## INTERNATIONAL STANDARD

ISO 13091-2

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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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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:

- Part 1: Methods of measurement at the fingertips
- Part 2: Analysis and interpretation of measurements at the fingertips

#### 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.

#### 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.

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

#### 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

#### ISO 13091-2:2003(E)

#### 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

#### reference vibrotactile perception threshold

value of the vibrotactile perception threshold for healthy persons

#### 3.1.9

#### 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

NOTE This procedure commonly involves applying a sequence of stimuli with successively increasing intensity to the 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

#### 3.1.19

#### psychometric function

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

#### 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

Not for Resale

#### 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

N number of subjects

number of fingers  $N_{\mathsf{F}}$ 

probability

slow-adapting, type 1 mechanoreceptors SAI

Gaussian distribution parameter for  $T(f_i)_{ref}$  at frequency  $f_i$  $s(f_i)$ 

baseline vibrotactile perception threshold at frequency  $f_i$  $T(f_j)_{\text{base}}$ 

*i*th vibrotactile perception threshold at frequency  $f_i$  $T(f_i)_i$ 

 $T(f_i)_{\mathsf{M}}$ mean vibrotactile perception threshold at frequency  $f_i$ 

observed vibrotactile perception threshold at frequency  $f_i$  $T(f_i)_{obs}$ 

reference vibrotactile perception threshold at frequency  $f_i$  $T(f_i)_{ref}$ 

mean reference vibrotactile perception threshold at frequency  $f_i$  $T(f_j)_{ref,M}$ 

test/retest variability

**VPT** vibrotactile perception threshold

reference threshold shift at frequency  $f_i$  $\Delta T(f_j)_{ref}$ 

 $\Delta T(f_j)_{\text{ref},i}$ *i*th reference threshold shift at frequency  $f_i$ 

 $\Delta T(f_i)_{\text{ref},M}$ mean reference threshold shift at frequency  $f_i$ 

 $\Delta T(f_i)_{\text{rel}}$ relative threshold shift at frequency  $f_i$ 

 $\Delta T(f_j)_{\mathsf{rel},i}$ *i*th relative threshold shift at frequency  $f_i$ 

 $\Delta T(f_j)_{\text{rel},M}$ mean relative threshold shift at frequency  $f_i$ 

Symbols using an upper case T refer to thresholds expressed in decibels (ref.  $10^{-6}$  m/s<sup>2</sup>). The equivalent NOTE 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

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

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

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.  $10^{-6}$  m/s<sup>2</sup>), 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.  $10^{-6}$  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

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#### ISO 13091-2:2003(E)

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.

#### 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.

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.

#### 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.

#### 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<sup>-6</sup> 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,  $\Delta T(f_i)_{rel}$ , at the jth frequency  $f_i$  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,  $T(f_j)_{\rm obs}$ , and the baseline VPT at the same frequency, or equivalent frequency,  $T(f_j)_{\rm base}$ , are expressed in decibels (ref.  $10^{-6}$  m/s<sup>2</sup>).

The equivalent expression for the relative threshold shift calculated from thresholds expressed in metres per second squared is:

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

NOTE 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 decibels (ref.  $10^{-6}$  m/s<sup>2</sup>), or the ratio of the two VPT values expressed in metres per second squared. The reference threshold shift,  $\Delta T(f_j)_{ref}$ , at the *j*th frequency  $f_j$  shall be expressed in decibels, and calculated at each measurement frequency, or equivalent frequency, as

$$\Delta T(f_j)_{\text{ref}} = T(f_j)_{\text{obs}} - T(f_j)_{\text{ref}}$$
 (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 decibels (ref.  $10^{-6}$  m/s<sup>2</sup>).

The equivalent expression for the reference threshold shift calculated from thresholds expressed in metres per second squared is

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

NOTE 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 may 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 decibels, is

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

and the mean reference threshold shift at frequency  $f_i$ , expressed in decibels, is

$$\Delta T(f_j)_{\text{ref,M}} = \frac{1}{n} \sum_{i=1}^{n} \Delta T(f_j)_{\text{ref},i}$$
(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 decibels on the ordinate, as shown in Figure 1. The threshold shift may range from –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 may 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.

If the tactogram is for one or both hands of an individual, the threshold shifts for individual fingers shall be identified by different symbols. Thresholds shifts for fingers on the right hand should be indicated by circles, and for fingers on the left hand by squares.

