INTERNATIONAL STANDARD

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Mechanical vibration and shock — Cold provocation tests for the assessment of peripheral vascular function —

Part 2: Measurement and evaluation of finger systolic blood pressure

Vibrations et chocs mécaniques — Essais de provocation à froid pour l'évaluation de la fonction vasculaire périphérique —

Partie 2: Mesurage et évaluation de la tension sanguine systolique des doigts

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 14835-2 was prepared by Technical Committee ISO/TC 108, *Mechanical vibration and shock*, Subcommittee SC 4, *Human exposure to mechanical vibration and shock*.

ISO 14835 consists of the following parts, under the general title *Mechanical vibration and shock — Cold provocation tests for the assessment of peripheral vascular function*:

— *Part 1: Measurement and evaluation of finger skin temperature*

— *Part 2: Measurement and evaluation of finger systolic blood pressure*

Introduction

Assessing finger systolic blood pressure (FSBP) before and after local cooling can help to identify the presence and extent of vasoconstriction of the digital arteries in response to cold provocation produced by appropriate finger cooling.

A low finger systolic blood pressure following local cooling compared to that measured before cooling can indicate digital arterial vasoconstriction caused by an exaggerated response to cold. The amount of any change in FSBP following local cooling can reflect the degree of arterial vasoconstriction.

Mechanical vibration and shock — Cold provocation tests for the assessment of peripheral vascular function —

Part 2: Measurement and evaluation of finger systolic blood pressure

1 Scope

This part of ISO 14835 specifies

a) the methods for measuring finger systolic blood pressures (FSBP) with local cold provocation,

b) the procedures for conducting the measurements, and

c) how to report the measurement results.

The methods in this part of ISO 14835 are designed to assist in the collection of data for a quantitative evaluation of the vascular response to cold provocation, and to enable specification of normative data.

The measurement of FSBP with local cold provocation can be used for the assessment of peripheral vascular function. This part of ISO 14835 is applicable to the assessment of vascular function in persons exposed to hand-transmitted vibration.

2 Normative references

The following referenced documents are indispensable for the application 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 60601-1, *Medical electrical equipment — Part 1: General requirements for safety*

3 Measurement equipment

3.1 General

FSBP may be measured using plethysmography. A typical measurement consists of applying an occluding pressure to a digit by means of a pressure cuff connected to a plethysmograph. The cuff may be perfused with water at a controlled temperature for application of local cooling. Alternatively, an air-inflated cuff may be used to apply an occluding pressure and a separate non-pressurized, water-perfused cuff may be used for the application of local cooling. After a period of cooling, the pressure in the occluding cuff is continuously released until a transducer situated distally to this cuff detects blood flow. The cuff pressure at which this blood flow is detected is equivalent to the maximum digital arterial pressure (systolic pressure) and the cuff pressure is noted as the FSBP.

The equipment consists of a device, or devices, for applying and controlling pressure around a digit whilst applying controlled local cooling to the digit. The equipment is capable of controlling the release of a

supra-systolic pressure around the digit whilst monitoring the blood flow distal to the occlusion so as to determine at what pressure arterial blood flow recommences.

There are several types of transducer commonly available for the detection of blood flow in the measurement of FSBP. Mercury-in-elastic strain gauges are sometimes used to detect volume changes; an increase in finger volume during release of pressure indicates the return of arterial blood flow. Photocells utilize a change in the intensity of light transmitted through or backscattered from the digital tissues to determine the return of blood flow. Laser-doppler flowmetry detects the return of blood flow by means of a frequency shift in reflected electromagnetic waves.

It is recommended that all equipment be maintained and calibrated according to the manufacturers' specifications.

3.2 Plethysmography

3.2.1 General

The device (or collection of devices) used to measure finger systolic blood pressures is commonly referred to as a plethysmograph and the measurement method is commonly referred to as plethysmography.

3.2.2 Cuffs

The choice of cuff size should be determined by the finger size of the individual under examination. The cuff length shall be sufficient to entirely surround the finger, while the cuff width should be at least 20 % greater than the diameter of the finger. The cuff surface should maintain contiguity with the surface of the digit throughout the measurement. Cuffs made of a material with a high thermal conductivity and/or with a thin wall are suitable for perfusion with water for thermal provocation. Cuffs should not inhibit blood flow when not pressurized.

