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Indian Standard

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Wearable Electronic Devices and Technologies

Part 406 Test Method for Measuring Surface Temperature of Wrist

Section 1 Worn Wearable Electronic Devices While in Contact with Human Skin

ICS 31.020

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NATIONAL FOREWORD

This Indian Standard (Part 406/Sec 1) which is identical to IEC 63203-406-1 : 2021 'Wearable electronic devices and technologies — Part 406-1: Test method for measuring surface temperature of wrist-worn wearable electronic devices while in contact with human skin' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendation of Wearable Electronic Devices and Technologies Sectional Committee and approval of the Electronics and Information Technology Division Council.

The text of IEC standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appears referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which is to be substituted in its place, is listed below along with its degree of equivalence for edition indicated. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

International Standard	*Indian Standard*	*Degree of Equivalent*
IEC 62368-1 : 2018 Audio/video, information and communication technology equipment — Part 1: Safety requirements	IS/IEC 62368-1 : 2018 Audio/video, information and communication technology equipment: Part 1 Safety requirements (*first revision*)	Identical

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard

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Indian Standard

WEARABLE ELECTRONIC DEVICES AND TECHNOLOGIES
PART 406 TEST METHOD FOR MEASURING SURFACE TEMPERATURE OF WRIST
SECTION 1 WORN WEARABLE ELECTRONIC DEVICES WHILE IN CONTACT WITH HUMAN SKIN

1 Scope

This part of IEC 63203 defines the terms, definitions, symbols, configurations, and test methods to be used to specify the standard measurement conditions and methods for determining the contact-surface temperature of wrist-worn wearable electronic devices intended to be worn directly on a human wrist and that can be worn continuously during use. The conditions of the test do not consider perfusion and results are therefore considered conservatively. The temperature increase is induced by the thermal energy of wearable electronic devices during operation. This document gives the general procedure for the test method applicable to various wrist-worn wearable electronic devices for use by ordinary persons which in the context of this document is a healthy human adult.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

3 Terms and definitions

For the purpose of this document, the following terms and definitions apply:

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

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

3.1
ambient temperature
average temperature of air or another medium in the vicinity of a wearable electronic device

Note 1 to entry: During the measurement of the ambient temperature the measuring instrument/probe should be shielded from draughts and radiant heating.

[SOURCE: IEC 60050-816:2004, 826-10-03, modified – In the definition, "the equipment" has been replaced with "a wearable electronic device".]

3.2
human skin-imitating fixture
test fixture with thermal conductivity similar to that of human skin including internal heater to imitate the temperature of human skin and its thermal conduction properties, as well as providing a surface on which the device is placed during the measurement

Note 1 to entry: The human skin-imitating fixture consists of a support equipped with a heater and cover material.

3.3
skin-imitating temperature
temperature on the surface of a human skin-imitating fixture that is controlled by heater to emulate the skin temperature of the human body

3.4
skin-contact surface
surface of the wearable electronic device that is physically in contact with the skin of the human body

3.5
contact-surface temperature
temperature of the skin-contact surface of the wearable electronic device

Note 1 to entry: Only that part of the device which may have an elevated temperature and is in contact with the skin shall be considered. It may not be necessary to measure the temperature of passive fixing devices, for example non-metallic wrist bands, outside the thermal footprint of the electronic device.

3.6
normal operating condition
mode of operation that represents as closely as possible the range of normal use that can reasonably be expected

[SOURCE: IEC 62368-1:2018, 3.3.7.4, modified – Notes to entry have been omitted.]

3.7
abnormal operating condition
temporary operating condition that is not a normal operating condition and is not a single fault condition of the equipment itself

[SOURCE: IEC 62368-1:2018, 3.3.7.1, modified – Notes to entry have been omitted.]

3.8
single fault condition
condition of equipment with a fault under normal operating condition of a single safeguard (but not a reinforced safeguard) or of a single component or a device

[SOURCE: IEC 62368-1:2018, 3.3.7.9, modified – Note to entry has been omitted.]

3.9
burn threshold
surface temperature defining the boundary between no burn and a superficial partial thickness burn caused by contact of the skin with a hot surface for a specified contact period

[SOURCE: IEC GUIDE 117:2010, 3.3]

4 Test conditions and test setup

4.1 Environmental conditions

The measurements shall be carried out under the following normal environmental conditions.

- Ambient temperature: 25 °C ± 5 °C,
- Relative humidity: 25 % RH to 85 % RH,
- Atmospheric pressure: 86 kPa to 106 kPa.