NOTE 2 It may be convenient to indicate the finger by a number within the symbol for the hand, or by different coloured symbols. Fingers are numbered as follows:

- digit 1, index finger;
- digit 2, middle finger;
- digit 3, ring finger;
- digit 4, little finger;
- digit 5, thumb.

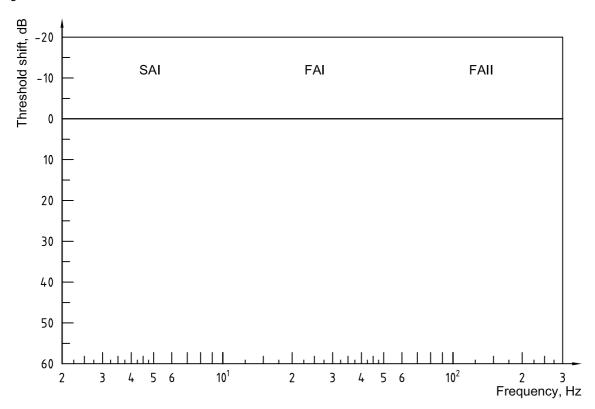


Figure 1 — Tactogram

#### 5.6 Consistency of threshold shifts

If VPTs have been determined at a single measurement site at more than one frequency, or equivalent frequency, mediated by a given mechanoreceptor population according to the provisions of ISO 13091-1, then the consistency of the relative, or reference, threshold shifts may be examined. The consistency is expressed by the difference in decibels between the relative or reference threshold shifts for frequencies, or equivalent frequencies, at which VPTs were mediated by a single mechanoreceptor population (see ISO 13091-1:2001, Table 3).

The consistency may be degraded in situations in which VPTs outside the range of expected values for healthy persons defined in 6.5 are found in only one mechanoreceptor population at the measurement site. Under these circumstances, it is possible for thresholds at some frequencies normally mediated by this population to be mediated by another receptor population with VPTs within the limits of expected values for healthy persons.

NOTE Calculation of the consistency between mechanoreceptor-specific threshold shifts determined according to the provisions of ISO 13091-1 facilitates the identification of errors in subject performance. Thresholds shifts mediated by the same receptor population that are error free will be identical.

#### 5.7 Mean mechanoreceptor population threshold shift

If VPTs have been determined at a single measurement site at more than one frequency, or equivalent frequency, mediated by a given mechanoreceptor population according to the provisions of ISO 13091-1, then the relative or reference threshold shift may be expressed in terms of the mean mechanoreceptor population threshold shift. The mean mechanoreceptor population threshold shift is the arithmetic mean of the relative or reference threshold shifts expressed in decibels for all frequencies, or equivalent frequencies, at which the VPTs were mediated by a single mechanoreceptor population. The allowed measurement frequencies are given in ISO 13091-1:2001, Table 3. The mean mechanoreceptor population threshold shift shall be expressed in decibels.

The mean relative threshold shift for a given mechanoreceptor population,  $\Delta T(f_i)_{rel,M}$ , is

$$\Delta T(f_j)_{\text{rel},M} = \frac{1}{m} \sum_{j=1}^{m} \Delta T(f_j)_{\text{rel}}$$
(9)

where the summation is over the m frequencies, or equivalent frequencies, at which the threshold is mediated by the same receptor population.

The mean reference threshold shift for a given mechanoreceptor population,  $\Delta T(f_i)_{ref.M}$ , is

$$\Delta T(f_j)_{\text{ref,M}} = \frac{1}{m} \sum_{j=1}^{m} \Delta T(f_j)_{\text{ref}}$$
(10)

where the summation is over the m frequencies, or equivalent frequencies, at which the threshold is mediated by the same receptor population.

The procedure should be applied with caution to situations in which VPTs outside the range of expected values for healthy persons defined in 6.5 are found in only one mechanoreceptor population at the measurement site. Under these circumstances, it is possible for thresholds at some frequencies normally mediated by this population to be mediated by another receptor population with VPTs within the limits of expected values for healthy persons.

NOTE Calculation of the mean mechanoreceptor-specific threshold shift facilitates the identification of small changes in mechanoreceptor, and hence tactile, acuity.

#### 6 Interpretation of vibrotactile perception thresholds and threshold shifts

#### 6.1 General

Values of VPTs and threshold shifts at the fingertips provide information related to peripheral sensory nerve function in the finger, hand and arm of the limb under investigation. The magnitude of changes in threshold may be reported in one or more of the following ways indicated in 6.2 to 6.5.

