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

Part 1:

Methods of measurement at the fingertips

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

Partie 1: Méthodes de mesure à la pulpe des doigts



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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 3.

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 part of ISO 13091 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 13091-1 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

The early detection of peripheral neuropathies in the upper extremities, which are often manifest as changes in tactile function, is of considerable interest. Such neuropathies may occur as a result of disease, or from occupations in which workers are exposed to neurotoxic agents or to mechanical vibration.

The tactile performance of the fingers is known to depend on neural activity in up to four populations of specialized nerve endings. These mechanoreceptor types are commonly described by their response to mechanical indentation of the skin surface (i.e. SAI: slowly adapting, type I; SAII: slowly adapting, type II; FAI: fast adapting, type II; and FAII: – fast adapting, type II). The SAI receptor acuity primarily determines the resolution of the spatial features of a surface, such as ridges and texture. These receptors respond to pressure. FAI and FAII receptor acuity is primarily responsible for information obtained from the motion of surfaces across the skin surface or conversely, moving fingertips across surfaces. Such information is used to provide information on surface finish, or smoothness, and to maintain an appropriate grip of objects (which is controlled by the detection of micro-slips). SAII receptors primarily signal skin stretch. Separate responses from SAI, FAI and FAII receptor populations can be determined psychophysically by using precisely defined measurement conditions and vibrotactile stimulation at different frequencies. In some circumstances, such as selective loss of receptor function, it may not be possible to obtain separate thresholds from each population.

Standardized methods for measuring vibrotactile perception thresholds are required to obtain meaningful results, and to compare results obtained using different apparatus. Without standardization, the thresholds obtained by different measurement methods may differ substantially, and often unpredictably, and so cannot be compared. Requirements for measurement methods and instruments stem from the properties of the mechanoreceptor populations from which they are designed to elicit responses. The overall goal of this part of ISO 13091 is to define optimized testing methods and measurement procedures.

This part of ISO 13091 describes methods that are designed to yield equivalent results for measuring vibrotactile perception thresholds (VPTs) at the fingertips. The methods are applicable to healthy and diseased persons, and are suitable for detailed clinical evaluation and for rapid screening. Values are recommended for all measurement parameters. Some parameters are specified by a central value with broad "tolerances" in recognition that different values are currently in use. The central values given are the preferred values. Using the methods described, the VPT at one test frequency can be determined in approximately 1 min once the subject has been trained in the measurement procedure (which may be completed in approximately 5 min). This information may be considered sufficient for some screening applications. ISO 13091-2 considers the analysis and interpretation of VPTs obtained using the methods specified in this part of ISO 13091.

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

Part 1:

Methods of measurement at the fingertips

1 Scope

This part of ISO 13091 specifies

- methods for measuring vibrotactile perception thresholds (VPTs) at the fingertips,
- procedures for conducting the measurements, and
- the reporting of results.

Measurement methods are defined in this part of ISO 13091 for obtaining perception thresholds at the fingertips mediated, separately, by SAI, FAI and FAII mechanoreceptor populations. The methods are designed to be applicable to healthy and diseased persons, and to be suitable for clinical assessment and for screening purposes.

The measurement of temporary shifts in vibrotactile perception threshold, or of thresholds at body sites other than the fingertip, is outside the scope of this part of ISO 13091.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 13091. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 13091 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 2041, Vibration and shock — Vocabulary.

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

IEC 60601-1, Medical electrical equipment — Part 1: General requirements for safety.

3 Terms and definitions, symbols and abbreviated terms

3.1 Terms and definitions

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

3.1.1

pure tone

oscillatory signal whose instantaneous magnitude is a sinusoidal function of time (i.e. at a single frequency)

3.1.2

tone burst

intermittent pure-tone signal

3.1.3

gliding tone

pure tone in which the frequency changes continually with time

3.1.4

equivalent frequency

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

3.1.5

total harmonic distortion

percentage pure-tone distortion expressed as 100 times the square root of the ratio of the sum of the squared amplitudes of harmonic components within a defined bandwidth to the squared amplitude of the fundamental

3.1.6

masking

mask, verb

process by which the perception threshold for one stimulus is raised by the presence of another (masking) stimulus of the same or different frequency

3.1.7

forward masking

process by which perception of the test stimulus currently being presented to a subject is rendered undetectable by a previous test stimulus of the same or different frequency

3.1.8

mechanoreceptor

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

3.1.9

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

3.1.10

neutral position

position naturally adopted by the hand when the hand and arm hang freely from the shoulder, when standing erect

NOTE This position normally involves no flexion or extension of the wrist.

3.1.11

stimulator

means for generating static indentation of the skin surface and/or continuous or intermittent oscillatory motion of the skin surface

3.1.12

probe

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

3.1.13

surround

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

3.1.14

contact force

static and dynamic components of the force with which a stimulating or sensing probe contacts the skin

3.1.15

indentation of skin

distance moved by the probe tip from the position of initial contact with the skin surface (where the contact force is zero) to the position at which thresholds are determined

3.1.16

aural cue(s)

sound caused by vibration of the stimulator

3.1.17

physiological "noise"

human body motion, including vibration, naturally occurring from physiological functions such as blood flow, heart beat, muscle tremor and respiration

3.1.18

background vibration

residual vibration at the fingertip, in the absence of the stimulus, when the subject is positioned to commence threshold measurements with the stimulating probe in contact with the fingertip

NOTE Background vibration can be caused by room vibration, the measurement apparatus and physiological "noise".