4.2 Human skin-imitating fixture

4.2.1 General

A human skin-imitating fixture shall be used when measuring the contact surface temperature of a wearable electronic device. This fixture shall imitate the thermal conduction property of the human skin and the temperature of the surface of the human skin.

4.2.2 Structure of the human skin-imitating fixture

The human skin-imitating fixture shall be equipped with a heater, and the skin temperature shall be imitated by the operation of the heater. The heater shall be covered with a material which imitates the thickness and thermal conductivity of human skin. The wearable electronic device shall be attached to the cover by the method specified by the manufacturer. All of the skin-contact surfaces shall be in contact with the heated area of the fixture. Other detailed descriptions about the structure can be defined as described in Annex B.

4.2.3 Monitoring skin-imitating temperature and heater control

A surface-mount-type thermocouple (TC 1) with adhesive tape made from a low-thermal-conductivity material (λ < 0,5 W/m K) shall be attached to the surface of the cover of the fixture, a small distance away from the device under test (DUT). The thermocouple wire shall be no more than 0,26 mm in diameter and the measurement accuracy shall be within ±1,0 °C. The position of the thermocouple is shown in Figure 1 and Figure B.2. By monitoring the temperature with TC 1, the heater shall be controlled to maintain a skin-imitating temperature of 32,5 °C ± 0,5 °C in normal environmental conditions. This is to ensure that the test is conducted under the appropriate operating conditions. A proportional-integral-derivative (PID) controller can be used to control the heater.

NOTE The temperature of human skin can vary with the ambient temperature, the part of the human body and the condition of the skin. The temperature of human skin is normally in the range of 30 °C to 35 °C.

Considerations should be given to the thermal mass and the heat flux of the device under test with respect to the applicability of the human skin-imitating fixture. It should be noted that the human skin-imitating fixture is considered as a conservative method in assessing thermal burn injuries as it does not consider perfusion/sweating or blood circulation of the body.

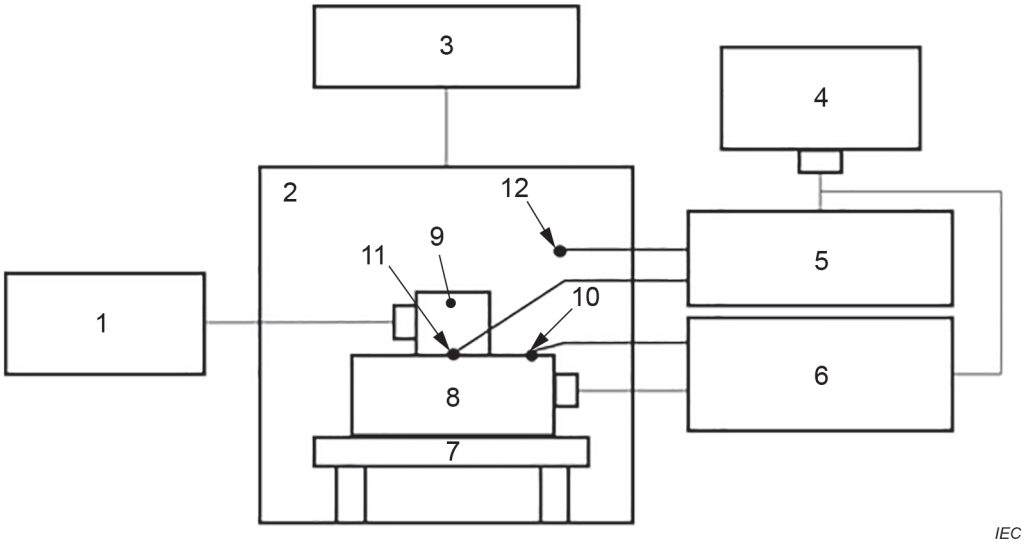
4.3 Stabilization time

The measurements shall be carried out after a sufficient stabilization time has elapsed. The first state stabilization time (step in Clause 5, list item c)) is defined as the time taken for the test chamber temperature to stabilize at the required ambient temperature ±1,0 °C. The second state stabilization time (step in Clause 5, list item e)) is defined as the time taken for the fixture surface to stabilize at the required contact-surface temperature ±1,0 °C.

4.4 Test setup

4.4.1 General

Figure 1 shows the test setup for measuring the electrical characteristics of a device being tested. To measure the contact surface temperature of a wearable electronic device and the ambient temperature, the device shall be mounted on a human skin-imitating fixture and thermocouples for temperature measurements shall be set at appropriate positions.