#### 6.2 Measurement error and statistical significance of observed VPTs

If the VPT at a fingertip is determined repeatedly according to the provisions of ISO 13091-1, then the measurement error applicable to the mean value of the observed VPTs, expressed in decibels, shall be the standard deviation calculated according to Equation (2) from the observed VPTs expressed in decibels.

Under circumstances in which it is not possible to calculate a meaningful standard deviation (e.g. if the VPT at a fingertip is determined only on one occasion), then the measurement error assumed applicable to the observed VPT shall be the test/retest variability estimated for the measurement method according to the provisions of 4.3. This shall be expressed in decibels as the standard deviation applicable to the observed VPT, and should be used for statistical analyses.

#### 6.3 Measurement error and statistical significance of relative threshold shifts

If the relative threshold shift at a fingertip is determined repeatedly, then the measurement error applicable to the mean value of the relative threshold shifts shall be the standard deviation, expressed in decibels, calculated from the observed relative threshold shifts expressed in decibels.

If the relative threshold shift at a fingertip is determined only once, that is, from two VPT values, then the measurement error applicable to the observed value of relative threshold shift shall be 1,414 times the test/retest variability estimated for the measurement method according to the provisions of 4.3. This shall be expressed in decibels as the standard deviation applicable to the observed relative threshold shift, and should be used for statistical analyses.

#### 6.4 Vibrotactile perception thresholds for healthy persons

It is often required to compare the VPTs observed at the fingertips of one person with those of a reference population group consisting of healthy persons. Values of VPTs for healthy persons at age 30 years are provided in Annex A in decibels (ref.  $10^{-6}$  m/s<sup>2</sup>), and in metres per second squared. The values are expressed in terms of the 2,5, 15, 50 (mean value), 85 and 97,5 percentiles of the population group for each stimulation frequency, or equivalent frequency, specified in ISO 13091-1. The thresholds approximate a Gaussian distribution when expressed in decibels.

The values in Annex A may be used for the interpretation of VPTs determined according to the provisions of ISO 13091-1. The 50 percentile values shall be used as the reference thresholds for the calculation and interpretation of reference threshold shifts, for example for the term  $T(f_j)_{ref}$  in Equation (5), and for  $t(f_j)_{ref}$  in Equation (6).

NOTE 1 The mean VPTs of healthy persons increase with age by approximately 0,03 dB per year at frequencies mediated by SAI receptors, 0,08 dB per year at frequencies mediated by FAI receptors, and from 0,25 dB per year to 0,35 dB per year at frequencies mediated by FAII receptors.

NOTE 2 For epidemiological studies, the VPTs used for the reference population group may be derived from a control group.

#### 6.5 Deviations from the VPTs of healthy persons

Deviations from the VPTs of healthy persons, and reference threshold shifts, shall be assessed in terms of the probability of the observed deviation from the mean value for healthy persons. The measurement errors associated with observed VPTs are determined according to the provisions of 6.2. There is no measurement error associated with the mean reference vibrotactile perception thresholds specified for healthy persons.

The 2,5 and 97,5 percentile threshold values for healthy persons given in Annex A may be taken as the upper and lower limits for the expected values to be obtained on an individual using a measurement method complying with the provisions of ISO 13091-1. Observed values of VPTs less than those experienced by 2,5 %, or greater than those experienced by 97,5 %, of healthy persons should be considered to be outside the range of expected values. Equivalently, observed values of reference threshold shift in excess of the reference threshold shift experienced by 2,5 % or 97,5 % of healthy persons should be considered to be outside the range of expected values.

NOTE For an *individual*, the probability of a given deviation in the threshold from the mean value for healthy persons, or reference threshold shift, does not necessarily correspond to a positive, or negative, predictive value for a symptom, disturbance or disorder believed to be associated with peripheral sensory nerve dysfunction.

#### 6.6 Physiological and clinical implications of changes in VPTs

The physiological, functional and clinical implications of threshold shifts are described in Annex B.

Vibrotactile perception may be used as an objective test for the detection of peripheral neuropathies, either generalized or focal, arising from disease and from exposure to neurotoxic chemical and physical agents. When VPTs are determined at several stimulation frequencies, or equivalent frequencies, calculating the sensibility index or plotting a tactogram may prove beneficial in the interpretation of the results. A repeated measurement of the relative threshold shift may prove beneficial in situations in which a pathological or recovery process is followed over time.