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

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

3.1.21

threshold

onset of the perception of a stimulus, or the loss of perception of a stimulus

3.1.22

ascending threshold

threshold obtained when stimuli of successively increasing intensity are applied to the skin until the stimulus is detected

3.1.23

descending threshold

threshold obtained when stimuli of successively decreasing intensity are applied to the skin until the stimulus is no longer detected

3.1.24

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

3.1.25

threshold shift

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

The baseline value can be, for example, a previous vibrotactile perception threshold obtained from the same subject. The baseline value can also be the mean threshold obtained from healthy persons of similar age without sign, symptom or history of peripheral neurological disease, or of exposure to neurotoxic agents or to hand-transmitted vibration. This subject is considered in ISO 13091-2.

3.1.26

temporary threshold shift

temporary elevation in the perception threshold (i.e. loss in acuity) that disappears with time

3.1.27

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 The procedure commonly involves applying a sequence of stimuli with successively increasing intensity to the skin until the subject signals that a 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). A "staircase" algorithm is an updown algorithm in which the sequence of stimuli are increased, and decreased, in steps of equal magnitude.

3.1.28

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

Symbols and abbreviated terms 3.2

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

FAI	fast adapting, type I mechanoreceptors
FAII	fast adapting, type II mechanoreceptors
SAI	slowly adapting, type I mechanoreceptors
VPT	vibrotactile perception threshold
$t_{a}(r)$	a sequence of ascending threshold levels
$t_{d}(r)$	a sequence of descending threshold levels
where	
r = 1, 2	2, 3,, <i>n</i>

is the number of ascending and descending threshold pairs, e.g. $t_a(1)$ and $t_d(1)$, $t_a(2)$ and $t_d(2)$, ..., $t_a(n)$ and $t_d(n)$.

Measurement methods

4.1 General

Requirements for measurement methods and procedures originate from the properties of the mechanoreceptor populations from which they are designed to elicit responses, and are summarized in Table 1.

Table 1 — Summary of requirements for measurement methods

_					
Stimulus (see 4.2)	SAI	FAI		FAII	
Frequency ^a , Hz	4,0	31,5		125	
other frequencies, Hz	3,15; 5,0	20; 25		100; 160	
Intermittent					
burst duration	< 10 s	< 10 s		0,6 s to 10 s	
 quiescent duration^b 	≥ 0,6 s	≥ 0,6 s		≥ 0,6 s	
Continuous					
— maximum duration	50 s	50 s		50 s	
 minimum rest, same site and receptor 	30 s	30 s		30 s	
Subject positioning (see 4.3)					
— support	forearm, hand and finger; seat with back rest		vith back rest		
Skin surface conditions (see 4.4)					
— skin temperature	27 °C to 35 °C, confirmed by measurement				
— test room temperature	20 °C to 30 °C				
Stimulating probe (see 4.5)					
geometry, finish, diameter	flat-ended cylinder, 0,2 mm ≤ edges radii ≤ 0,7 mm				
	smooth to touch, 4,0 mm \pm 2,1 mm diameter				
Skin-stimulator contact (see 4.6)	Method A, no surround		Method B, with surround		
skin indentation	1,5 mm ± 0,8	1,5 mm ± 0,8 mm		mm \pm 0,8 mm	
— probe-surround gap	_		1,5 mm ± 0,6 mm		
— surround force	_		0,	,7 N to 2,3 N	
Psychophysical algorithm (see 4.7)					
— independent of stimulus	variant of up-down, or von Békésy				
Subject's response (see 4.8)					
— detection	automatic and unambiguous				
— inconsistency	automatic detection				
Skin motion (see 4.9)					
probe, at skin surface	r.m.s. magnitude of stimuli, and background vibration (and frequency if gliding tones used)				
System check (see 4.10)					
- before VPT test performance of measurement system to be confirmed				o be confirmed	
a The minimum requirement is for one mea	asurement frequency.				
b And not less than half the stimulus duration					

And not less than half the stimulus duration.

Stimulus 4.2

Stimulator 4.2.1

Measurement methods shall provide a stimulator to generate oscillatory (motional) stimuli for the determination of vibrotactile perception thresholds of persons at the fingertips.

4.2.2 Stimulus waveform

The displacement amplitude of the stimulus shall be no greater than 1,0 mm. For pure-tone stimuli, the maximum distortion is given in Table 2. Intermittent stimuli shall possess a waveform envelope shaped to ensure that the stimulus detected by the subject is that of the underlying oscillatory motion and not of the switching transients.

A stimulator for all frequencies specified in this part of ISO 13091 will produce r.m.s. acceleration levels of up to 150 dB (ref. 10⁻⁶ m/s²), subject to a maximum displacement amplitude of 1,0 mm.

Measured parameter: acceleration ^a					
Stimulus frequency	Total harmonic distortion				
Hz	%				
3,15 to 31,5	30 ^b				
100 to 160	10°				

Table 2 — Maximum total harmonic distortion of stimulus

4.2.3 Stimulus frequency

Stimulation shall be provided at at least one frequency or equivalent frequency. Stimulation should be provided at a minimum of three frequencies, or equivalent frequencies, if it is required to establish the acuity of the three populations of mechanoreceptors primarily involved in the sense of touch (SAI, FAI and FAII). The recommended three frequencies, or equivalent frequencies, are: 4,0 Hz (SAI), 31,5 Hz (FAI) and 125 Hz (FAII). If more frequencies are used for stimulation they should be selected from: 3,15 Hz, 4,0 Hz and 5,0 Hz (SAI); 20 Hz, 25 Hz and 31,5 Hz (FAI) and 100 Hz, 125 Hz and 160 Hz (FAII). The mechanoreceptor population mediating the VPT when measurements are conducted according to the provisions of this part of ISO 13091 are summarized in Table 3.