3.2.3 Sensors

The sensors used to detect the return of blood flow during release of cuff pressure should not, themselves, occlude digital blood flow. They should neither thermally influence the digit nor provide thermal insulation from the environment. A high sensitivity and accuracy is recommended and sensors able to detect blood flow within 1 s of its occurrence are the most appropriate. Sensors with different response characteristics may not be comparable; care should be taken when comparing measurements made with different sensors.

3.2.4 Temperature of thermal provocation

The application of thermal provocation at controlled temperatures of between 35 °C and 10 °C is required.

3.2.5 Pressure control

The device is required to control pressure between a supra-systolic value ($>$ 250 mmHg is recommended) and the minimum measurable FSBP (0 mmHg is recommended). For pressure measurements, a transducer accuracy of $\pm$1 mmHg is acceptable.

NOTE The pressure of 1 mmHg is equal to 133,322 Pa.

When measuring the pressure in cuffs perfused with water, there are effects of hydrostatic pressure in the system. The hydrostatic pressure effects may be avoided by ensuring the water level in the system is at the same height as the cuff. If the sensor used to measure cuff pressure is submersed in the water, placing it at the height of the cuffs eliminates the hydrostatic pressure effect. Alternatively, a correction for the effects of hydrostatic pressure in the system shall be made. If the hydrostatic pressure is positive and the measured FSBP is zero, the true FSBP can lie anywhere between zero and the hydrostatic pressure, and it is not possible to apply a correction.

The duration of pressure application is defined for measurements of FSBP and should be controlled with an accuracy of ± 5 s.

The rate of release of pressure can affect the measurement. Rates of pressure reduction between 1 mmHg/s and 3 mmHg/s are appropriate if sensors are capable of the rapid detection of the return of blood flow (< 1 s).

3.2.6 Data recording

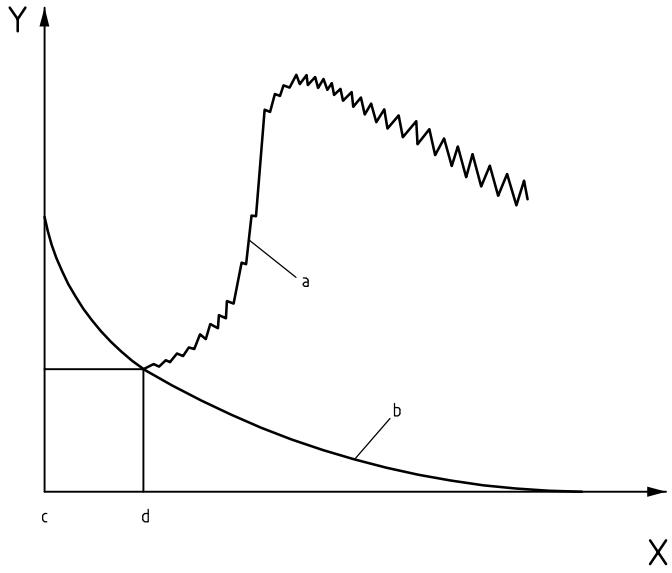
Finger systolic blood pressure (FSBP) is the quantity to be measured. It is expressed in millimetres of mercury (mmHg). The cuff pressure at which the return of blood flow is detected, which represents the FSBP, shall be recorded.

NOTE For strain-gauge plethysmography, the volume-pressure plot is the recording of interest. For photoplethysmography, the light intensity-pressure plot is the recording of interest. For laser-doppler flowmetry, the frequency-pressure plot is the recording of interest.

A general example of a signal-pressure plot is shown in Figure 1.

3.2.7 Calibration

The calibration of all equipment shall be traceable to a recognized standard.



Key

X Pressure (mmHg)

Y Transducer signal

a Signal from transducer.

b Cuff pressure.

c Supra-systolic pressure.

d FSBP

NOTE The transducer signal shown is for a strain gauge; the transducer signal will differ with different transducer types.

Figure 1 — Example of signal-pressure plot showing how the cuff pressure at which a change in the transducer signal occurs corresponds to the FSBP

4 Measurement procedure

4.1 Conditions of examination

4.1.1 General

To obtain reproducible data, the test conditions and procedures shall be controlled. Environmental conditions influencing the measurements shall also be controlled.

4.1.2 Examination room

The room temperature should be maintained at (21 ± 1) °C over the whole length of the body, for the duration of the test. Warmer room temperatures may result in normal FSBP in persons with mild vibration-induced white finger (VWF).

