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

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

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

ICS:

31.080.99	Drugi polprevodniški elementi	Other semiconductor devices
59.080.80	Inteligentne tekstilije	Smart textiles

oSIST prEN IEC 63203-402-3:2022 **en**

124/196/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 63203-402-3 ED1**	
DATE OF CIRCULATION: **2022-10-14**	CLOSING DATE FOR VOTING: **2023-01-06**
SUPERSEDES DOCUMENTS: **124/167/CD, 124/193/CC**	

IEC TC 124 : WEARABLE ELECTRONIC DEVICES AND TECHNOLOGIES

SECRETARIAT: Korea, Republic of	SECRETARY: 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:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☐ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
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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:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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WEARABLE ELECTRONIC DEVICES AND TECHNOLOGIES

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

FOREWORD

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International Standard IEC 63203-402-3 has been prepared by IEC technical committee 124: Wearable Electronic Devices and Technologies.

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

FDIS	Report on voting
XX/XX/FDIS	XX/XX/RVD

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.

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

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- withdrawn,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

WEARABLE ELECTRONIC DEVICES AND TECHNOLOGIES

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

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.

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.

ANSI/CTA-2065 Physical Activity Monitoring for Heart Rate

3 Terms and definitions

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

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

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

3.1 heart rate

HR

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

3.2 body mass index

BMI

person’s weight in kilograms (kg) divided by his or her height in meters squared

3.3 heart rate monitoring device

HRMD

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

3.4 plethysmograph

device to produce an plethysmogram

3.5 photoplethysmogram

PPG

graphic record of the variation with time of optically measured volume of blood circulation at the skin’s surface

4 Test methods and procedures

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).

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 transitions), wide ranging temperatures (cold and warm), wide range of ambient noises, incorporation of clothing that may have the potential to interfere with devices (e.g., tightness, thickness, or that which restricts ideal wearing of device), body or wrist positions during certain protocols (e.g., for cycling applications: bent wrist or straight arms), position of device on the body electrical interference from outside sources, potential for signal loss between the measurement device and data repository (e.g., mobile app or other).

4.3 Setup and configuration

4.3.1 PPG simulator test

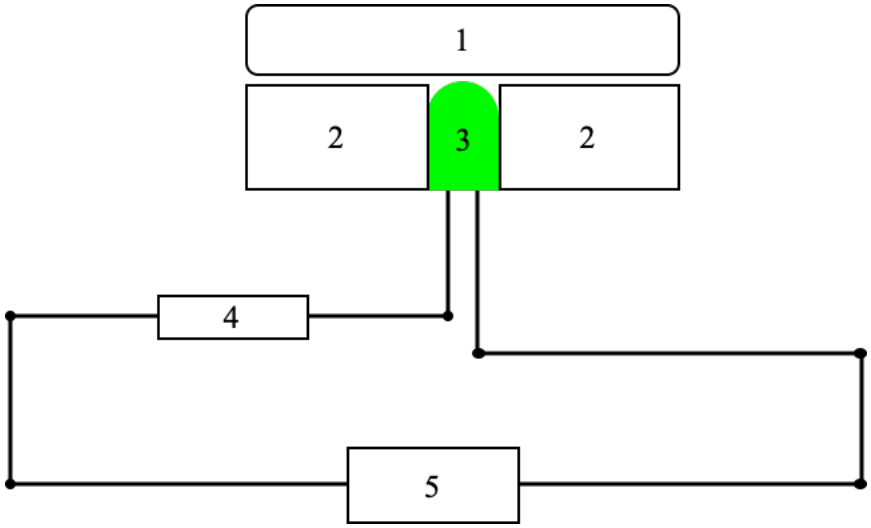
- A PPG simulator is prepared as shown in Figure 1. A light emitting diode is connected with a current limiting resistor in series and powered with a function generator. The wavelength (or color) of the LED shall match that of the PPG device under test. The value of the current limiting resistor is determined 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.



Key

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

Figure 1 – A PPG simulator circuit and setup

4.3.2 Comparative test with a reference ECG device

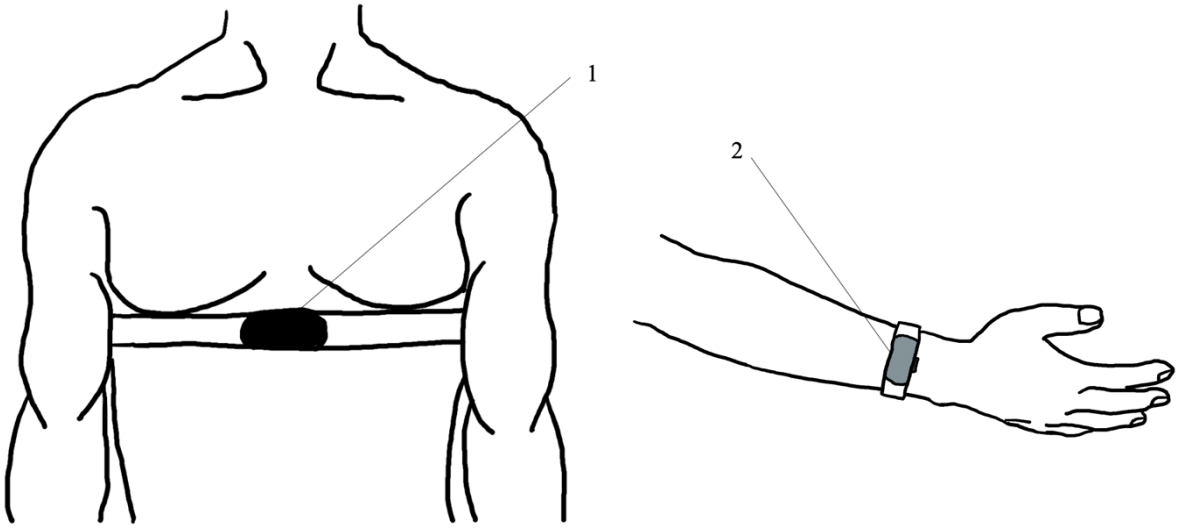
- A participant wears both a PPG wearable device and a chest type ECG wearable device as shown in Figure 2 and following the manufacturer's instruction manual. The chest type ECG wearable device used as a control device shall have a certified, approved or verified accuracy as base reference device for 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.



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);

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

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)

4.4 Participant considerations

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.

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.

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/m^2 and
- At least 25% of participants above 25 kg/m^2.