC on technica n the relevant subjects since Committees.	al matters express, as nearly e each technical committee	as possible, an international has representation from all				
 66 3) IEC Publications have t 67 Committees in that sens 68 Publications is accurate 69 misinterpretation by any 	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.						
 70 4) In order to promote interface 71 transparently to the main of the transparent to the main of the transparent to the tr	In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications ransparently 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.						
 74 5) IEC itself does not prov 75 assessment services an 76 services carried out by ir 	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.						
77 6) All users should ensure t	hat they have the latest edition	on of this publication.					
 78 7) No liability shall attach t 79 members of its technical 80 other damage of any na 81 expenses arising out of 82 Publications. 	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.						
 83 8) Attention is drawn to the indispensable for the cor 	 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. 						
 Attention is drawn to the patent rights. IEC shall n 	9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.						
 International Standard IEC 63203-402-3 has been prepared by IEC technical committee 124: Wearable Electronic Devices and Technologies. 							
89 The text of this International Standard is based on the following documents:							
	FDIS	Report on voting					
	XX/XX/FDIS	XX/XX/RVD					

90

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

⁹³ This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

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

- 97 reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.
- 101

iTeh STANDARD PREVIEW (standards.iteh.ai)

oSIST prEN IEC 63203-402-3:2022 https://standards.iteh.ai/catalog/standards/sist/fd6099ce-41f7-471d-bf54b962df282423/osist-pren-iec-63203-402-3-2022

WEARABLE ELECTRONIC DEVICES AND TECHNOLOGIES

102 103

Dort 402 2: Dorformance measurement of wearehing

104

105 106

Part 402-3: Performance measurement of wearables – Series 2: Accuracy of Heart Rate Determination

107 **1** Scope

This part of IEC 63203 specifies terms and a measurement protocol, and a test to evaluate the accuracy of wearables that measure heart rate with a photoplethysmography (PPG) sensor. This measurement protocol is not intended to evaluate medical devices associated with IEC 60601 or IEC/ISO 80601 series.

112 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

117 ANSI/CTA-2065 Physical Activity Monitoring for Heart Rate

118 3 Terms and definitions

- For the purposes of this document, the following terms and definitions apply.
- 120 ISO and IEC maintain terminological databases for use in standardization at the following 121 addresses:
- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at <u>http://www.iso.org/obp</u>

https://standards.iteh.ai/catalog/standards/sist/fd6099ce-41f7-471d-bf54-

b962df282423/osist-pren-iec-63203-402-3-2022

- 125 **3.1 heart rate**
- 126 **HR**

124

- the 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
- 129 **3.2 body mass index**
- 130 **BMI**
- person's weight in kilograms (kg) divided by his or her height in meters squared

132 **3.3 heart rate monitoring device**

- 133 HRMD
- device that captures pulsation signals and calculates the pulse rate at regular intervals

135 3.4 plethysmograph

136 device to produce an plethysmogram

137 3.5 photoplethysmogram

138 **PPG**

graphic record of the variation with time of optically measured volume of blood circulation atthe skin's surface

141 **4** Test methods and procedures

142 **4.1 General**

A wearable device with heart rate monitoring based on photoplethysmogram (PPG) is tested with a PPG simulator at various frequencies. The PPG wearable device is used for comparative test with a chest type electrocardiogram (ECG) device. A participant wearing both a PPG wearable device and a chest type ECG wearable device performs various physical activities including walking, jogging, and running as well as no physical activity (being sedentary).

149 **4.2 Other considerations**

Even though this standard is limited in scope, manufacturers should consider factors that could impact testing.

