IEC 63203-402-3

Edition 1.0 2024-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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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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

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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

3.1.5
photoplethysmogram
PPG
graphic record of the variation with time of an optically measured volume of blood circulation at the skin's surface

3.1.6
pulse rate
PR
increase in arterial pressure that can be felt and measured by a pulse (typically measured per minute)

Note 1 to entry: Pulse rate is used interchangeably with the term heart rate by many manufacturers describing features of wearables. However, some countries use the term pulse rate differently than heart rate.

3.2 Abbreviated terms

BMI body mass index

ECG electrocardiogram

HR heart rate

HRMD heart rate monitoring device

LED light emitting diode

MAPE mean absolute percentage error

PPG photoplethysmogram

PR pulse rate

4 Test methods and procedures

4.1 General

A wearable device with heart rate monitoring based on a photoplethysmogram (PPG) is tested with a PPG simulator at various frequencies A chest type electrocardiogram (ECG) is used for comparative test. 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

Manufacturers should consider the following factors that can impact testing.

Test conditions:

– variable ambient light (e.g., direct, indirect, and sun or shadow transitions);
– wide ranging temperatures (cold and warm);
– wide range of ambient noises;
– use of clothing that can have the potential to interfere with devices (e.g., tightness, thickness, or clothing which restricts the ideal wearing of the device);
– body or wrist positions during certain protocols (e.g., for cycling applications: bent wrist or straight arms);
– position of PPG wearable 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

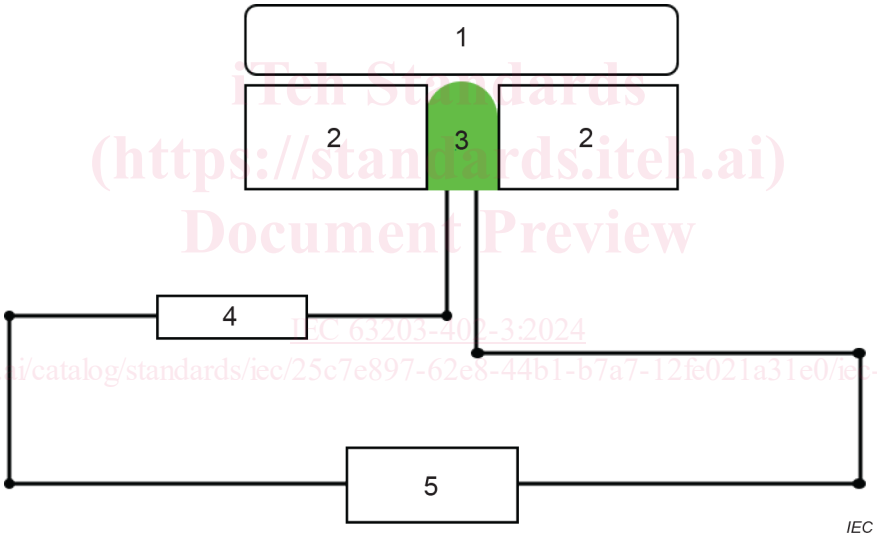
– A PPG simulator is prepared as shown in Figure 1. A light emitting diode (LED) is connected with a current limiting resistor in series and powered with a function generator. The wavelength (or colour) of the LED shall match that of the PPG wearable device under test. The value of the current limiting resistor is determined considering the LED forward voltage and current found in the LED data sheet. A PPG wearable device manufacturer can 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 are 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 V and 5 V is supplied to the PPG simulator circuit to make the LED blink.

– Between 5 s to 10 s after the PPG simulator starts to operate at a frequency and the PPG function of the PPG wearable device is on, the heart rate readout on the PPG wearable device is recorded for 1 min.

– The accuracy of the PPG wearable device is analysed by comparing the measured heart rate and the frequency setting in the simulator. Results shall be reported in accordance with Clause 6.



Key

1 PPG wearable device;

2 jig for the PPG simulator;

3 light emitting diode;

4 current limiting resistor (100 Ω to 500 Ω);

5 function generator (sine wave with 5 V_{p-p} and 2,5 V_{offset});

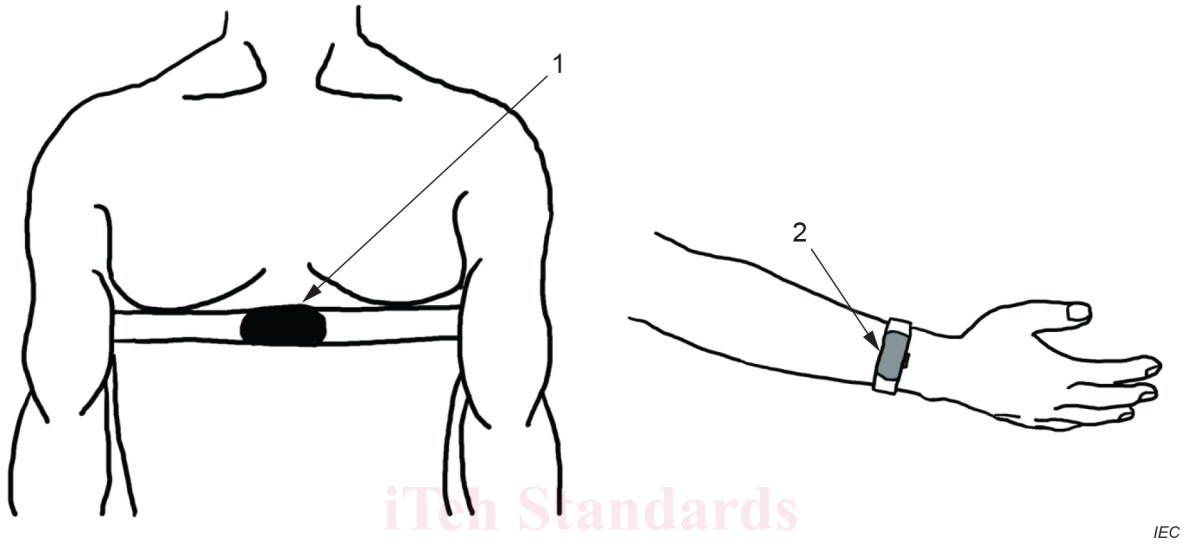
Figure 1 – PPG simulator circuit and setup

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 for both the PPG and ECG wearable devices. The chest type ECG wearable device used as a control device shall have a certified, approved or verified accuracy as a base reference device for comparison.

– For physical activities, humidity, temperature, and light intensity are measured and recorded in accordance with Clause 6.

– The participant performs a described physical activity in accordance with the test protocols defined in 4.5.3.
– While performing the physical activity, the heart rates displayed in the PPG wearable device under test and the reference ECG device are simultaneously recorded.
– The accuracy in the heart rate measurement of the PPG wearable device is analysed by comparing the measured heart rates from the PPG wearable device under test and the reference ECG device.



Key

1 Reference ECG wearable device (a chest belt type as shown in this example is recommended but other types having an ECG module mounted on the chest can be used).

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

Figure 2 – Example of PPG to be tested and reference ECG devices

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 (an example is shown in Annex A). Testing shall be done with at least 20 participants representative of the characteristics identified in 4.4.2 to 4.4.7. 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 with a lighter skin range (1 to 3 on the Fitzpatrick Scale); and
– at least 25 % of participants with a darker skin range (4 to 6 on the Fitzpatrick Scale).

It is recommended to try and meet the range on the Fitzpatrick Scale but exceptions to the Fitzpatrick Scale are allowed in some countries and regions.