The frequency of stimulation shall be carefully chosen to obtain responses from individual mechanoreceptor populations, because each population could respond in frequency ranges that overlap.

Using the skin-stimulator contact parameters specified in this part of ISO 13091, stimulation at frequencies of NOTE 1 6,3 Hz, or less, will permit the determination of the threshold of SAI mechanoreceptors; stimulation at frequencies between 16 Hz and 32 Hz will permit the determination of the threshold of FAI mechanoreceptors; and stimulation at frequencies of 100 Hz or more will permit the determination of the threshold of FAII mechanoreceptors.

For some applications a simple measurement system confined to restricted stimuli, in particular to one of the three recommended frequencies or equivalent frequencies, can be appropriate. This part of ISO 13091 also defines the requirements for the presentation of a wider range of stimuli for detailed clinical evaluation and research.

The acceleration level of mechanoreceptor-specific VPTs increases with increasing frequency, rendering perception of a distorted stimulus insensitive to frequencies higher than the fundamental stimulus frequency (e.g. harmonic distortion products).

The total harmonic distortion is evaluated for harmonic components at frequencies from the pure-tone stimulation frequency up to 160 Hz.

The total harmonic distortion is evaluated for harmonic components at frequencies up to three times the stimulus frequency.

Table 3 — Measurement frequencies

Type of mechanoreceptor	Frequency range of receptor mediating threshold	Recommended frequencies ^a			
		One	More than one		
	Hz	Hz	Hz		
Slowly adapting I, SAI	≤ 6,3	4,0	3,15; 4,0; 5,0		
Fast adapting I, FAI	16 to 32	31,5	20; 25; 31,5		
Fast adapting II, FAII	≥ 100	125	100; 125; 160		
$^{\mathrm{a}}$ The tolerance on frequency is \pm 10 %.					

4.2.4 Intermittent stimulation

Intermittent stimulation is preferred for all measurements to introduce a quiescent interval. Intermittent stimulation reduces the possibility of a suprathreshold stimulus producing a temporary threshold shift, and hence causing an error in the measurement of a VPT. The quiescent interval also serves to contrast the applied stimulation with the background vibration, and can improve definition of the threshold in situations in which there is substantial background vibration.

Intermittent stimuli shall be constructed with a waveform envelope shaped to ensure that the stimulus detected by the subject is that of the underlying oscillatory motion. The switching transients associated with the commencement and termination of the intermittent stimulus shall not be perceived by the subject.

This condition may be achieved by an appropriate stimulus control system, or by restricting the rise and fall times at the beginning and end of each stimulus.

NOTE Experience has shown that there does not appear to be much change in VPT with the envelope rise and fall times of tone bursts.

The stimulus duration measured at the half-power points shall be no greater than 10 s, in order to limit temporary threshold shift. The quiescent interval shall be not less than half the stimulus duration and under no circumstances less than 0,6 s, in order to ensure recovery from any temporary threshold shift and to avoid forward masking.

For measurement of the acuity of FAII receptors, the stimulus duration of tone bursts shall be not less than 0,6 s.

4.2.5 Continuous stimulation

Continuous sinusoidal stimulation with time-varying amplitude, and sometimes time-varying frequency, may be used to determine VPTs (von Békésy method).

Methods that employ continuous stimulation shall provide a pure-tone signal that varies in r.m.s. acceleration level by no more than 3 dB per second during threshold determinations used in the calculation of the VPT (see 6.4), to minimize forward masking. A variation in r.m.s. acceleration level of up to 5 dB per second may be used to establish the first ascending and descending thresholds, i.e. $t_a(1)$ and $t_d(1)$, which are not used in the calculation of VPT.

If stimulation involves a continuous change in frequency with time (gliding tone), then the rate of change of stimulus frequency with time during threshold determinations shall be no more than one-twentieth of an octave per second. A gliding tone should contain frequencies selected to be in the range from 3,15 Hz to 160 Hz.

NOTE Rates of change of stimulus amplitude with time, and/or frequency with time, in excess of these values may introduce errors in perception thresholds.

For measurement methods employing continuous stimuli, the maximum permitted continuous stimulus duration without rest breaks shall be no greater than 50 s, in order to limit temporary threshold shift. If stimulation of the same receptor population is to be continued at the same test site, a stimulus-free recovery period of no less than 30 s shall be provided.

4.2.6 Unwanted vibration during a measurement

The subject shall not experience any environmental or instrumentally induced vibration that could mask the perception of the intended stimulus.

Motion between the subject's finger and the probe unrelated to the stimulus can mask the stimulus and introduce NOTE errors in threshold determinations (e.g. motion from floor vibration, instrument vibration, involuntary body motion from physiological "noise").

The residual background vibration at the fingertip shall be measured with the apparatus used to conduct threshold measurements before the beginning of each measurement session (see 6.5).

4.2.7 Unwanted sound during a measurement

The subject shall not experience any environmental or instrument-generated sound that could provide aural cues or otherwise interfere with the perception of the intended stimulus. The subject shall not be exposed to environmental or instrument-generated noise with 60 s time-averaged, A-weighted sound level [as defined in IEC 60050(801] in excess of 50 dB.

This requirement may be satisfied by the subject wearing hearing protection, or a headset producing appropriate masking sounds at the ears.