Key

1 controller/driver
2 temperature controlled environment chamber
3 temperature/humidity controller
4 computer for recording
5 thermometer
6 heater controller
7 support table
8 human skin-imitating fixture
9 device under test
10 thermocouple 1 (TC 1)
11 thermocouple 2 (TC 2)
12 thermocouple 3 (TC 3)

Figure 1 – Test setup for evaluating the contact-surface temperature of a wearable electronic device

4.4.2 Placement of device under test (DUT)

The device being tested shall be positioned on the human skin-imitating fixture in the geometric centre of the chamber by adjusting the position of the human skin-imitating fixture. The human skin-imitating fixture may be placed on a support table to adjust the position of the device under test. Any support table shall be made from a low thermal conductivity material (λ < 0,5 W/mK). The positioning of the device on the human skin-imitating fixture shall follow, where provided, the method specified by the manufacturer to attach the device on the human body. The device shall be attached to ensure firm contact with no significant separation from the human skin-imitating fixture. There shall be no structures above the device being tested which may disturb the convection air flow. There shall be no significant external air movement sources affecting the device being tested, such as fan-forced air movement or ambient air movement.

4.4.3 Thermocouple placement

Thermocouple TC 2 for measuring the contact-surface temperature shall be positioned at the hottest point of the skin-contact surface. The hottest point is defined as the region with the highest temperature on the skin-contact surface of the wearable electronic device. This point has the shortest thermal path from the heat source inside the wearable electronic device to the contact-surface and can be determined by obtaining a thermographic mapping image of the skin-contact surface using infrared imaging by operating the wearable electronic device before placement on the human skin-imitating fixture. Thermocouple TC 3 for measuring the ambient temperature shall be positioned inside the test chamber such that disturbance of the convection air flow is avoided.

4.4.4 Device operating conditions

The normal operating conditions, abnormal operating conditions, and single fault conditions shall be set according to methods defined in IEC 62368-1:2018, Annex B when measuring the contact-surface temperature during device operation. The device operating mode may be set according to its functions. Further guidance is given in Annex C. An external power source to operate the DUT may be used instead of an internal power source such as a battery inside the device if the heat from the internal power source is negligible.

NOTE IEC 62368-1 defines only the test temperature and thermal criteria for skin burn without providing detailed test conditions. In this document, test conditions considering human skin and detailed measurement setup for the precise temperature measurement are defined to prevent low-temperature skin burn during long periods of contact with wearable electronic devices. See Annex A.

5 Test method

The procedure for testing a wearable electronic device is performed as follows.

a) The human skin-imitating fixture is placed inside the test chamber.

b) Thermocouples are placed:
   - inside the test chamber for ambient temperature measurement (TC 3);
   - on the surface of the human skin-imitating fixture as indicated in Figure B.2 and connected to the heater controller for skin-imitating temperature control (TC 1); and
   - on the DUT for contact-surface temperature measurement (TC 2).

c) The test chamber ambient temperature and humidity shall reach stabilization before continuing (first state stabilization time). The chamber temperature should be set at 25,0 °C +0 °C, −5 °C according to IEC GUIDE 117:2010, 3.7.

d) The heater of the human skin-imitating fixture is set such that the skin-imitating temperature is maintained within the designated temperature range.

e) The human skin-imitating fixture shall reach stabilization before continuing (second state stabilization time).

f) The DUT with the attached thermocouple is placed on the human skin-imitating fixture.

g) The operating conditions of the DUT are set. The device may be using an internal or external power source.

h) The contact-surface temperature measurements start by operating the DUT.

i) The measurements end when the contact-surface temperature reaches its maximum stable value within 1,0 °C in 20 min.

j) Repeat steps from list items g) to i) according to each operating condition.

6 Test report

Alongside the measured maximum contact surface temperature, the report shall include the following information:

a) identification (number and date) of this document;
b) identification and details of the test lab;
c) identification and details of the sample and manufacturer;
d) environmental conditions during the test execution;
e) test scenario;
f) device position conditions;
g) any deviations from the conditions or procedures described in this document;
h) date of test;
i) other remarks and observations.

Annex A
(informative)

Low-temperature burn caused by wearable electronic devices

A.1 General

When a wearable electronic device is being worn directly on the human body for a prolonged period, proteins in the human skin can get damaged, even when the skin remains in contact with a wearable electronic device at a raised temperature that is lower than the value at which a human being would experience pain. Low-temperature burn caused by a wearable electronic device can occur during continuous operation and during direct long-term contact with the human skin. To determine whether a wearable electronic device meets the conditions under which low-temperature burn is prevented, the contact surface temperature of a wearable electronic device during operation can be measured.

