INTERNATIONAL STANDARD

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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

Vibrations mécaniques — Seuils de perception vibrotactile pour l'évaluation des troubles neurologiques —

Partie 2: Analyse et interprétation des mesures obtenues à la pulpe 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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee 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 13091-2:2003), which has been technically revised.

The main changes compared to the previous edition are as follows:

— The contents of Annex A have been updated to include studies of the vibrotactile perception thresholds of healthy persons published since the first edition of the standard.

— The Bibliography has been updated to include the studies listed in Annex A.

A list of all parts in the ISO 13091 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 document 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.

This edition of ISO 13091-2 contains an updated analysis of the vibrotactile perception thresholds for healthy males and females and provides reference thresholds for all frequencies specified in 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.

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

Part 2: Analysis and interpretation of measurements at the fingertips

1 Scope

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, *Mechanical vibration, shock and condition monitoring — Vocabulary*

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

ISO 13091-1, *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

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 Terms and definitions

3.1.1
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 has not been exposed to a neurotoxic agent, vibration, or excessive repetitive motion, or diagnosed with diabetes or a metabolic disorder

3.1.2
population group
group of persons defined by one or more common factors

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

3.1.3
baseline vibrotactile perception threshold
initial vibrotactile perception threshold used for the comparison of results

3.1.4
reference vibrotactile perception threshold
value of the vibrotactile perception threshold for healthy persons

3.1.5
reference threshold shift
persistent shift in threshold from the corresponding *reference vibrotactile perception threshold* (3.1.4) recorded at the same frequency, or equivalent frequency

3.1.6
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

3.1.7
predictive value
prediction of the risk of disease, or symptoms, from the results of an objective test of some human property or function (see also positive and negative predictive values)

3.1.8
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

3.1.9
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

3.1.10
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

3.1.11
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 1 to entry: 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.

3.1.12
tactogram
graphical representation of threshold shifts as a function of frequency

3.2 Symbols and abbreviated terms

The following symbols and abbreviated terms are used in this document:

FAI	fast-adapting, type 1 mechanoreceptors
FAII	fast-adapting, type 2 mechanoreceptors
N	number of subjects
N_F	number of fingers
p	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^{th} vibrotactile perception threshold at frequency f_j
$T(f_j)_M$	mean vibrotactile perception threshold at frequency f_j
$T(f_j)_{obs}$	observed vibrotactile perception threshold at frequency f_j
$T(f_j)_{ref}$	reference vibrotactile perception threshold at frequency f_j
$T(f_j)_{ref,M}$	mean reference vibrotactile perception threshold at frequency f_j
$V(f_j)$	test/retest variability at frequency f_j
VPT	vibrotactile perception threshold
$\Delta T(f_j)_{ref}$	reference threshold shift at frequency f_j
$\Delta T(f_j)_{ref,i}$	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^{th} relative threshold shift at frequency f_j
$\Delta T(f_j)_{rel,M}$	mean relative threshold shift at frequency f_j
$\Delta T(\text{SAI, FAI or FAII})_{ref,M}$	mean reference threshold shift for SAI, FAI, or FAII receptor population
$\Delta T(\text{SAI, FAI or FAII})_{rel,M}$	mean relative threshold shift for SAI, FAI, or FAII receptor population

NOTE Symbols using an uppercase T refer to thresholds expressed in dB (ref. 10^{-6} m/s^2). The equivalent threshold expressed in m/s^2 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, it is necessary to know

the expected variability in the VPTs if the measurement were to be repeated on another occasion (e.g. a different day).

Two situations are considered in this document. 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 dB (ref. 10^{-6} m/s^2), using Formula (1):

$$T(f_j)_{\mathrm{M}} = \frac{1}{n}\sum_{i=1}^{n} T(f_j)_i \tag{1}$$

where $T(f_j)_i$ and $T(f_j)_{\mathrm{M}}$ are expressed in dB (ref. 10^{-6} m/s^2).

NOTE The mean VPT calculated from the arithmetic mean of observed VPTs expressed in dB (ref. 10^{-6} m/s^2), as in Formula (1), is equivalent to the geometrical mean of the observed VPTs expressed in m/s^2.

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, $V(f_j)$, at a given stimulation frequency or equivalent frequency, f_j, (calculated using Formula [2]) 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 dB (ref. 10^{-6} m/s^2), then:

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

where $T(f_j)_{\mathrm{M}}$ is the mean of n repeated measurements expressed in dB (ref. 10^{-6} m/s^2).