Changes in VPTs, and reference threshold shifts, may be expected to influence specific aspects of tactile function, and may reflect underlying disease. Reference threshold shifts recorded at different frequencies, or equivalent frequencies, are found to possess distinctive patterns when plotted as tactograms. Examples are given in Annex B.

## Annex A

(informative)

### Vibrotactile perception thresholds for healthy persons

Several studies of the VPTs of healthy persons have used test methods essentially in agreement with the provisions of ISO 13091-1; they are listed in Table A.1. As all studies were completed before publication of this part of ISO 13091, there are minor departures from the requirements of ISO 13091 that are identified in the footnotes to Table A.1.

The sources of the threshold values are identified in the left-hand column of Table A.1. The reported probe diameter and surround diameter, if used, are listed in columns 2 and 3. The skin indentation was measured and controlled directly in the study published as reference [25]. The static skin indentation listed for the other studies has been estimated from the measured probe contact force and, where appropriate, the probe and surround contact forces (column 4). All studies in Table A.1 employed a controlled skin-stimulator contact force and, in addition, a controlled skin-surround contact force when a surround was used. The psychophysical algorithm type is also identified in Table A.1, as are the sex (male M, and female F) of the subjects, the number of persons studied, N, and the mean age for which the VPTs were reported.

A brief description is provided of the human population group(s) from which the VPTs were obtained. The medical screening of subjects for signs, symptoms and history of peripheral neurological disease, or of exposure to neurotoxic agents or to hand-arm vibration, is also reported when performed. The VPTs reported in all studies are for healthy persons.

Values for the VPTs of healthy males, and females, applicable to thresholds determined according to the provisions of ISO 13091, are given in Table A.2 in decibels (ref.  $10^{-6}$  m/s<sup>2</sup>), and Table A.3 in metres per second squared. The values are expressed in terms of the 2,5, 15, 50 (mean value), 85 and 97,5 percentiles of the population group for each stimulation frequency, or equivalent frequency, specified in Table 1 of ISO 13091-1:2001. The thresholds approximate a Gaussian distribution when expressed in decibels. Thresholds for percentiles other than the mean may be estimated for VPTs expressed in decibels (ref.  $10^{-6}$  m/s<sup>2</sup>) at a given frequency, or equivalent frequency,  $f_j$ , from the expression

$$p(T(f_j)_{\text{ref}}) = \frac{1}{\sqrt{2\pi} \cdot s(f_j)} e^{-\left(T(f_j)_{\text{ref}} - T(f_j)_{\text{ref},M}\right)^2 / \left(2s^2(f_j)\right)}$$
(A.1)

where the values for the mean reference VPT,  $T(f_i)_{ref,M}$ , and  $s(f_i)$  are given in Tables A.2 and A.4, respectively.

The VPTs in Table A.2 are weighted values constructed from the data sets listed in Table A.1, adjusted to a mean age of 30 years. The total number of fingers from which the thresholds are calculated,  $N_{\rm F}$ , is shown for each stimulation frequency, or equivalent frequency. The weighting of each data set is given by the number of fingers at the stimulation frequency, or equivalent frequency, under consideration. The VPTs are derived from thresholds obtained on digits 2 and 3 (see Note 2 in 5.5), and digit 5 if there was no significant difference observed between thresholds mediated by the median and ulnar nerves.

NOTE Small differences in VPTs can occur from using alternate measurement methods specified in ISO 13091-1. The residual, unexplained difference between the mean VPTs for each study listed in Table A.1 and the 50 percentile values in Table A.2 is typically less than 2 dB. In some studies, an increase in VPT (i.e. reduction in acuity) has been observed in fingers innervated by the ulnar nerve.

Normal hormonal changes during the menstrual cycle influence the VPTs of females, particularly at frequencies mediated by the FAII receptors (i.e. 100 Hz, 125 Hz and 160 Hz). This may explain the increased values of  $s(f_i)$  for females compared to those for males in Table A.4.

The mean VPTs of healthy persons increase with age by approximately 0,03 dB per year at frequencies mediated by SAI receptors, 0,08 dB per year at frequencies mediated by FAI receptors, and from 0,25 dB per

year to 0,35 dB per year at frequencies mediated by FAII receptors. The effect of ageing at thresholds mediated by the FAII receptors appears to depend on the measurement frequency, with the mean VPTs measured at 100 Hz tending to increase less with age than those at 160 Hz. The mean VPTs for healthy persons at ages other than 30 years may be estimated from this information. For an individual, the change in threshold with age may deviate significantly from that of the mean VPT for healthy persons, and so should not be estimated from this information.