This document specifies conditions under which contact-surface temperature is measured to ensure that the contact-surface temperature of the device is below a temperature which can cause burns to human skin, taking into consideration the device use conditions and the effect of human skin temperature.

This document does not specify temperature limits. Temperature limits are specified in other documents, such as IEC 62368-1. Temperature limits from IEC 62368-1 are based on an ambient temperature of 25 °C.

A.2 Low-temperature burn threshold

For devices with substantial thermal mass and an infinite heat flux, the low-temperature burn threshold is specified as being at 43 °C according to IEC Guide 117 if the contact time exceeds 8 h. The skin-contact temperature of a wearable electronic device should be maintained below the limits specified in end product standards, for example, TS1 (43 °C to 48 ºC) in IEC 62368-1:2018, 9.3 to prevent low-temperature skin burn in normal operation conditions. If a wearable electronic device is worn for less than 8 h, the burn threshold temperature may be determined by the criteria of ASTM C1055, Figure 1, or further guidance is available in IEC 62368-1.

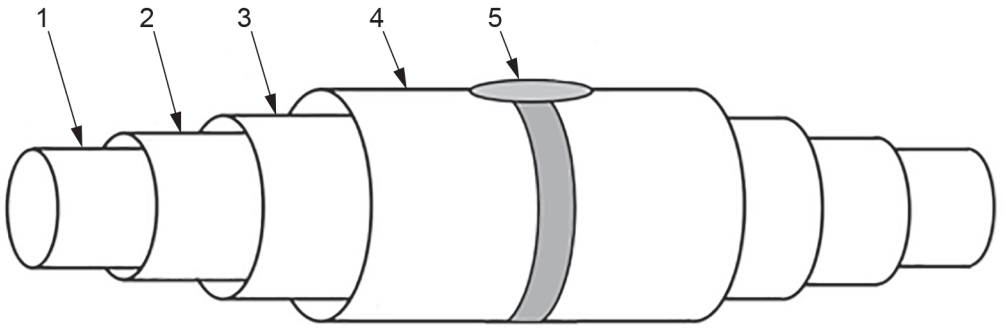
Annex B
(informative)

Human skin-imitating fixture

B.1 General structure

The human skin-imitating fixture consists of a support with a heater, a heat spreader and a cover. Figure B.1 shows the general structure of the human skin-imitating fixture. The support consists of, for instance, flame-retardant and heat-resistant polymers with a film-type heater on a surface controlled by an external controller. The support should be a low thermal conductivity material (λ < 0,5 W/mK). The support and entire fixture generally will have a rounded shape, simulating the shape of a human wrist as shown in Figure B.1. A model or replica of the human wrist on which the wearable electronic device is intended to be worn may also be used as a support if its thermal conductivity is less than 0,5 W/mK.

NOTE The thermal conductivity of the human body is mainly less than 0,5 W/mK except for bones, for which it is 0,63 W/mK.



Key

1 support

2 heater

3 heat spreader

4 cover

5 device under test

NOTE Figure B.1 intends to show the general structure of the fixture.

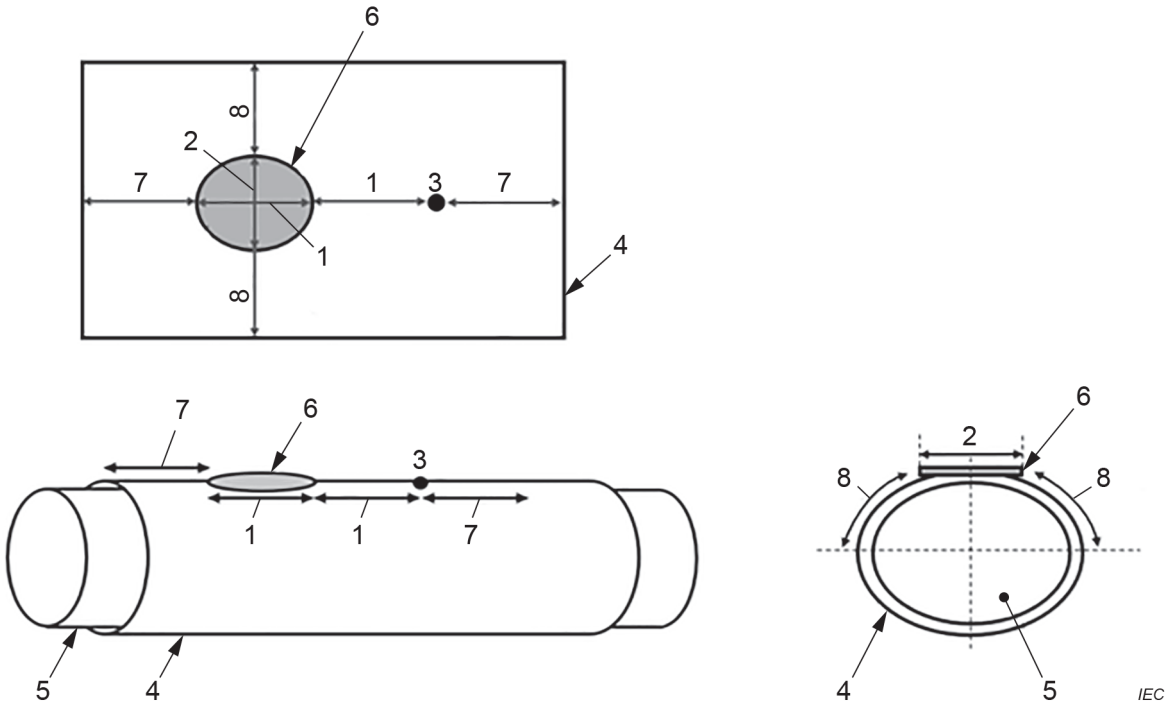
Figure B.1 – Structure of human skin-imitating fixture

