INTERNATIONAL STANDARD

**ISO 14835-1**

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 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.

#### 4.2.4 Subject preparation

##### 4.2.4.1 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.

##### 4.2.4.2 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 cold provocation test 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.

##### 4.2.4.3 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 An approximate clo value of the above clothing of 0,7 to 0,8 is suggested.

##### 4.2.4.4 Adaptation of subject

At least 30 min in the examination room without physiological or psychological stress is needed for thermal adaptation. Initial FST measurements are recommended and FSTs should be confirmed to have reached stable values for at least 2 min prior to starting cold exposure.

##### 4.2.4.5 Subject posture

A seated and relaxed posture should be used during the entire test including the adaptation period in principle.

Both hands should be at heart height during settling and recovery and preferably during provocation, with the wrists in a neutral position.

### 4.3 Cold provocation

#### 4.3.1 Cold-water bath

The cold-water bath shall be surrounded with heat-insulating materials to prevent cooling of other body parts. The edge of the water bath shall have a protective layer to insulate the subject's arm from the transmitted cold stimuli.

The water should be stirred to maintain constant temperature.

#### 4.3.2 Water temperature and duration of immersion

One of the following four test conditions shall be maintained to provide potentially useful measurements while minimizing stress. Test condition a) is the recommended condition and should be preferred.

a) Water temperature (12 ± 0,5) °C and an immersion duration of 5 min or

b) water temperature (12 ± 0,5) °C and an immersion duration of 2 min or

c) water temperature (15 ± 0,5) °C and an immersion duration of 5 min or

d) water temperature (10 ± 0,5) °C and an immersion duration of 10 min.

The applied test condition [a), b), c) or d)] shall be reported.

NOTE 1 Severity of cold-stress during the cold provocation test is the main factor determining the diagnostic value for vascular disorder. The severity is principally determined by the water temperature and immersion duration. The diagnostic values of the tests with use of water at temperatures between 5 °C and 15 °C have been reported.

NOTE 2 Immersion duration of less than 5 min might be too short to obtain sufficient severity of cold-stress for heat equilibration from skin to deeper structures. Although a lower water temperature, such as 5 °C, can provide more diagnostic data, the subject suffers considerable pain during immersion at this temperature. Suffering during the test becomes more severe in inverse proportion to the water temperature, and in proportion to the immersion duration.

#### 4.3.3 Choice of test hands and fingers

Wherever possible, both hands shall be immersed simultaneously for evaluation. If only one hand is selected for measurements, this should be the dominant hand or the hand with the greatest reported symptoms.

It is recommended that measurements be made on all possible digits. If less than 10 digits are selected for measurements, they should include the greatest reported symptoms.

The hands shall be immersed down into the water up to wrist levels, and the bottom wall of the cold-water bath should not be touched by the hands or fingers. The minimum volume of the water is recommended to be 10 l.

#### 4.3.4 Waterproof covering

The use of waterproof covering during immersion will prevent cooling of the hands after removal from the water due to evaporation. The waterproof covering should have high thermal conductivity and should be tight enough to avoid trapped air during immersion.

The waterproof covering shall be put on just before the immersion and shall be removed at the end of the immersion duration. If waterproof covering is not used, the immersed hands shall be gently wiped dry immediately after cold provocation.