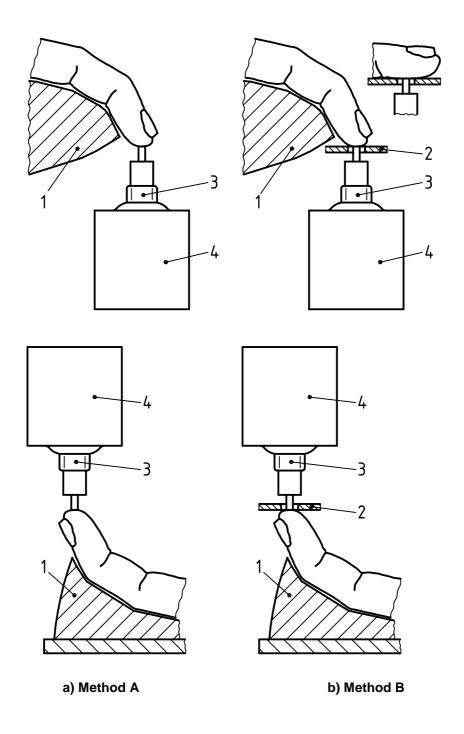
The 60 s time-averaged, A-weighted sound level of any masking sound produced at the ears should also not exceed 50 dB.

4.3 Subject comfort and positioning

Measurement methods shall provide support along the full length of the forearm, hand and finger being tested. For examples of alternative finger support, see Figure 1. The hand shall be as close as possible to the neutral position.

The more complete and comfortable the body supports, the more the potential for reducing the physiological "noise" at the fingertip. Orienting and supporting the limb to be tested, and providing a chair with back support to enhance the comfort of the subject, will facilitate threshold determinations.

The precision and repeatability of threshold measurements can be influenced by the motivation and concentration of the subject. Any distractions from the intended task such as discomfort shall be avoided.



Key

- 1 Finger support
- 2 Surround
- 3 Sensor
- 4 Stimulator

NOTE Methods for supporting the stimulator and surround are not shown.

Figure 1 — Sketch of fingertip-probe contact for methods A and B showing examples of alternative orientations and finger support

4.4 Conditions for skin surface

4.4.1 Skin and room temperatures

All measurements shall be performed in an environment in which the temperature is in the range from 20 °C to 30 °C, and on hands with skin temperature in the range from 27 °C to 35 °C. Means shall be provided for measuring the surface skin temperature at each skin area that includes a vibrotactile test site (see 6.6).

NOTE The vibrotactile perception thresholds of SAI and FAI (and, when the stimulation frequency is less than 200 Hz, the FAII) receptors are not significantly influenced by skin surface temperature in the range from 27 °C to 35 °C.

4.4.2 Skin thickness and stimulation

The stimulating probe shall be positioned to avoid contacting thick skin. This requirement can usually be satisfied by positioning the centre of the stimulating probe tip on the glabrous skin of the distal phalanx at a point no more proximal than the centre of the whorl, as described in 4.5.1. Positioning the stimulating probe directly on callosities or damaged skin, as evidenced by scars, burns or crush injuries, shall be avoided.

4.5 Stimulating probe

4.5.1 Probe location

The centre of the stimulating probe tip shall be positioned on the glabrous skin of the distal phalanx at a point no more proximal than the centre of the whorl, within the segment of the circle centred at the centre of the whorl and arc between the distal corners of the fingernail. No part of the probe tip in contact with the skin shall be closer than 2,0 mm to the fingernail. The range of suitable probe tip positions is shown in Figure 2.

4.5.2 Probe tip geometry

Control of the geometry of the probe tip with which the stimulator contacts the skin is required to obtain precise and repeatable threshold values.

The stimulating probe in contact with the finger shall be a flat-ended cylinder with diameter 4,0 mm \pm 2,1 mm. The probe tip surface in contact with the skin shall be the flat circular end of the cylinder. The stimulating end of the probe shall be tangential to the undisturbed skin at the initial point of contact, so that the direction of stimulation is normal to the skin surface.

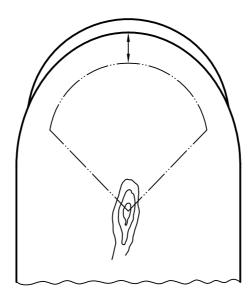
4.5.3 Probe surfaces

The probe shall be constructed with surfaces in contact with the skin that are smooth to the touch, and with edges in contact with the skin having radii of not less than 0,2 mm and not more than 0,7 mm.

NOTE A surface smooth to the touch may be obtained with a surface finish roughness (defined according to ISO 4287) of $Ra = 1.6 \mu m$, or better.

The surface finish shall apply to both the probe tip and the surround if the latter is used in the measurement method.

All material in direct contact with the skin shall possess low electrical and low thermal conductivity.



NOTE The dash-dot lines are from the centre of the whorl to the distal corners of the fingernail, and show the limits for the position of the centre of the probe tip. The dash-dot arc, which is 2,0 mm from the fingernail (as indicated by arrows), shows the closest any part of the probe tip may approach the fingernail. The probe tip may be positioned anywhere within the area bounded by the dash-dot lines.

Figure 2 — Sketch of fingertip showing range of probe-tip positions (see 4.5.1)

4.6 Skin-stimulator contact

4.6.1 General

The stimulus shall be perceived where the stimulating probe contacts the skin. Overall motion of the finger, or hand, resulting from the stimulus shall be avoided.

NOTE Overall motion of the finger, or hand, resulting from the stimulus is unlikely with the provision of finger and hand support, the location defined for the stimulating probe, and with the maximum stimulus displacement amplitude restricted to 1,0 mm, as required by this part of ISO 13091.