The environment shall be controlled to prevent extraneous conditions that might influence examination results.

Atmospheric temperature during the test should be strictly controlled. It is necessary to control room temperature at different vertical levels to prevent temperature differences at different parts of the body. Atmospheric temperature around the entire body should be maintained within the allowable range by mild air circulation. Stronger air circulation can increase skin cooling and alter the effective ambient room temperature.

4.1.3 Time

4.1.3.1 Time of year

Because the season can affect the measurement, it is desirable to make measurements in the cold season. If periodic examination at two or more times per year is required for follow-up in addition to the examination in the cold season, a test may be conducted in the autumn or summer.

4.1.3.2 Time of day

It is not known if daily variations have a significant effect on the FSBP. However, to avoid potential effects of circadian biorhythm, examination between 9:00 and 18:00 is recommended.

4.1.3.3 Time lag between previous test(s)/examination(s)

A delay of 3 h between any cold provocation test and a subsequent FSBP test is recommended so as to avoid the effects of prior cold exposure. This includes a cold provocation test that has been aborted after cold provocation has begun. If a test is repeated, this shall be noted. If cold provocation has been applied only to one hand during the 3 h period, the FSBP test may be conducted on the other. When an FSBP test consists of multiple measurements, these should be conducted consecutively without a recovery period.

4.1.4 Subject preparation

4.1.4.1 Recommendations to subject prior to examination

Strenuous physical exercise and smoking and other stimulants such as caffeine shall be avoided for 3 h prior to examination. Drinking of alcohol and intake of vasoactive medical drugs, such as calcium channel blockers and beta-blockers, shall be avoided for 12 h prior to examination. Intake of prescribed vasoactive drugs that cannot be avoided shall be reported. Vibration exposure should be avoided for at least 12 h prior to examination. This helps to minimize their effects on measurements.

It is desirable that white finger attacks prior to examination on the examination day are avoided. In winter, wearing gloves during transport to the examination room is recommended if the outdoor temperature is below 15 °C, and reporting of white finger attacks during the transport is also recommended.

4.1.4.2 Time lag between food intake and time of test

Food intake increases the metabolic rate and can induce circulatory changes. The intake of food prior to measurements can possibly change the response of the peripheral circulation to cold provocation. Therefore, the cold test should be avoided at time points of less than 1 h after a meal and more than 4 h of fasting. If this is not possible, the time between eating and the cold provocation test should be reported.

4.1.4.3 Clothing

Appropriate clothing to maintain thermal comfort, with only the hands and head uncovered, is recommended. Four items of clothing (two each for upper and lower body) together with socks is suggested.

NOTE The approximate clo value of the above clothing of 0,7 to 0,8 is suggested.

4.1.4.4 Adaptation of subject

At least 30 min in the environment of the examination room without physiological or psychological stress is needed for thermal adaptation. A longer period may be required for older subjects or in colder climates. Warming of the limbs is not recommended.

4.1.4.5 Subject posture

Keeping the hands at approximately heart height during the test avoids the potential effects on FSBP of hydrostatic variations within the body.

A seated or supine relaxed posture is appropriate during the test.

4.2 Cold provocation

4.2.1 Finger cooling

Finger cooling shall be performed so as to obtain the prescribed quantity of cold provocation. Finger cooling without body cooling is preferred but body cooling may be used. If body cooling is used, the method of cooling, duration of cooling, extent of body surface area cooled, and temperature of cooling shall be reported.

4.2.2 Cooling cuff

The cooling cuff may either be the pressure cuff or a separate cuff placed distal to the pressure cuff. The cuffs are placed so as to thermally provoke only one phalanx of a test digit. Tubes used to transport water shall not thermally influence other parts of the hand.

4.2.3 Control of water temperature

Circulation of water is required so as to maintain a constant temperature throughout the body of water. A maximum temperature variance of $\pm$ 0,5 °C from the set temperature is unlikely to adversely influence the measurement.

The diagnostic value of the change in FSBP at water temperatures of 6 °C, 10 °C or 15 °C compared to the FSBP at water temperatures of 30 °C or 35 °C have been reported.

4.2.4 Duration of cold provocation

The duration of cold provocation during ischemia is recommended to be 5 min. Longer cooling times may not be beneficial. Cooling periods of less than 5 min may be too short to obtain sufficient severity of cold-stress. A cooling period of 5 min duration during ischemia of a digit has been suggested as being sufficient to cool the digital arterial walls to the water temperature.