The 50 percentile values in Tables A.2 and A.3 are to be used as reference thresholds for the calculation and interpretation of reference threshold shifts. Thus values for the term  $T(f_j)_{ref}$  in Equation (5), and for  $t(f_j)_{ref}$  in Equation (6), are given by the 50 percentile values in Tables A.2 and A.3, respectively.

Table A.1 — Sources of VPTs for healthy persons determined using methods close to those in ISO 13091-1

Source	Probe diameter	Surround	Skin indentation	Algorithm			Ø	Subjects
	шш	шш	mm		Sex	Number of subjects	Mean age	Population description
					male, M			
					female, F	N	years	
Reference [4] <sup>a</sup>	9	10	2,8 b	von Békésy	M	10	30,1	Manual workers, medically screened
Reference [4] <sup>a</sup>	9	10	2,8 b	von Békésy	ш	15	32,3	Manual workers, medically screened
Reference [5]	3	none	q 6'0	uwop-dn	×	38	40,8	Caucasian and Asian professional and manual workers, medically screened
Reference [24]	9	10	2,8 b	von Békésy	M	29	36	Manual workers
Reference [25]	9	none	1,0	von Békésy <sup>c</sup>	M, F	11	≈ 25	Students and professional workers
Reference [29] <sup>a</sup>	9	10	2,8 b	von Békésy	M	6	28,8	Professional workers
Reference [36]	9	10	2,8 b	von Békésy <sup>d</sup>	≥	165	40	Professional and manual workers, medically screened
Reference [36]	9	10	2,8 b	von Békésy <sup>d</sup>	Н	126	40	Professional and manual workers, medically screened

The VPT was calculated from a linear measure of ascending and descending thresholds, which introduces a bias in the VPT (an apparent elevation of VPT by typically 1,5 dB, see reference [36]).

Skin indentation estimated from contact force (after references [23] and [33]).

A rate of change of stimulus amplitude with time in excess of 3 dB/s was used at frequencies above 50 Hz, which may introduce an error in VPT (usually an apparent elevation of VPT). A rate of change of stimulus amplitude with time in excess of 3 dB/s was used, which may introduce an error in VPT (usually an apparent elevation of VPT.)

Table A.2 — Vibrotactile perception thresholds for healthy persons expressed in decibels  $({\rm ref.~10^{-6}~m/s^2})$ 

		Age					Frequency				
		years					Hz				
			3,15	4	2	20	25	31,5	100	125	160
Males	2,5 percentile	30	8'£9	0,79	71,3	82,0	84,8	0'68	2,76	94,0	97,3
	15 percentile	30	0,69	72,0	76,0	8,98	89,5	94,3	102,8	100,5	102,3
	50 percentile	30	75,0	77,5	81,5	92,3	95,0	100,3	108,5	107,8	108,0
	85 percentile	30	81,0	83,0	87,0	8,76	100,5	106,3	114,3	115,0	113,8
	97,5 percentile	30	86,3	88,0	91,8	102,5	105,3	111,5	119,3	121,5	118,8
	Number of fingers used in the estimate, $N_{\rm F}$		11	110	110	159	11	382	110	283	110
Females	2,5 percentile	30				8,08		88,3		92,3	
	15 percentile	30				87,3		94,8		100,8	
	50 percentile	30				94,8		101,8		110,0	
	85 percentile	30				102,3		108,8		119,3	
	97,5 percentile	30				109,0		115,3		127,5	
	Number of fingers used in the estimate, $N_{\rm F}$					09		186		186	

Table A.3 — Vibrotactile perception thresholds for healthy persons expressed in metres per second squared

