## INTERNATIONAL STANDARD



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# Mechanical vibration — Vibrotactile perception thresholds for the assessment of nerve dysfunction —

Part 2: Analysis and interpretation of iTeh STmeasurements at the fingertips

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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 13091-2 was prepared by Technical Committee ISO/TC 108, *Mechanical vibration and shock*, Subcommittee SC 4, *Human exposure to mechanical vibration and shock*.

ISO 13091 consists of the following parts, under the general title *Mechanical* vibration — Vibrotactile perception thresholds for the assessment of nerve dysfunction:

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- Part 1: Methods of measurement at the fingertips
- Part 2: Analysis and interpretation of measurements at the fingertips https://standards.iteh.av/catalog/standards/sist/be5bc990-13aa-4b95-a066-511093188661/iso-13091-2-2003

#### Introduction

Early detection of peripheral neuropathies in the upper extremities, which are often manifest as changes in tactile function and hence changes in mechanoreceptor acuity, is of considerable interest. Such neuropathies can occur as a result of disease, or of exposure to chemical or physical, neurotoxic agents. With a suitable choice of measurement conditions, as provided in ISO 13091-1, separate responses from the slow-adapting type 1 (SAI) and fast-adapting types 1 and 2 (FAI and FAII) mechanoreceptor populations can be determined by using vibrotactile stimulation at different frequencies.

This part of ISO 13091 defines the analysis and interpretation of vibrotactile thresholds measured at the fingertips according to the provisions of ISO 13091-1. Procedures for describing statistically significant changes in vibrotactile perception thresholds are provided for the situation in which the threshold is determined on a single occasion, as well as when the threshold is determined repeatedly.

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## Mechanical vibration — Vibrotactile perception thresholds for the assessment of nerve dysfunction —

## Part 2: Analysis and interpretation of measurements at the fingertips

#### 1 Scope

This part of ISO 13091 specifies methods and procedures for analysing and interpreting vibrotactile perception thresholds and threshold shifts. Procedures for describing statistically significant changes in vibrotactile perception thresholds are recommended.

This part of ISO 13091 is applicable to vibrotactile perception thresholds determined at the fingertips according to the provisions of ISO 13091-1.

Values for the vibrotactile perception thresholds of healthy persons, applicable to thresholds determined according to the provisions of ISO 13091-1, are given in Annex A.

The implications of observed changes in vibrotactile perception thresholds are considered in Annex B.

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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.

ISO 2041, Vibration and shock - Vocabulary

ISO 5805, Mechanical vibration and shock — Human exposure — Vocabulary

ISO 13091-1:2001, Mechanical vibration — Vibrotactile perception thresholds for the assessment of nerve dysfunction — Part 1: Methods of measurement at the fingertips

#### 3 Terms, definitions, symbols and abbreviated terms

#### 3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 2041, ISO 5805 and ISO 13091-1, together with the following, apply.

#### 3.1.1

2

#### equivalent frequency

frequency selected as representing the measurement frequency when frequency is changed with time during the measurement of vibrotactile perception

#### 3.1.2

#### healthy person

person who, in the opinion of a qualified physician, is free from signs or symptoms of peripheral neurological disease as determined by physical examination and other clinical or objective tests deemed necessary to support the opinion, and who is not exposed to a neurotoxic agent or to vibration

#### 3.1.3

#### population group

group of persons defined by one or more common factors

EXAMPLE Common factors can be geography, age, sex, diet or occupation.