4.3 Conduct of the test

4.3.1 General

The higher water temperature inhibits vasoconstriction and provides a basal reading. For standardization, 30 °C is recommended for a basal reading.

The lower water temperature is used to provoke vasoconstriction and provides information about the extent of vasoconstriction in response to cold. Discomfort during the test is more severe when using low water temperatures. Although the clinical utility of measurements at 6 °C has been reported, a minimum water temperature of 10 °C is suggested; this temperature provides sufficient diagnostic accuracy without causing added discomfort. A temperature of 15 °C can elicit vasoconstriction in more severe cases of VWF but may not elicit vasoconstriction in mild cases of VWF. It is recommended that measurements be made at both 10 °C and 15 °C.

If time constraints prevent measurements at both 10 °C and 15 °C, a measurement at 10 °C is most likely to elicit a positive result in subjects with mild VWF. If a measurement at 15 °C elicits a positive test result, a measurement at 10 °C may not be necessary.

There may be cumulative effects of multiple cold provocations. To prevent excessive carry-over effects of cooling, performing more than two cold-water measurements is not recommended.

4.3.2 Choice of test hands and fingers

4.3.2.1 Test hands and fingers

Wherever possible, both hands shall be tested. If only one hand is selected for measurements, this should be the hand with the greatest reported symptoms. It is recommended that measurements be made on all possible digits. If only one measurement can be made, the finger most affected or the middle or ring finger is most suitable.

4.3.2.2 Reference fingers

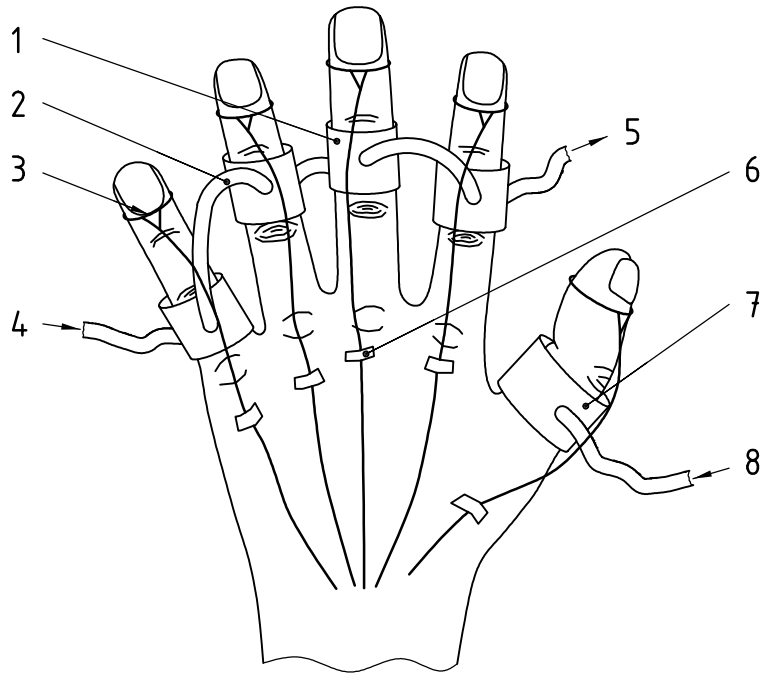
A reference measurement (one without cooling) may be made simultaneously with measurements to correct for changes in systemic systolic blood pressure. The thumb is the most appropriate location for this measurement. If this is not possible, the selection of a finger not affected with symptoms of VWF is recommended. If no finger is asymptomatic, the thumb may be used as the reference and the symptoms on the thumb reported. The brachial blood pressure may be used as an alternative reference location; its method of measurement and timing relative to the FSBP measurement shall be reported.

4.3.3 Placement of cuffs and sensors

When the cooling cuff and pressure cuff are combined, the middle phalanx of the digit is the suggested cuff location (proximal phalanx of the little finger to take account of its smaller circumference) (see Figure 2). If the cooling cuff and pressure cuff are separate, the pressure cuff may be placed on the proximal phalanx with the cooling cuff placed on the middle phalanx of the digit (see Figure 3).

The pressure cuff for reference measurements is placed on the proximal phalanx of the thumb or, if the thumb is not used as the reference, the middle phalanx of the reference finger.