Test conditions: variable ambient light (e.g., direct, indirect, and sun/shadow 152 transitions), wide ranging temperatures (cold and warm), wide range of ambient noises, 153 incorporation of clothing that may have the potential to interfere with devices (e.g., 154 tightness, thickness, or that which restricts ideal wearing of device), body or wrist 155 positions during certain protocols (e.g., for cycling applications: bent wrist or straight 156 arms), position of device on the body electrical interference from outside sources, 157 potential for signal loss between the measurement device and data repository (e.g., 158 mobile app or other). 159

160 **4.3 Setup and configuration**

161 4.3.1 PPG simulator test

- A PPG simulator is prepared as shown in Figure 1. A light emitting diode is connected with a current limiting resistor in series and powered with a function generator. The wavelength (or color) of the LED shall match that of the PPG device under test. The value of the current limiting resistor is determined considering the LED forward voltage and current found in the LED data sheet. A PPG wearable device manufacturer may use a commercially available simulator.
- A PPG wearable device is placed over a PPG simulator that is located in a chamber or room wherein humidity, temperature, and light intensity is measured and recorded.
- By using the function generator, the frequency is configured to 0,5 Hz, 1,0 Hz, 1,5 Hz, 2,0 Hz, 2,5 Hz, 3,0 Hz, and 3.5 Hz, sequentially. At each frequency, a sinusoidal wave between 0 and 5 V is supplied to the PPG simulator circuit to blink the LED.
- At 5~10 seconds after the PPG simulator starts to operate at a frequency and the PPG function of the device is on, the heart rate readout on the PPG device is recorded for 1 minute.
- The accuracy of the PPG device is analysed by comparing the measured heart rate and the frequency setting in the simulator.

124/196/CDV

IEC CDV 63203-402-3 © IEC 2022



178

179 **Key**

- 180 1. PPG wearable device;
- 181 2. Jig for the PPG simulator;
- 182 3. Light emitting diode;
- 183 4. Current limiting resistor (100 ~ 500 ohm);
- 184 5. Function generator (sine wave with 5 V_{p-p} and 2,5 V_{offset});
- 185

Figure 1 – A PPG simulator circuit and setup

186 4.3.2 Comparative test with a reference ECG device

- A participant wears both a PPG wearable device and a chest type ECG wearable device as shown in Figure 2 and following the manufacturer's instruction manual. The chest type ECG wearable device used as a control device shall have a certified, approved or verified accuracy as base reference device for comparison.
- For physical activities, humidity, temperature, and light intensity is measured and recorded.
- The participant performs a described physical activity for a given duration as noted in the comparative test protocols below.
- While performing the physical activity, heart rates displayed in the PPG device under test and the reference ECG device are simultaneously recorded.
- The accuracy in the heart rate measurement of the PPG device is analysed by comparing measured heart rates from the PPG device under test and the reference ECG device.

8



200

201 Key

1. Reference ECG wearable device (a chest belt type shown in this example is recommended and other
 types having ECG module mounted on the chest may be used);

204 2. PPG device (wrist type shown but not limited to that type);

205

Figure 2 – Wearing both PPG to be tested and reference ECG devices (a chest belt type shown in this example is recommended and other types having ECG module mounted on the chest may be used)

209

<u>SIST prEN IEC 63203-402-3:2022</u>

210 4.4 Participant considerations

211 4.4.1 General considerations

Participants shall be in good health, with no medical conditions, especially, heart related diseases. Participants are asked to fill out the Physical Activity Readiness Questionnaire (PAR-Q) to determine their eligibilities for the comparative test. Testing shall include at least 20 participants representative of the characteristics identified in the below subsections. If the number of participants in the participant test group is greater than 150% of this minimum, a good faith effort shall be made to maintain a similar ratio of participants with the specified characteristics.

219 4.4.2 Skin Tones

Using the Fitzpatrick Scale, at minimum the following number of participants should have skin tones in the range specified:

- At least 25% of participants lighter skin range (1-3 on Fitzpatrick Scale) and
- At least 25% of participants darker skin range (4-6 on Fitzpatrick Scale).

To try and meet the range on the Fitzpatrick scale is encouraged but exceptions to the Fitzpatrick Scale are allowed in some countries and regions.

226 4.4.3 BMI Range

- Prior to the test, height and weight of each participant are measured with light clothing and without shoes. At a minimum, participants should be within the BMI ranges as follows:
- At least 10% of participants below 20 kg/m² and
- At least 25% of participants above 25 kg/m².