#### 3.1.4

#### mechanoreceptor

nerve ending specialized for transforming mechanical deformation of the skin into nerve impulses

#### 3.1.5

#### mechanoreceptor-specific vibrotactile perception threshold

#### receptor-specific vibrotactile perception threshold

vibrotactile perception threshold at which the stimulus is mediated by one population of mechanoreceptors at the point of stimulation

#### 3.1.6

#### vibrotactile perception threshold

skin surface acceleration level at which there is a 50 % positive response rate for detecting a pure-tone oscillatory stimulus in the psychometric function

#### 3.1.7

#### baseline vibrotactile perception threshold

initial vibrotactile perception threshold used for the comparison of results

#### 3.1.8 Teh ST ANDARD PREVIEW

#### reference vibrotactile perception threshold

value of the vibrotactile perception threshold for healthy personsteh.ai)

#### 3.1.9

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threshold shift change in vibrotactile perception threshold from a previously established baseline value that persists over time

#### 3.1.10

#### reference threshold shift

persistent shift in threshold from the corresponding reference vibrotactile perception threshold recorded at the same frequency, or equivalent frequency

#### 3.1.11

#### relative threshold shift

persistent shift in threshold from the corresponding value recorded previously for the same person at the same fingertip and frequency, or equivalent frequency, using the same measurement method

#### 3.1.12

#### psychophysical algorithm

measurement procedure in which physical stimuli are presented to a subject to elicit a predetermined sensory response, such as perceiving the presence or character of an externally applied skin motion

#### 3.1.13

#### up-down algorithm

psychophysical measurement procedure in which two limiting thresholds (ascending and descending) are determined by presenting to a subject a sequence of short-duration stimuli, each of constant but different intensity

This procedure commonly involves applying a sequence of stimuli with successively increasing intensity to the NOTE skin until the subject signals that the stimulus has been detected (ascending threshold). Successive stimuli are then decreased in intensity until the subject signals that the stimulus can no longer be felt (descending threshold).

#### 3.1.14

#### von Békésy algorithm

psychophysical measurement procedure in which a continuous stimulus with changing intensity, often accompanied by a change in frequency with time (gliding tone), is used to determine sequentially ascending and descending thresholds

#### 3.1.15

#### predictive value

prediction of the risk of disease, or symptoms, from the results of an objective test of some human property or function

#### 3.1.16

#### positive predictive value

fraction (or percentage) of a population group in whom the presence of disease, or symptoms, can be correctly predicted from the positive result of an objective test

#### 3.1.17

#### negative predictive value

fraction (or percentage) of a population group in whom the absence of disease, or symptoms, can be correctly predicted from the negative result of an objective test

#### 3.1.18

#### association

statistical measure of the chance of one human property or function observed in a person co-existing with the presence of a second property or function **iTeh STANDARD PREVIEW** 

#### 3.1.19

#### psychometric function

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function expressing the relationship between the proportion, or percentage, of positive responses indicating a stimulus has been detected by a subject and a physical measure of the magnitude of the stimulus

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### 3.1.20 sensibility index

ratio of the observed difference in threshold from a baseline of 150 dB to that of healthy persons of the same age from the same baseline, summed for each measurement frequency, or equivalent frequency

NOTE An increase in vibrotactile perception threshold, which is associated with a reduction in acuity, will result in a decrease in the sensibility index from the value of unity for healthy persons.

#### 3.1.21

#### tactogram

graphical representation of threshold shifts as a function of frequency

#### 3.1.22

#### probe

means by which external motional and oscillatory stimuli are coupled to the skin surface

#### 3.1.23

#### surround

static, rigid, flat surface on which a fingertip rests, containing a hole through which a probe may contact the skin surface

#### 3.2 Symbols and abbreviated terms

The following symbols and abbreviated terms are used in this part of ISO 13091:

FAI	fast-adapting, type 1 mechanoreceptors
FAII	fast-adapting, type 2 mechanoreceptors
Ν	number of subjects
$N_{F}$	number of fingers
р	probability
SAI	slow-adapting, type 1 mechanoreceptors
$s(f_j)$	Gaussian distribution parameter for $T(f_j)_{ref}$ at frequency $f_j$
$T(f_j)_{base}$	baseline vibrotactile perception threshold at frequency $f_j$
$T(f_j)_i$	<i>i</i> th vibrotactile perception threshold at frequency $f_j$
$T(f_j)_{M}$	mean vibrotactile perception threshold at frequency $f_j$
$T(f_j)_{\sf obs}$	observed vibrotactile perception threshold at frequency $f_j$
$T(f_j)_{ref}$	(standards.iteh.ai) reference vibrotactile perception threshold at frequency $f_j$
$T(f_j)_{ref,M}$	ISO 13091-2:2003 mean reference vibrotactile perception threshold at frequency f <sub>j</sub> 4b95-a066- 511093188661/iso-13091-2-2003
V	test/retest variability
VPT	vibrotactile perception threshold
$\Delta T(f_j)_{ref}$	reference threshold shift at frequency $f_j$
$\Delta T(f_j)_{ref,i}$	<i>i</i> th reference threshold shift at frequency $f_j$
$\Delta T(f_j)_{ref,M}$	mean reference threshold shift at frequency $f_j$
$\Delta T(f_j)_{rel}$	relative threshold shift at frequency $f_j$
$\Delta T(f_j)_{rel,i}$	<i>i</i> th relative threshold shift at frequency $f_j$
$\Delta T(f_j)_{rel,M}$	mean relative threshold shift at frequency $f_j$

NOTE Symbols using an upper case *T* refer to thresholds expressed in decibels (ref.  $10^{-6}$  m/s<sup>2</sup>). The equivalent threshold expressed in metres per second squared is given by the lower case symbol *t*.

#### 4 Treatment of vibrotactile perception thresholds

#### 4.1 General

The information required for the reporting, analysis and interpretation of VPTs determined in accordance with the provisions of ISO 13091-1 is specified in ISO 13091-1:2001, Clause 7. A subject's VPTs are commonly measured on a single occasion. In order to be interpretable, the expected variability in the VPTs if the measurement were to be repeated on an another occasion (e.g. a different day) must be known.

Two situations are considered in this part of ISO 13091. If the VPT of a subject is determined repeatedly at the same fingertip over a period of several days, then the test/retest variability applicable to the mean value of the observed VPTs, expressed in decibels, shall be the standard deviation calculated from the observed VPTs when expressed in decibels. Alternatively, in circumstances in which it is not possible to calculate a meaningful standard deviation from the measurements performed (e.g. when only a single measurement is made of a subject's VPT), then the test/retest variability of the observed VPT shall be estimated for the measurement method employed. The estimate shall be based on repeated measurements conducted on healthy persons using the same measurement method.

#### 4.2 Mean value of repeated measurements

If the VPT at a given stimulation frequency or equivalent frequency,  $f_j$ , is determined repeatedly at a fingertip according to the provisions of ISO 13091-1, then the mean value of the VPT shall be calculated as the mean of the observed VPTs expressed in decibels (ref.  $10^{-6}$  m/s<sup>2</sup>), i.e. as

$$T(f_j)_{\mathsf{M}} = \frac{1}{n} \sum_{i=1}^{n} T(f_j)_i^{\mathsf{T}} \mathbf{A} \mathbf{STANDARD PREVIEW}$$
(1)  
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where  $T(f_j)_i$  and  $T(f_j)_M$  are expressed in decibels (ref. 10<sup>-6</sup> m/s<sup>2</sup>).

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NOTE The mean VPT calculated from the arithmetic mean of observed VPTs expressed in decibels (ref.  $10^{-6}$  m/s<sup>2</sup>), as in Equation (1), is equivalent to the geometrical mean of the observed VPTs expressed in metres per second squared.

#### 4.3 Test/retest variability of threshold measurements

If the VPT is repeatedly determined at the same fingertip of a subject on separate occasions (e.g. on different days), then the intra-individual test/retest variability in threshold shall be calculated for this subject. The test/retest variability, *V*, shall be expressed in decibels as one standard deviation from the mean value of the VPTs, expressed in decibels, as determined by repeated measurements. If the VPTs,  $T(f_j)_i$ , found by repeated measurements at a given stimulation frequency or equivalent frequency,  $f_j$ , are expressed in decibels (ref.  $10^{-6} \text{ m/s}^2$ ), then:

$$V = \left[\frac{1}{n-1} \sum_{i=1}^{n} \left(T(f_{j})_{i} - T(f_{j})_{M}\right)^{2}\right]^{1/2}$$
(2)

where  $T(f_j)_{M}$  is the mean of *n* repeated measurements expressed in decibels (ref. 10<sup>-6</sup> m/s<sup>2</sup>).