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 fingertips of healthy persons using the same measurement method. The standard deviation shall be based on at least 10 measurements of VPTs 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 Formula (2). The within subject standard deviation 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 (one-way analysis of variance).

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 might believe that unresolved errors have occurred during threshold measurements. Also, errors might 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 document 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 document.

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 can be examined to confirm the presence of errors.

4.5 Treatment of suspected increase in test/retest variability

Under some circumstances, the examiner might believe that the test/retest variability applicable to the measurement method is not applicable to a subject. The opinion might 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 document 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 dB (ref. 10^{-6} m/s^2), or the ratio of the two VPT values expressed in m/s^2, 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, $\Delta T(f_j)_{\text{rel}}$, at the j^{th} frequency, f_j, shall be expressed in decibels, and calculated at each measurement frequency, or equivalent frequency, using Formula (3):

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

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

The equivalent expression for the relative threshold shift calculated from thresholds expressed in m/s^2 is shown in Formula (4):

$$\Delta T(f_j)_{\text{rel}} = 20 \lg\left[t(f_j)_{\text{obs}} / t(f_j)_{\text{base}}\right] \tag{4}$$

NOTE The calculation of relative threshold shifts facilitates the identification of patterns of change in tactile acuity affecting an individual. Determining relative threshold shifts has proved beneficial in situations in which a known pathological, or repair, process is followed in an individual over a period of time. Under these circumstances, the baseline VPT is usually the original VPT recorded on the subject.

5.3 Reference threshold shift

The reference threshold shift shall be calculated as the difference between the observed and reference VPT values when both are expressed in dB (ref. 10^{-6} m/s^2), or the ratio of the two VPT values expressed in m/s^2. The reference threshold shift, $\Delta T(f_j)_{\text{ref}}$, at the j^{th} frequency, f_j, shall be expressed in dB, and calculated at each measurement frequency, or equivalent frequency, using Formula (5):

$$\Delta T(f_j)_{\text{ref}} = T(f_j)_{\text{obs}} - T(f_j)_{\text{ref}} \tag{5}$$

where the observed VPT at the j^{th} frequency, $T(f_j)_{\text{obs}}$, and the reference VPT at the same frequency, or equivalent frequency, $T(f_j)_{\text{ref}}$, are expressed in dB (ref. 10^{-6} m/s^2).

The equivalent expression for the reference threshold shift calculated from thresholds expressed in m/s^2 is shown in Formula (6):

$$\Delta T(f_j)_{\text{ref}} = 20 \lg\left[t(f_j)_{\text{obs}} / t(f_j)_{\text{ref}}\right] \tag{6}$$

NOTE The calculation of reference threshold shifts facilitates the identification of patterns of tactile abnormality that are interpretable in terms of changes in mechanoreceptor or nerve function. An association has been found between reference threshold shifts and symptom reports. Reference threshold shifts can be associated with neuropathies affecting the upper extremities.

5.4 Mean value of threshold shift

If the threshold shift for a given stimulation frequency, or equivalent frequency, is determined repeatedly at a fingertip under circumstances in which it is not expected to change, then the arithmetic mean value of the relative, or reference, threshold shift shall be calculated from the threshold shifts expressed in decibels. The mean relative threshold shift at frequency, f_j, expressed in dB, is calculated using Formula (7):

$$\Delta T(f_j)_{\text{rel,M}} = \frac{1}{n} \sum_{i=1}^{n} \Delta T(f_j)_{\text{rel},i} \tag{7}$$

The mean reference threshold shift at frequency, f_j, expressed in dB, is calculated using Formula (8):

$$\Delta T(f_j)_{\text{ref,M}} = \frac{1}{n} \sum_{i=1}^{n} \Delta T(f_j)_{\text{ref},i} \tag{8}$$

5.5 Tactogram

A tactogram shall consist of a logarithmic plot of frequency, or equivalent frequency, on the abscissa and threshold shift expressed in dB on the ordinate, as shown in Figure 1. The threshold shift can range from, typically, –20 dB to 60 dB. The frequency ranges in which thresholds are mediated by different mechanoreceptor populations may be indicated.

NOTE 1 The frequency ranges at which VPTs determined according to the provisions of ISO 13091-1 are mediated by the SAI, FAI or FAII mechanoreceptor populations are listed in ISO 13091-1:2001, Table 3.

A tactogram can be constructed for individual fingers, hands, subjects, or groups of subjects, and the applicable values of the relative, or reference, threshold shifts shall be plotted as ordinates. Values at different frequencies, or equivalent frequencies, for individual fingers, hands, subjects, or groups of subjects, as applicable, may be connected by lines.