INTERNATIONAL STANDARD

ISO 14835-2

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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

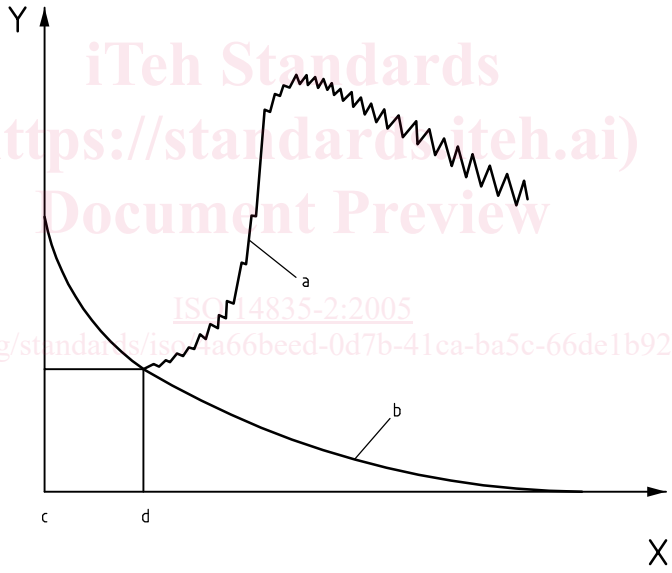
Finger systolic blood pressure (FSBP) is the quantity to be measured. It is expressed in millimetres of mercury (mmHg). The cuff pressure at which the return of blood flow is detected, which represents the FSBP, shall be recorded.

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.