		Age					Frequency				
		years					Ϋ́				
			3,15	4	5	20	25	31,5	100	125	160
Males	2,5 percentile	30	0,0015	0,0022	0,003 7	0,013	0,017	0,028	220,0	0,050	0,073
	15 percentile	30	0,0028	0,004 0	0,0063	0,022	0,030	0,052	0,14	0,11	0,13
	50 percentile	30	9 500'0	0,0075	0,012	0,041	0,056	0,10	0,27	0,25	0,25
	85 percentile	30	0,011	0,014	0,022	0,078	0,11	0,21	0,52	0,56	0,49
	97,5 percentile	30	0,021	0,025	0,039	0,13	0,18	0,38	0,92	1,19	0,87
	Number of fingers used in the estimate, $N_{\rm F}$		11	110	110	159	11	382	110	283	110
Females	2,5 percentile	30				0,011		0,026		0,041	
	15 percentile	30				0,023		990'0		0,11	
	50 percentile	30				0,055		0,12		0,32	
	85 percentile	30				0,13		0,28		0,92	
	97,5 percentile	30				0,28		85'0		2,37	
	Number of fingers used in the estimate, $N_{\rm F}$					09		186		186	

Table A.4 — Values of  $s(f_j)$  for Equation (A.1), expressed in decibels

		Age					Frequency				
		years					Ϋ́				
			3,15	4	5	20	25	31,5	100	125	160
Males	$s(f_j)$	30	5,75	5,35	5,25	5,25	5,25	2,75	5,5	0,7	5,5
	Number of fingers used in the estimate, $N_{\rm F}$		11	110	110	159	11	382	110	283	110
Females $s(f_j)$	$s(f_j)$	30				7,2		6,85		0,6	
	Number of fingers used in the estimate, $N_{\rm F}$					09		186		186	

## Annex B

(informative)

## Implications of changes in vibration perception thresholds

#### B.1 Use in clinical medicine

Interest in determining the perception of vibration as an aid to neurological diagnosis has been documented for over 100 years. Early investigators reported reduced vibrotactile perception (i.e. increased VPTs) in cases of diabetes mellitus, peripheral neuritis and pernicious anaemia, and hypersensitivity (i.e. reduced VPTs) in cases of Parkinson's disease. More recently, vibrotactile perception has been proposed as a technique for detecting various peripheral neurological diseases, either generalized or focal, arising from disease and from exposure to chemical or physical agents. The technique has been applied to a diverse range of conditions including carpal tunnel syndrome, radial tunnel syndrome, repetitive strain injury, ulnar neuropathy, polyneuropathy, and persons exposured to hand-arm vibration. When VPTs are determined at several stimulation frequencies, or equivalent frequencies, calculating the sensibility index or plotting a tactogram has proved beneficial in the interpretation of the results.

A repeated measurement of relative threshold shift, provided it is conducted using the same apparatus and measurement protocol, has proved beneficial in situations in which a known pathological process is followed over time. In this way, systematic errors introduced by the apparatus are avoided, and the utility of the test then depends ultimately on the intra-subject test/retest variability. The use of relative threshold shifts as a measure of disease severity has been reported for diabetics, renal dialysis patients, cancer patients undergoing chemotherapy, and for workers exposed to chemical and physical neurotoxic agents. Relative threshold shifts have also been used to monitor the progress of nerve repair and rehabilitation of hand function.

The use of VPTs as an objective test in clinical medicine has also been validated. The associations between VPTs and other methods for assessing peripheral nerve dysfunction, and in particular nerve conduction and other modalities of quantitative sensory testing, have been documented. These subjects are considered in the following.

The absence of standardized methods for determining VPTs and the limited sources of normative values for healthy hands have, in the past, hindered widespread acceptance of the technique in clinical practice. These limitations are addressed in this part of ISO 13091. The standardization of measurement methods that result in VPTs mediated only by one population of mechanoreceptors at a given stimulation frequency, or equivalent frequency, provides more information concerning tactile nerve function than generally available in the past. The implications of this additional information are also considered in this annex.

#### B.2 Tactile physiology and threshold shifts

The tactile performance of the hand depends on the neural activity in up to four populations of specialized nerve endings located at the fingertips. The different mechanoreceptor populations are usually classified by their response to skin indentation and by the extent of their receptive fields. The VPTs of three of the populations may be determined by the methods of ISO 13091-1. The fourth receptor population, for which no method of measurement is provided in ISO 13091-1, signals skin stretch.

The three mechanoreceptor populations at the fingertips for which VPTs may be obtained are: the slowadapting type 1 receptors (SAI) which correspond anatomically to the Merkel disks; the fast-adapting type 1 receptors (FAI) which correspond anatomically to the Meissner corpuscles; and the fast-adapting type 2 receptors (FAII) which correspond anatomically to the Pacinian corpuscles. SAI receptor acuity primarily determines the resolution of spatial features of a surface, such as ridges and texture. In contrast, FAI and FAII receptor acuity is primarily responsible for information obtained from the motion of surfaces across the skin. In addition to tactile exploration, the gripping of objects between the fingertips and thumb depends on the detection of microscopic slippage of the object, which is signalled primarily by the FAI receptors, and so is effectively controlled by tactile acuity rather than by neuromuscular function.