B.2 Heater for imitating skin temperature

A film-type heater consists of, for instance, a resistive heating element such as metal foil inside polyimide film. The cover material should be a material with low thermal conductivity (λ < 0,5 W/mK), and having elasticity sufficient to have a firm surface contact against the DUT with thermocouple (TC 2) placed between them, consisting of, for instance, silicone rubber (polysiloxane). The thickness of the cover imitating the human skin should be 2,0 mm ± 0,1 mm. A heat spreader with good thermal conductivity, such as a copper plate or graphite sheet, should be placed between the film type heater and the cover, to achieve an even temperature distribution over the complete contact area.

NOTE The human skin is composed of the epidermis, dermis, and hypodermis. The thickness of the skin varies with the parts of the body and normally ranges from 0,5 mm around the eyelids to 2,0 mm on the back except for the palms and soles where the thickness is over 4,0 mm.

The dimensions of the heating area and the cover should be at least 12 times larger than the size of the skin-contact surface as defined in Figure B.2. The skin-contact surface does not include the accessory to secure the wearable electronic device on the human body. The cover, heater and heat spreader may be rounded to conform to the shape of the support. Thermocouple TC 1 should be positioned to avoid thermal interference from the DUT. It should be placed at a distance of Lx, the size of the skin-contact surface, measured from the edges of the skin-contact surface in x direction.



Key

1 length of the skin contact surface in X-direction (Lx)

2 length of the skin contact surface in Y-direction (Ly)

3 thermocouple (TC 1)

4 heater, heat spreader, cover

5 support

6 skin-contact surface of wearable electronic device

7 minimum Lx

8 minimum Ly

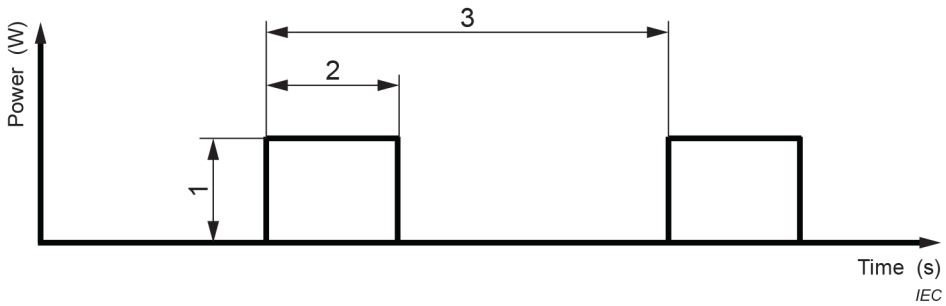
Figure B.2 – Minimum size of cover, heater, and the position of thermocouple to monitor skin-imitating temperature

Annex C
(informative)

Device operation scenario for the temperature test

C.1 Normal operating condition scenario

The normal operating condition scenario is the condition of the test system simulating use on the body by a person. A battery or an external power supply may power the device to simulate the normal operating condition scenario. The power and duty cycle may be set according to the normal operating condition scenario as shown in Figure C.1.



Key

1 power (W)

2 working period (s)

3 duty cycle (s)

Figure C.1 – Working period and duty cycle under device operating conditions

C.2 Abnormal operating condition scenario

An abnormal operating condition may arise as a result of improper use of the wearable electronic device. Abnormal operating conditions may be tested by adjusting power level, working period and duty cycle to simulate the worse conditions considered by the manufacturer.

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