Under circumstances in which it is not possible to calculate a meaningful standard deviation for a subject (e.g. when only a single measurement is made of a subject's VPT), then the test/retest variability of the observed VPT shall be estimated for the measurement method used. The estimate shall be derived from the standard deviation of VPTs determined at the fingertip of a healthy person using the same measurement method. The standard deviation shall be based on at least 10 measurements of VPT performed on separate occasions (e.g. 10 different days). The measurements shall be performed in accordance with the provisions of ISO 13091-1, and the standard deviation, expressed in decibels, shall be calculated from the observed VPTs expressed in decibels using Equation (2). The arithmetic mean of the standard deviations recorded from three or more

healthy persons at a given frequency, or equivalent frequency, shall be used as the estimate for the intra-individual test/retest variability at that frequency, or equivalent frequency.

Normal hormonal changes during the menstrual cycle induce changes of up to 20 dB in the FAII receptor thresholds of females. When estimating the test/retest variability for the FAII thresholds of females, that is, for VPTs at measurement frequencies of 100 Hz, 125 Hz and 160 Hz, this tendency for the threshold to cycle should be taken into account. The threshold changes occur several days before and after ovulation.

#### 4.4 Treatment of unresolved errors

Under some circumstances, the examiner may believe that unresolved errors have occurred during threshold measurements. Also, errors may have been introduced by conducting measurements on a defective skin site as described in ISO 13091-1.

In these situations, analysis and interpretation of VPTs using the methods and procedures contained in this part of ISO 13091 are only possible if additional information is obtained. A second set of measurements shall be performed according to the provisions of ISO 13091-1 if it is believed that more reliable VPTs may be obtained. The second set of VPTs shall be treated as described in this part of ISO 13091.

NOTE If, at a single measurement site, the VPTs are determined at two or more frequencies, or equivalent frequencies, mediated by the same mechanoreceptor population, then the consistency of the threshold shifts calculated according to the provisions of 5.6 may be examined to confirm the presence of errors.

#### 4.5 Treatment of suspected increase in test/retest variability

Under some circumstances, the examiner may believe that the test/retest variability applicable to the measurement method is not applicable to a subject. The opinion may be based on the lack of consistency in determining ascending and descending thresholds as described in ISO 13091-1:2001, 6.3, or on other information.

In these situations, analysis and interpretation of VPTs using the methods and procedures contained in this part of ISO 13091 are only possible if the variability applicable to the subject is established. A subject-specific test/retest variability is established by conducting repeated threshold measurements on the subject according to the provisions of 4.3.

#### 5 Calculation of threshold shift

#### 5.1 General

The interpretation of VPTs is facilitated by calculation of the change in observed threshold from a predefined value. The calculation of threshold shift shall be performed for each frequency, or equivalent frequency, and fingertip at which VPTs have been obtained according to provisions of Clause 4.

#### 5.2 Relative threshold shift

The relative threshold shift shall be calculated as the difference between two VPT values expressed in decibels (ref.  $10^{-6}$  m/s<sup>2</sup>), or the ratio of the two VPT values expressed in metres per second squared, one being the observed VPT and the other a baseline VPT. The two VPTs shall be obtained from the same fingertip of a subject using the same measurement method, and measurement frequency or equivalent frequency. The relative threshold shift,  $\Delta T(f_j)_{rel}$ , at the *j*th frequency  $f_j$  shall be expressed in decibels, and calculated at each measurement frequency, or equivalent frequency, as

$$\Delta T(f_j)_{\text{rel}} = T(f_j)_{\text{obs}} - T(f_j)_{\text{base}}$$
(3)

where the observed VPT at the *j*th frequency,  $T(f_j)_{obs}$ , and the baseline VPT at the same frequency, or equivalent frequency,  $T(f_j)_{base}$ , are expressed in decibels (ref. 10<sup>-6</sup> m/s<sup>2</sup>).