Changes in the VPTs of SAI, FAI and FAII receptors may thus be expected to influence specific aspects of tactile function, and the holding and manipulation of objects. In a clinical setting, the changes can reflect underlying disease. The threshold shifts recorded at the fingertips at different frequencies are found to possess distinctive patterns. The patterns are most easily distinguished by plotting the threshold shifts as tactograms, as shown for two fingers (from different subjects) in Figure B.1. Reference threshold shifts have been plotted in each case.

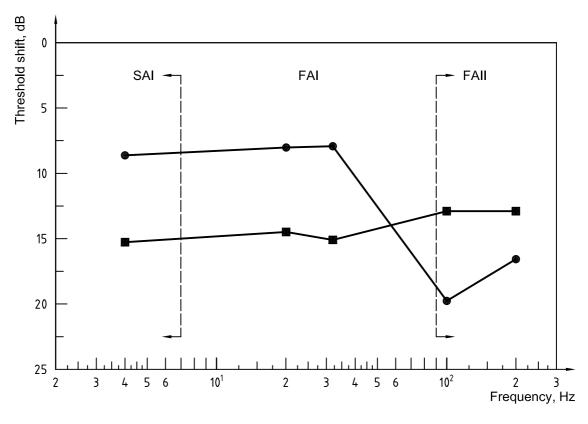


Figure B.1 — Tactogram showing patterns of reference threshold shift in the fingers of two chain saw operators

As shown by these examples, threshold shifts of similar magnitude are usually observed at frequencies mediated by the same mechanoreceptor population (e.g. at 20 Hz and 31,5 Hz). In some fingers, the threshold shifts are found to be similar in magnitude for all receptor populations, as shown by the filled squares in the example of Figure B.1. The threshold shifts can, however, differ between different receptor populations in the same fingertip. Thus the threshold shifts shown by the filled circles in Figure B.1 can be seen to be of similar magnitude for the SAI and FAI receptor populations, but are of greater magnitude for the FAII receptors. The difference in threshold shift between that of the FAII population and those of other receptor populations in this finger is statistically significant.

The patterns of threshold shift provide information on the nature of changes in sensory nerve function, or nerve injury, and are suggestive of either changes occurring in the whole nerve (squares in Figure B.1) or of changes involving only in one or two receptor populations (circles in Figure B.1). The latter may imply selective distal involvement of nerve fibres or receptors.

#### B.3 Association between VPTs, common clinical tests and nerve conduction

There have been several studies of persons with upper extremity complaints to assess the efficacy of different clinical tests. In one such study involving both vibrotactile perception and nerve conduction, neurological symptoms were reported by 98 % of shipyard employees who used power tools at work. In this population group, the VPTs at 120 Hz were uniformly elevated when compared with an industrial group of healthy manual workers, and were consistently the most abnormal of the laboratory tests, including nerve conduction.

In another study, the associations between VPTs measured on digits 1 and 5 of each hand (see Note 2 in 5.5), the results of a traditional neurological examination of the hand and arm involving the perception of vibration (tuning fork) and pain (pin prick), proprioception (joint position) and nerve conduction were established in a series of patients attending for an unrelated diagnostic evaluation. The strongest associations were found between VPTs and the tuning fork data from the same finger (p < 0.001). A statistically significant association was also found between VPTs and proprioception (p < 0.01), and a weaker association between VPTs and pin prick (p < 0.05). A similar association was also observed between VPTs and the sensory nerve compound action potentials and conduction velocities in the corresponding finger (p < 0.05). The associations were of similar magnitude for fingers innervated by the median and the ulnar nerves.

The use of VPTs as a diagnostic aid for carpal tunnel syndrome has led to conflicting results. At least part of the reason must lie in the performance limitations of the apparatus used to obtain the VPTs, none of which satisfied the requirements of ISO 13091-1. A prevailing view is that the associations are extremely dependent on the normative values used, as well as the diagnostic criteria employed for the target disorder, an observation that is equally applicable to other applications of VPTs as an aid to diagnosis.