4.6.2 Skin-stimulator contact force and skin indentation

The static component of the force with which the stimulating probe and surround, if any, contact the skin shall not be sufficient to obstruct blood flow, cause pain, or puncture or otherwise endanger the integrity of the skin. The skin-stimulator static contact force or skin indentation shall be controlled in all measurements of VPT.

Measurement conditions shall be established so that the stimulating probe produces a static skin indentation of $1.5 \text{ mm} \pm 0.8 \text{ mm}$.

NOTE Control of the skin indentation caused by the probe or, if more convenient, the static component of the force with which the stimulating probe contacts the skin, increases the precision and repeatability of threshold determinations, and reduces inter-subject variability.

Active muscular contraction can increase hand and finger tremor and so introduce errors in the measurement of VPT. Measurements should be conducted with the finger in a relaxed position. According to the provisions of this part of ISO 13091, the position of the finger is maintained by a support.

Measurement methods without a surround shall be referred to as method A, and those employing a surround as method B.

--,,...,...

4.6.3 Method A: Without a surround

A method of controlling the static force with which the stimulating probe contacts the skin surface shall be used, such as by counterbalancing the weight of the stimulator, or by controlling the static skin indentation produced by the probe. Active muscular contraction to maintain this condition shall be avoided.

The required static skin indentation of 1,5 mm \pm 0,8 mm may be obtained by a static probe contact force of 0.15 N \pm 0.09 N.

NOTE A 4,0 mm diameter probe impressed on the skin with a static contact force of 0,15 N will produce, on average, a skin indentation of 1,5 mm. A larger contact force could be required to produce a skin indentation of 1,5 mm if a stimulating probe with a diameter of more than 4,0 mm is used and, conversely, a smaller contact force could be required to obtain a skin indentation of 1,5 mm if a stimulating probe with a diameter of less than 4,0 mm is used.

4.6.4 Method B: With a surround

A method shall be used to control the static skin indentation and/or static force with which the probe contacts the skin surface, by requiring the fingertip to rest against a fixed surround containing a hole coaxial with the probe. The gap between the stimulating probe and the edge of the hole in the surround shall be 1,5 mm \pm 0,6 mm. Active muscular contraction to maintain these conditions shall be avoided.

NOTE 1 Use of the maximum probe diameter (6,1 mm) and gap between probe and surround (2,1 mm) will result in a 10,2 mm diameter hole in the surround, which may equal, or exceed, the width of small fingertips. Measurement of vibrotactile perception is not possible using method B in these circumstances.

NOTE 2 The thresholds of FAI and FAII mechanoreceptors are influenced by the difference in diameters (i.e. gap) between the stimulating probe and the hole in the surround.

For measurements in which the skin indentation is controlled by the stimulating probe protruding through the surround, the required static skin indentation of 1,5 mm \pm 0,8 mm may be obtained by a static probe contact force of 0.5 N \pm 0.3 N.

The force with which the surround contacts the fingertip shall be $1,0_{-0,3}^{-1,3}$ N (i.e. the minimum and maximum surround forces are 0,7 N and 2,3 N, respectively).

NOTE 3 A 4,0 mm diameter probe impressed on the skin with a static contact force of 0,5 N, together with a 7,0 mm diameter surround impressed on the skin with a static force of 1,0 N, will produce, on average, a skin indentation of 1,5 mm. With no change in probe contact force, increasing the static force with which the surround is impressed on the skin could be expected to decrease skin indentation. With no change in the surround force, a larger probe contact force could be required to produce a skin indentation of 1,5 mm if a stimulating probe with a diameter of more than 4,0 mm is used and, conversely, a smaller contact force could be required to obtain a skin indentation of 1,5 mm if a stimulating probe with a diameter of less than 4,0 mm is used.

NOTE 4 Active muscular contraction to maintain a static surround-fingertip force can increase hand and finger tremor and so can introduce errors in the measurement of VPTs.

4.7 Psychophysical algorithm

The psychophysical measurement procedure employed for the determination of VPTs shall use a variant of the updown or the von Békésy algorithms. Whatever the stimulus waveform (i.e. intermittent or continuous), the maximum rate of amplitude adjustment shall be 3 dB per second during threshold determinations included in calculation of the VPT (see 6.4).

NOTE 1 Algorithms that adjust the rate of stimulus change to the performance of the subject can reduce the measurement time.

NOTE 2 It is desirable that the amplitude change by less than 3 dB per second as the measurement procedure converges to the final threshold.

NOTE 3 Experience has shown that lower vibration perception thresholds are obtained if the initial stimulus is not perceived by the subject; i.e. the amplitude is less than the threshold of perception.

4.8 Subject's response

4.8.1 Method for subject's response

An unambiguous indication of the subject's response to the stimulus is required. An automated system shall be used, such as a hand-operated switch, the status of which is monitored.

4.8.2 Detection of inconsistent subject responses

A procedure for identifying inconsistent subject responses and/or thresholds shall be provided. Inconsistent patterns of subject responses are identified by examining the variability of ascending and descending thresholds in the up-down or von Békésy algorithms (see 6.3).

NOTE 1 A subject's response may be inconsistent or erroneous due to changing criteria of response, fatigue, discomfort, interference with peripheral blood circulation, increase in physiological "noise", inexperience and/or lack of concentration or motivation. The inconsistent performance can remain even after taking all the precautions described in this part of ISO 13091. A procedure that detects inconsistent responses or thresholds can permit these limitations in the subject's performance to be identified and appropriate corrective measures to be undertaken.

