INTERNATIONAL STANDARD

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

Part 1: Measurement and evaluation of finger skin temperature

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

Partie 1: Mesurage et évaluation de la température de la peau des doigts

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 108, *Mechanical vibration, shock and condition monitoring*, Subcommittee SC 4, *Human exposure to mechanical vibration and shock.*

This second edition cancels and replaces the first edition (ISO 14835-1:2005), of which it constitutes a minor technical revision. The main change is the specification of additional test conditions in 4.3.2.

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

Finger skin temperature (FST) is related indirectly to finger blood flow and reflects the contribution of feed capillaries, nutritive capillaries and arteries. Mechanical, physiologic and pharmacologic effects at any of these levels may affect FST.

Assessing FST over a sufficient observation time can identify the presence and extent of finger vasoconstriction in response to cold provocation produced by appropriate hand cooling.

The changes in FST during hand cooling normally reflect the degree of vasoconstriction and resistance to blood flow caused by cold provocation, and possibly also alterations of this physiological process. The changes in FST after cold provocation reflect different neurovascular processes that control recovery from cold exposure and the return to steady-state circulatory conditions. The measurement of FST during cold provocation is carried out in a well-controlled environment.

FST indicates intra- and inter-individual variability to some extent. The test results of cold provocation are interpreted together with subjective symptoms, signs and history, including vibration exposure.

After having gained experience with the use of ISO 14835-1:2005 over several years, it turned out that cold provocation tests are carried out in some countries using slightly different test parameters. In particular, the test conditions 12 °C water temperature and 5-min immersion duration are not generally used. A survey of ISO/TC 108/SC 4 revealing the current measurement practice of four countries constitutes the background for the development of this second edition of this part of ISO 14835.

The intention is to open the possibility to undertake the tests with specified different test parameters (in particular water temperature and immersion duration) in a clearly defined way in order to make the test results nevertheless comparable. Finally, the overall usage of this International Standard needs to be promoted.

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

Part 1: Measurement and evaluation of finger skin temperature

1 Scope

This part of ISO 14835 specifies

a) the methods for measuring the finger skin temperature (FST),

b) the procedures for conducting the measurements (including the performance of cold provocation tests), and

c) how to report the measurement results.

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

This part of ISO 14835 is applicable to the measurement of FST in response to cold provocation for the assessment of various peripheral vascular disorders in persons exposed to hand-arm vibration, and is intended to be used together with a battery of tests for diagnosing hand-arm vibration syndrome.

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.

ISO 5349-1, *Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 1: General requirements*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Measurement equipment

3.1 General

Several types of transducers are available for the measurement of FST. Thermocouples and thermistors (point transducers) are often used. They are simple to use and practical for following up. Thermal imaging devices have also been used, sometimes with infrared sensors. These devices, however, tend to be expensive and difficult to calibrate accurately compared with point transducers.

It is recommended that all equipment be checked for correct operation before and after use.

3.2 Thermometry

3.2.1 General

The advantage of contact thermometry and non-contact point thermometry using infrared in the field of vascular assessment methods is that the apparatus is less expensive and easier to maintain than thermography. Although FST is usually measured at one fixed point for each finger, depending on how many hands are being measured at once, an alternative is to measure on the distal phalanx of all fingers and the middle and proximal phalanges when measuring just one hand.

3.2.2 Sensors

It is important that sensors do not influence temperature changes at the measurement location and do not provide thermal insulation from the exterior environment or cold provocation. The sensors should be highly sensitive and accurate, with a maximum thermal discrimination of 0,1 °C within the physiological temperature range (5 °C to 40 °C).

3.2.3 Recorders

All FST data obtained during the test shall be recorded, and data storage on a computer may be performed. The time interval between temperature measurements of each finger shall not exceed 1 min. During recording, the temperatures may be displayed in real time. The recorded data, as numerically stored in the recorder, may be transferred to a computer for further processing, either manually after printing on paper, or directly through an electronic interface. A recorder with an integrated keyboard may permit control and digital display of the recording parameters.

3.2.4 Calibration

Calibration of the temperature sensors should be carried out by inserting a calibrated reference thermometer and all sensors into the cold-water bath. The sensors should be within ±0,2 °C of the reference thermometer. The range of temperatures registered using the sensors should not exceed 0,1 °C.

3.3 Thermography

3.3.1 General

The advantage of non-contact thermography in the field of vascular assessment methods is that, during the cold provocation test, the skin temperature of more than one point on a single finger may be measured and registered. Non-contact thermography methods show thermal images of whole hands. In this way, peripheral blood circulation disturbances in local parts of the hands and fingers may be detected and may indicate the severity of impairment to health.

3.3.2 Remote-sensing techniques

Remote-sensing systems involve infrared radiation. They usually consist of a high-resolution sensor unit (i.e. plane array sensor with at least 250 pixels per line and 250 lines per image), cooling system, operating unit, digital image recorder, digital computer, colour monitor and colour printer for reproduction of the thermogram. The maximum range of temperature to be measured shall be at least from 5 °C to 40 °C, but shall be variable within different steps. The maximum thermal discrimination shall be 0,1 °C within the mentioned temperature range.

3.3.3 Data processing

Data are recorded as an image of the hand with the FST coded as a colour map. Images should be recorded at possible maximum intervals not exceeding 1 min. The times at which cold provocation begins and ends should be recorded with the image. The relationship between colour and FST should be recorded for quantitative interpretation of results.

3.3.4 Calibration

Calibration may be accomplished in different ways. A cavity radiator as a black body may be used for calibration. Internal reference data for automatic comparison during measurement interruption may serve for testing the stability of measurements.

4 Measurement procedure

4.1 Quantity to be measured

FST is the quantity to be measured. It is expressed in degrees Celsius (°C).

4.2 Conditions of examination

4.2.1 General

To obtain precise data, the test conditions and procedures shall be sufficiently controlled. Measurement of FST should be carried out in a well-controlled environment.

4.2.2 Examination room

FST is strongly affected by room temperature. The room temperature shall be maintained at (22 ± 1) °C over the whole length of the body, for the duration of the test.

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. The 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.

4.2.3 Time

4.2.3.1 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.

4.2.3.2 Time of day

With respect to circadian biorhythm, examination between 9:00 and 18:00 is recommended.

NOTE It has been reported that the time of day has an influence on FSTs, but it is unknown whether these daily variations have a significant effect on the FST response to cold provocation.

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

A delay of 3 h between cold provocation tests, including test described in ISO 14835-2, and FST measurements is recommended so as to avoid the effects of prior cold exposure. This includes a cold provocation that has been aborted after cold provocation has begun.