### 4.4 Conduct of the test

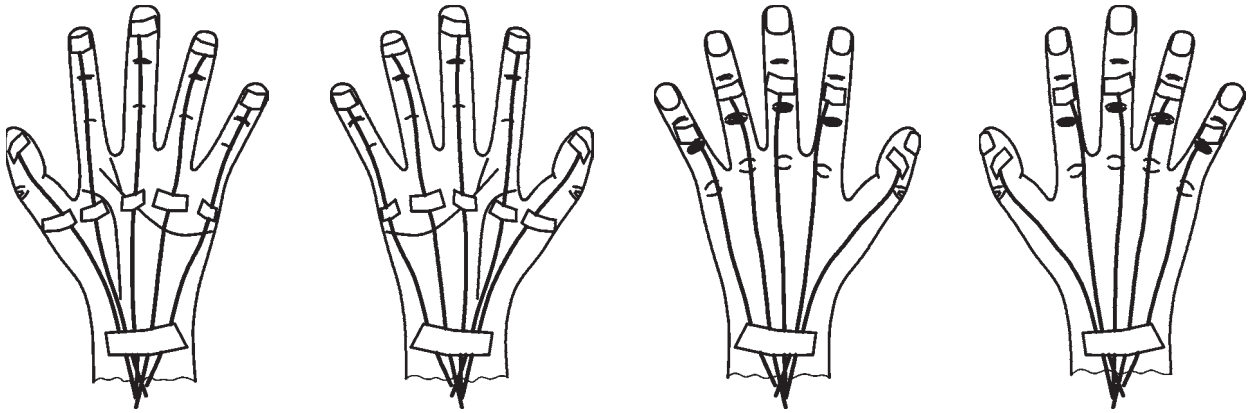
#### 4.4.1 General

Under ordinary circumstances, rhythmic fluctuations in the finger vessels involve periods possibly from about 0,5 min to about 5 min. Therefore, repeated measurements of FST for an adequate duration with adequate intervals are needed. FST also varies with the skin position measured. In the case of point measurement, a fixed point of skin shall be measured.

#### 4.4.2 Placement of sensors

##### 4.4.2.1 Contact sensing

In principle, the sensor should be set to detect a small point directly on the fingertip, and optionally, on the dorsal surfaces of the distal or middle phalanges. Sensors should be placed centrally to the phalanges, i.e. midway between the tip and the base of the phalanges and along the midline. FST can be measured by means of thermal sensors properly attached to the skin on the ventral surfaces of the distal phalanges, and optionally, on the dorsal surfaces of the distal phalanges. The fingers may be placed on fixed sensors or the sensors may be attached to the fingers with adhesive tape. To ensure that blood flow is not occluded, adhesive tape tension and pressure on any surface on which the hands rest should be kept to a minimum. A typical attachment of sensors is shown in Figure 1.



**a) Left hand** **b) Right hand** **c) Left hand** **d) Right hand**

NOTE Attachment of sensors on the fingertips is recommended [see a) and b)]. An optional method of attachment on the dorsal surfaces of the distal (thumb) or middle phalanges is also shown [see c) and d)].

**Figure 1 — Typical setup for measurement of FSTs using sensors**

##### 4.4.2.2 Remote sensing

FST on the ventral or the dorsal surfaces of the distal phalanges should be measured by means of non-contact point thermometry using infrared. The palmar side of the whole hand may be measured by means of non-contact thermography.

#### 4.4.3 Measurement periods

##### 4.4.3.1 Measurement before cold provocation

FSTs should be stable prior to baseline measurements. FST measurements should be recorded for at least 2 min before cold provocation.

##### 4.4.3.2 Measurement during cold provocation

Only if contact thermometry with sensors attached on the fingers is used, measurements may be continued during immersion.

##### 4.4.3.3 Measurement after cold provocation

Measurements shall be continued for a minimum of 10 min. It is preferable to continue measurements until complete recovery is achieved.

# 5 Safety aspects

## 5.1 General

A few sensitive subjects may experience either elevated arterial pressure or vasogenic shock 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 during immersion of the hands in cold water. All apparatus shall meet the safety requirements of IEC 60601-1 concerning electrical hazards to the subject or operator of the apparatus. In particular, the examiner shall receive sufficient instruction in the safety procedure for water immersion.

## 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 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 the subject, and the conduct of FST measurements and cold provocation tests. The examiner shall have sufficient knowledge of the diagnostic significance and risk of the test, and should be aware of all technical aspects of the test. The procedure for testing should be approved by a medical doctor. Also, if the subjects have diseases other than the peripheral vascular disorders to be examined, an examination by a medical doctor should be required.

# 6 Data reporting

## 6.1 General

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

## 6.2 Examination conditions

### 6.2.1 Test conditions

Time of year, time of day, room temperature, adaptation period, and the time lag 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 Temperature measurement

Identification of the apparatus used or a full specification of sensors, recorder and data processing system shall be reported. Skin positions of FST measurements shall also be reported.

### 6.2.4 Hand cooling

The number of hands immersed, the water temperature and immersion duration shall be reported. If special methods such as observation of ischemia during immersion, or hand gloves for waterproofing, are used, this 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, and 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[13] 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 entire rewarming process, and values before and during cold provocation, should be reported. If special evaluation parameters (such as rewarming time, rewarming rate to the baseline temperature) are used, reporting of the data together with the parameters of the rewarming process is recommended. If comparison data between the vibration-exposed group and the control group are obtained, information concerning the diagnostic value of the test method [such as sensitivity, specificity, predictive value and receiver-operating characteristic (ROC) curve] should be reported.

# 7 Assessment of normative values and limits

The normative values for FST vary with the influence of various conditions (see ISO 5349-1). Normative values should be based on epidemiological data, and the sensitivity, specificity and predictive value of the test methods used should be considered.

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