Sensors are placed to detect blood flow in the distal phalanx.

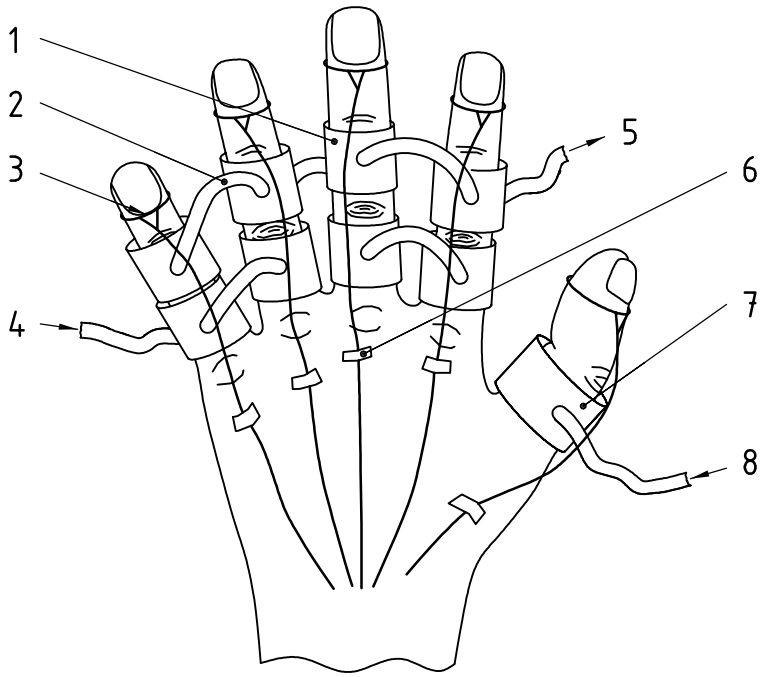


Key

1 double-inlet water cuffs
2 connecting pipes
3 transducers for detecting return of blood flow
4 water in
5 water out
6 tape to hold transducers
7 single-inlet air cuff
8 air in

NOTE Water, air and electrical connections are to the plethysmograph. Measurement on fewer fingers will have fewer water-perfused cuffs.

Figure 2 — Example of the set-up for measurement of FSBPs showing the positioning of cuffs and transducers for measurements on four fingers using strain-gauge plethysmography



Key

1 double-inlet water cuffs
2 connecting pipes
3 transducers for detecting return of blood flow
4 water in
5 water out
6 tape to hold transducers
7 air cuff
8 air in

NOTE Water, air and electrical connections are to the plethysmograph. Measurement on fewer fingers will have fewer water-perfused cuffs.

Figure 3 — Example of a set-up for measurement of FSBPs showing the positioning of cuffs and transducers for measurements on four fingers using strain-gauge plethysmography with separate cooling and pressure cuffs

4.3.4 Measurement sequence

Inflate the pressure cuffs to 50 mmHg above arm systolic pressure. Circulate water at a controlled temperature through the cooling cuff (or pressure cuff if the cooling cuff and pressure cuff are combined). After the cooling period of 5 min has elapsed, reduce the pressure in the pressure cuff at a rate of (2 ± 1) mmHg/s.

The order in which measurements are made can affect the results. It is recommended that the measurement of FSBP is first made at the warmer temperature of 30 °C followed by the measurement at a temperature of 15 °C. A final measurement, at a temperature of 10 °C, is then made. If a zero pressure is detected at 15 °C, the measurement at 10 °C need not be performed for diagnostic purposes.

NOTE To remove blood from the digits so that stronger signals are elicited on return of blood flow during pressure reduction, the tips of each instrumented finger can be squeezed while the pressure cuffs are being inflated to the full pressure.

5 Safety aspects

5.1 General

A few sensitive subjects may experience elevated arterial pressure due to excessive response to cold stress. Persons affected with hypertensive vascular disease should have their blood pressure monitored during the cold test.

The cold provocation test shall be stopped if requested by the subject or if finger blanching is observed.

5.2 Electrical safety

Effective procedures are needed to prevent electric shock, especially since water is used as a coolant. All apparatus shall meet the requirements of IEC 60601-1 concerning electrical hazards to the subject or operator of the apparatus.

5.3 Contraindications

In some subjects, disease symptoms can be affected by cold provocation, which would intensify the subject's adverse reaction to cold-stress.