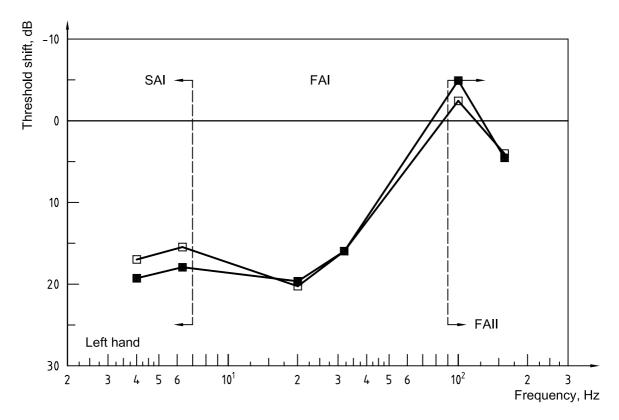
The finding of a lack of an association between VPTs and the results of another test modality in a group of subjects is not necessarily a cause for concern, as one test may detect physiological or pathological changes undetectable by the other. An example of a tactogram from a case series with normal nerve conduction and non-specific hand dysfunction is shown in Figure B.2. This 42-year-old former shipyard grinder with wrist pain and difficulty coordinating the movements of a computer control puck possesses statistically significant reference threshold shifts in the SAI and FAI receptors of both hands, but not the FAII receptors. The subject was assessed as neurologically normal by nerve conduction. Moreover, the threshold shifts are strikingly similar in digits 3 and 5 of each hand, and the same pattern was observed in both hands.

#### B.4 Association between threshold shifts and hand function

The determination of VPTs provides a quantitative procedure for evaluating the somatosensory pathways conveying tactile information to the brain. From a functional perspective, the afferent output is essential for the tactile identification of objects and, as part of the sensorimotor loop, for the manipulation and control of objects.

An association between VPTs at the fingertips and symptoms of reduced manipulative function established by responses to a questionnaire has been demonstrated in a group of manual workers. In this study, mechanoreceptor-specific vibrotactile thresholds were determined for the SAI, FAI and FAII receptors at the fingertip using a measurement procedure consistent with ISO 13091-1. Statistically significant reference threshold shifts were found in the SAI and/or FAII receptor populations for persons responding affirmatively to questions concerning finger or hand numbness and difficulty in buttoning clothing. The best predictors of the observed reference threshold shifts were questions relating to the difficulty in manipulating small objects, and buttoning clothing, which yielded positive predictive values from 90 % to 100 % and false positive rates from 0 % to 2,8 %.

The potential for early detection of relative and reference threshold shifts in order to prevent the development of functional incapacity in the case of deteriorating acuity, and to follow nerve repair or recovery in the case of improving acuity, has also been studied. A cohort of manual workers (operating lightweight chain saw) has been followed, 30 % of whom reported symptoms suggestive of changes in neurosensory or neuromuscular function at the commencement of the study. The VPTs were compared with the results of functional tests of hand grip, hand and arm strength, and symptoms established during physical examinations conducted over a 5-year period. Statistically significant reference threshold shifts were found in 3 % of the group on first examination, and in 14 % of the hands 5 years later. Statistically significant relative threshold shifts were observed in a majority of the hands over the 5-year period (p < 0.025), even though most workers remained symptom free.



#### Key

digit 3: filled squares digit 5: open squares

Figure B.2 — Tactogram showing the reference threshold shift in the left hand of a shipyard worker

#### B.5 Acute threshold shifts and temporary changes in hand function

Acute, that is temporary, reference or relative threshold shifts can occur in some situations (e.g. induced loss of sensation, exposure of the hand to vibration). There is evidence from laboratory experiments that the biomechanical control of hand and arm position is affected by exposure of the hand to vibration, so that the ability to control or hold objects can be temporarily impeded. There is also evidence that the precision of hand movement is affected.

For operators of vibrating hand-held power tools, there is an association between the temporary relative threshold shift, the magnitude of the vibration exposure, and the severity of neurological symptoms of the hand-arm vibration syndrome. There is thus potential for the acute changes in VPT occurring throughout a workday to impede job performance, or increase the risk of injury from loss of control of a vibrating hand tool. However, laboratory-based experiments attempting to link exposure of the hand to vibration to measures of deterioration in hand function have been unable to confirm this hypothesis. More detailed interpretation of such experiments must take into consideration the receptor population(s) influenced by the exposure and the magnitudes of the threshold shifts imposed.

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