NOTE 2 Inconsistent responses that lead to inconsistent VPTs can be deduced from mechanoreceptor-specific VPTs provided two, or more, thresholds are obtained from the same receptor type and the results are then compared (see ISO 13091-2).

4.9 Skin motion

A sensor and conditioning means shall be provided for measuring the r.m.s. magnitude of skin motion resulting from vibrotactile stimuli and background vibration. The sensor shall be located so as to measure the motion of the stimulating probe in contact with the skin. If a measurement method employs stimuli involving gliding tones, then means shall be provided for measuring the frequency of the stimuli.

The r.m.s. magnitude of the motion shall be obtained by digital or analog means equivalent to time averaging at least one cycle, and preferably multiple cycles, of the stimulus for up to 0,3 s. The value recorded for calculating the threshold shall be that occurring at the time of the subject's response, or within 1 dB of that value.

Information on the motion of the stimulating probe shall be provided to the examiner during vibrotactile testing (see clause 6).

NOTE A dynamic range of 90 dB [i.e. for acceleration levels from 60 dB to 150 dB (ref. 10^{-6} m/s²)], and a bandwidth of from 2,5 Hz to 200 Hz will be required to measure VPTs at all frequencies specified in this part of ISO 13091.

4.10 System check and calibration

The correct functioning of the measurement system shall be established before conducting vibrotactile perception tests. This requires tests of both mechanical and electrical components. A suitable test of the electrical components is to provide a drive signal of known magnitude and frequency to the stimulator and to record the resulting motion of the stimulating probe, in the absence of a subject. Confirmation of the correct functioning of the measurement system shall be undertaken at least once during each day in which vibrotactile tests are conducted, and shall be reported in the results.

Calibration of the complete measurement system including software, if any, traceable to national standards shall be performed at least annually.

4.11 Hazards to the subject

All apparatus shall satisfy the requirements of IEC 60601-1 concerning electrical hazards to the subject or operator of the apparatus.

No part of the apparatus that contacts the subject shall present a biological or other health hazard to the subject.

5 Preparation and instruction of subjects before vibrotactile testing

5.1 General

The preparation and instruction of subjects, and the conduct of vibrotactile perception tests, shall be undertaken by a qualified examiner. A qualified examiner is deemed to be someone who has completed a course of instruction in the practice of vibrotactile testing, and has demonstrated competence in the conduct of such measurements. This qualification may be specified by national authorities and may require certification according to a prescribed training.

5.2 Prior to testing

5.2.1 Before testing, the subjects shall

- a) not be exposed to hand-transmitted vibration, nor engage in activity involving repetitive hand/arm motion, nor consume beverages containing alcohol, for at least 3 h before commencing a vibrotactile test,
- b) not consume other vasoactive or neuroactive agents (e.g. smoke cigarettes, drink beverages containing caffeine), nor engage in vigorous exercise for at least 1 h before commencing a vibrotactile test,
- c) not undertake an electrophysiologic test of nerve conduction in the upper extremities for at least 2 h before commencing a vibrotactile test,
- d) not undertake an objective vascular or sensory test of hand function for at least 30 min before commencing a vibrotactile test.
- e) be present and resting seated in a room with a temperature from 20 °C to 30 °C for at least 5 min, or until the fingertip skin temperature at potential measurement sites is between 27 °C to 35 °C, and
- f) undergo an inspection of potential measurement sites for injuries, scars, callosities, or other skin defects that could influence the test result.

The use of prescription drugs is not to be included in 5.2.1 b) but should be reported in the test report.

If any of conditions 5.2.1 a) to e) is not satisfied, the measurement of vibrotactile thresholds shall be postponed. Forced hand warming, for example by means of a heating device or by immersing the hand in hot water, shall not be used to increase skin temperature.

NOTE Elimination of the physiological effects associated with the activities listed in 5.2.1 a) would need a recovery period of at least 12 h prior to vibrotactile testing.

If condition 5.2.1 f) is not satisfied, the examiner shall select other skin sites or fingertips. If no acceptable measurement sites can be found, the test may be conducted provided the defective skin condition is reported in the test report.

5.2.2 The subject shall be instructed

- a) to remove wrist watch, rings or other jewellery, and clothing that may introduce discomfort or impede the measurement of vibrotactile thresholds when the hand and arm are supported by the armrest,
- b) to sit comfortably with hand and arm positioned in the armrest, and
- c) to remain still during the vibrotactile perception test.

5.3 Instruction of subject about the test procedure

The same explanation about the test procedure shall be given by the examiner to each subject. The briefing shall include

- a) an overall explanation of the test, including which fingers are to be tested,
- b) a description of the sensations likely to be perceived (e.g. "vibration", "buzz", "tingle", "flutter" or "push"),
- c) a statement that the stimuli may be very faint, and might not always be perceived,
- d) a description of the response task to be performed when the stimulus is perceived (e.g. depressing a handoperated switch),
- e) a description of the response task to be performed when the stimulus is no longer perceived (e.g. releasing a hand-operated switch), and
- f) any additional instructions required by national authorities.

After the briefing, the examiner shall ask the subject whether the test procedure has been understood. If the examiner is in doubt as to the subject's knowledge of the test procedure, the briefing shall be repeated.

6 Conduct of vibrotactile perception test

6.1 Familiarization

The subject shall be familiarized with the stimuli and response task to be performed before commencing a vibrotactile perception measurement. It is recommended that the subject experience all sensations to be presented during measurements, and perform the response task.