The contraindications for the cold provocation test are an age of over 70 years, heart disease, hypertensive vascular disease, central circulatory diseases, and peripheral vascular disorders other than that to be examined. They are relative contraindications that should be checked out and, if necessary, considered by a medical doctor who should to make a decision as to whether the subject should be examined by the cold provocation test or whether any precautions should be taken.

5.4 Informed consent

Informed consent should be obtained from subjects in accordance with any legislation enforced by national governing bodies. The subject shall be instructed as to the purpose and risk of the cold provocation test. The examiner shall obtain confirmation of the subject's consent after replying to any questions the subject may pose. The subject shall be told that the cold provocation test will be stopped at any time on request.

5.5 Examiner and medical supervision

A suitably qualified examiner should undertake the preparation and instruction of subject and the conduct of the FSBP test. The examiner shall have sufficient knowledge about the risks inherent in the test, together with the technical aspects of the measurement. The procedure for testing should be approved by a medical doctor. Also, if the subjects have diseases other than peripheral vascular disorders to be examined, an examination by a medical doctor should be required.

6 Data reporting

6.1 General

For interpreting the data, and for evaluating the validity of measurements, it is recommended that information on test conditions, subject conditions, measurement devices, measurement parameters, subject characteristics, and symptoms and signs observed during examination be reported with the results, as described below.

6.2 Examination conditions

6.2.1 Test conditions

Time of year, time of day, room temperature, adaptation period and time period between test(s)/examination(s) affecting circulatory function of the test hands, if tests are performed on the same day, should be reported.

6.2.2 Subject conditions

The posture and clothing of the subjects during the test should be reported.

6.2.3 Measurement devices

Identification of apparatus used, or the characteristics of sensors, cuffs, plethysmograph and data recording system shall be reported.

6.2.4 Measurement parameters

The test finger(s) and reference finger(s), the position of the cuffs on the fingers, the temperature and duration of the cold provocation shall be reported.

6.3 Subject characteristics

General characteristics such as age, sex, body mass index (or body mass and height), nicotine intake, alcohol consumption, medications and health conditions influencing circulatory function of the hands should be reported.

In the case of subjects exposed to hand-transmitted vibration, their occupation, tools or machines used, estimated parameters of exposure (such as vibration magnitude, daily hours, days per week, years) should be reported.

It is recommended that the stages of vascular and neurological disturbances, and prior/current medical therapy be reported, if applicable. For the staging of the hand-arm vibration syndrome, the Stockholm Workshop Scales [22] may be used.

6.4 Symptoms and signs during examination

If subjects experience extraordinary symptoms or signs during examination (such as pale colour of fingers, severe pain, palpitation), these should be reported.

6.5 Results

The calculation and reporting of percentage FSBP shall be performed to correct for systemic systolic blood pressure (SBP) changes at a reference location between measurements:

$$F_t = \frac{F_{\text{test},t}}{F_{\text{test},30\,^\circ\text{C}} - \left(S_{\text{ref},30\,^\circ\text{C}} - S_{\text{ref},t}\right)} \times 100\ \% \qquad (1)$$

where

F_t is the percentage FSBP at 10 °C or 15 °C;

$F_{\text{test},t}$ is the FSBP of the test finger after thermal provocation at 10 °C or 15 °C;

$F_{\text{test},30\,^\circ\text{C}}$ is the FSBP measured on the test finger after thermal provocation at 30 °C;

$S_{\text{ref,30 °C}}$ is the systolic blood pressure measured at the reference site after thermal provocation of the test finger at 30 °C;

$S_{\text{ref},t}$ is the systolic blood pressure measured at the reference site after thermal provocation of the test finger at 10 °C or 15 °C.

The percentage FSBP is the preferred result. If a different method is used to correct for changes in systemic systolic pressure than that given by Equation (1), reporting the SBP at test sites and reference sites for each measurement temperature allows interpretation of results with respect to the preferred result. If comparable data for a vibration-exposed group and a control group are available, it is useful to report the diagnostic value of the measurement, such as sensitivity, specificity, predictive value, receiver operating characteristic (ROC) curve.

7 Assessment of normative values and limits

The normative values for percentage FSBP vary with the influence of various conditions. Normative values should be based on epidemiological data, considering the sensitivity, specificity and predictive value of the test methods employed.

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