One, or more, practice runs of the measurement procedure used to obtain vibrotactile thresholds shall be conducted to satisfy the examiner that the subject can perform the task.

6.2 Measurement of ascending and descending thresholds

- **6.2.1** The examiner shall first confirm that
- a) the subject is sitting comfortably, and
- b) a suitable measurement site has been selected, and any skin defect at the site reported.
- **6.2.2** The procedure for establishing skin-stimulator contact shall include the following steps.
- a) The hand and arm shall be positioned on the armrest so as to maintain the comfort of the subject during the measurements, and to permit the finger at which ascending and descending thresholds are to be determined to make contact with the stimulator. The arm and/or hand restraints, if provided, shall be adjusted at this time.
- b) The fingertip, the probe and, if present, the surround shall be brought into contact.
- c) The contact conditions prescribed for method A or B shall be established.
- **6.2.3** The procedure for establishing the validity of the measurements shall include the following steps.
- a) The subject shall confirm that the stimulus can be felt, and the examiner shall confirm that the subject's response to the stimulus is detected by the apparatus.
- b) The background vibration at the fingertip shall be measured with the subject in position to commence threshold measurements, the stimulating probe and surround, if used, in contact with the skin, and with no stimulus.
- **6.2.4** The threshold measurement shall include the following steps.
- a) The examiner shall confirm that the subject is ready to undertake the measurement.

- Stimulation shall commence according to the algorithm. b)
- A sequence of at least four ascending and four descending thresholds shall be determined c)
 - at a recommended frequency, or
 - if the frequency is changed during the measurement, at a recommended equivalent frequency.

The thresholds obtained are the first ascending threshold value, the first descending threshold value, the second ascending threshold value, the second descending threshold value, etc., i.e. $t_a(1)$, $t_d(2)$, $t_d(2)$, ...

- Steps 6.2.4 b) to c) shall be repeated
 - for each frequency selected for measurement, or
 - if the frequency is changed during the measurement, for each equivalent frequency selected for measurement.

Variability of ascending and descending threshold values

The acceptability of ascending and descending threshold values for the calculation of the VPT is determined from the consistency of the subject's responses. Ascending and descending threshold values are acceptable if the following conditions are satisfied by the second, and succeeding, ascending and descending threshold values:

- the ascending threshold values differ by less than 10,0 dB (or a ratio of 3,15); a)
- the descending threshold values differ by less than 10,0 dB (or a ratio of 3,15); b)
- the mean of each ascending and descending threshold pair differ by less than 6,0 dB (or a ratio of 2), that is, C) for threshold values with levels expressed in decibels (ref. 10^{-6} m/s²):

$$\left| \frac{t_{a}(r) + t_{d}(r)}{2} - \frac{t_{a}(r+i) + t_{d}(r+i)}{2} \right| < 6.0 \text{ dB}$$
 (1)

where

r = 2, 3, ..., n;

i = 1, 2, ... for each value of r;

 $t_a(r)$, $t_d(r)$ are expressed in decibels (ref. 10^{-6} m/s²).

If the conditions 6.3 a) to c) are not satisfied, the measurement of ascending and descending thresholds shall be repeated as specified in 6.1 and 6.2.2 c) to 6.2.4 c).

- NOTE 1 Tests for the acceptability of ascending and descending threshold values are based on subjective evaluations of the stimulus magnitude near threshold, and are expressed in terms of the logarithm of the physical measure of the stimulus.
- The first ascending and descending threshold values are excluded from the calculation of the VPT (see 6.4). NOTE 2
- NOTE 3 Calculation of the standard deviation of ascending threshold values, and the standard deviation of descending threshold values, could assist the identification of inconsistent subject responses.

Calculation of vibrotactile perception threshold

The VPT shall be estimated for 50 % positive responses in the psychometric function

at each frequency, or

— if the frequency is changed during the measurement, at each equivalent frequency.

The VPT should be calculated from the arithmetic mean of ascending and descending threshold values when each are expressed in decibels (ref. 10⁻⁶ m/s²).

The first ascending and descending threshold values measured

- at each frequency, or
- if the frequency is changed during the measurement, at each equivalent frequency,

are to be excluded from the calculation of the VPT.

At least three ascending and three descending threshold values shall be used in the calculation of the VPT. For example, for threshold values expressed in decibels (ref. 10⁻⁶ m/s²):

$$VPT = \frac{1}{n-1} \sum_{r=2}^{n} \frac{t_{a}(r) + t_{d}(r)}{2}$$
 (2)

with

$$n \geqslant 4$$

 $t_a(r)$, $t_d(r)$ and VPT are expressed in decibels (ref. 10^{-6} m/s²).

NOTE The VPT calculated from the arithmetic mean of the ascending and descending threshold values expressed in decibels (ref. 10⁻⁶ m/s²), as in equation (2), is identical to the VPT calculated from the geometric mean of the ascending and descending threshold values expressed in metres per second squared. The VPT is less than the arithmetic mean of the ascending and descending threshold values expressed in metres per second squared.

VPTs shall be reported as r.m.s. acceleration levels expressed in decibels (ref. 10^{-6} m/s²), or as r.m.s. accelerations in metres per second squared (m/s²). The VPT expressed in decibels (ref. 10^{-6} m/s²) is related to the VPT expressed in metres per second squared by the relation

$$VPT[dB] = 20 lg \frac{VPT[m/s^2]}{10^{-6}m/s^2} dB$$
 (3)

6.5 Measurement of background vibration

The background vibration shall be measured with the subject in position to commence threshold measurements, the stimulating probe in contact with the skin, and with no stimulus. The measurements shall be performed by the sensor and conditioning means used to measure skin motion.

The background vibration shall be determined

- at each frequency selected for the measurement of vibrotactile perception, or
- if the frequency is changed during the measurement of vibrotactile perception, for each band of frequencies selected as representing an equivalent frequency for the purposes of measuring vibrotactile perception.

The background vibration shall be measured with sufficient bandwidth to include all recommended stimulation frequencies listed in Table 3 for the mechanoreceptor type selected for the measurement of vibrotactile perception (e.g. a bandwidth of at least from 100 Hz to 160 Hz when the frequency selected for measurement is 125 Hz).

The background vibration shall be reported as a r.m.s. acceleration level expressed in decibels (ref. 10^{-6} m/s²), or as a r.m.s. acceleration in metres per second squared

- at each frequency selected for the measurement of vibrotactile perception, or
- if the frequency is changed during the measurement of vibrotactile perception, for each band of frequencies selected as representing an equivalent frequency for the purposes of measuring vibrotactile perception.

The background vibration shall be less than the VPT at a frequency (or within the band of frequencies defining an equivalent frequency) at which the VPT is to be calculated. If the background vibration is greater than 0,63 times the VPT when both are reported as r.m.s. accelerations, or less than 4,0 dB less than the VPT when both are reported as r.m.s. acceleration levels (e.g. 3,9 dB less than the VPT, etc.), then the measurement of ascending and descending thresholds shall be repeated as specified in 6.2 after the background vibration has been reduced.

Failure to satisfy this condition will result in a masked (i.e. erroneous) VPT.

6.6 Measurement of skin temperature

The surface skin temperature shall be measured for each skin area that includes a vibrotactile test site with a precision of at least ± 1.0 °C. The skin temperature shall be determined before commencing vibrotactile measurements, and within 5 min of commencing the process of familiarizing the subject with the vibrotactile test procedure (see 6.1).

The skin temperature should also be determined after conducting vibrotactile measurements if the VPTs are believed to fall outside the expected range of values (see ISO 13091-2). In these circumstances, if the skin temperature is not between 27 °C to 35 °C, then the measurement of ascending and descending thresholds should be repeated as specified in 6.2 when the skin temperature is within the acceptable range.

7 Reporting of results

Values of VPTs shall be reported

- at each frequency, or
- if the frequency is changed during the measurement, at each equivalent frequency,

together with the following information:

- a) the subject's age and sex;
- b) hand and fingertip at which VPT was measured;
- c) skin temperature at fingertip at which VPT was measured;
- d) if applicable, any defective skin condition at the measurement site;
- e) measurement method (either A or B);
- f) stimulus frequency or equivalent frequency;
- g) if the stimulation is regularly intermittent the "on" and "off" periods or, if variable, the range of periods;
- h) stimulating probe tip diameter;
- i) probe contact force and/or skin indentation;
- j) if a surround is used, the diameter of the hole in the surround, and the force with which the fingertip contacts the surround;

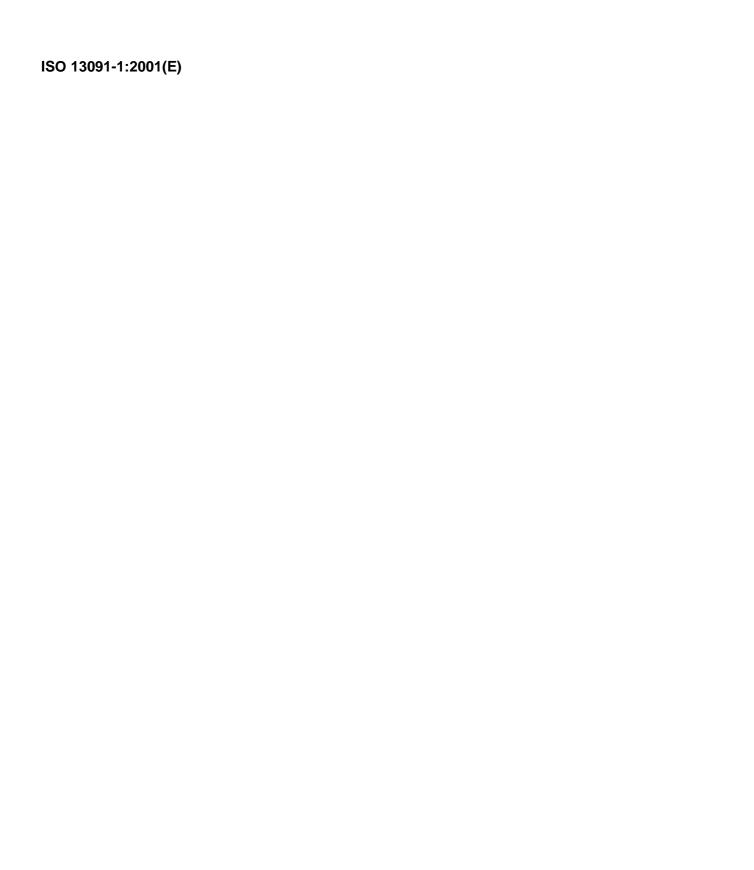
- k) the psychophysical algorithm;
- I) information on the calibration of the measurement system;
- m) pre-test conformation of the correct functioning of the measurement system;
- n) the background vibration at the fingertip for each frequency selected for the measurement of vibrotactile perception, or, if the frequency is changed during the measurement of vibrotactile perception, for each frequency band selected as representing a measurement "frequency".

The subject's medical diagnosis and use of prescription drugs should also be reported, if applicable.

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