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

Part 1: Methods of measurement at the fingertips

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

Partie 1: Méthodes de mesure à la pulpe des doigts

AMENDEMENT 1

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Foreword

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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.

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Page 6, 4.2.3

Delete the second paragraph.

Page 13, 4.10

Add at the end of first paragraph:

> "Tests for verifying the performance of apparatus for measuring vibrotactile perception are described in Annex A."

Page 19, Clause 7, item m) (English version only)

Replace "conformation" by "confirmation".

Page 20

Add Annex A (see next page) before the Bibliography.

Annex A
(informative)

Tests for verifying the performance of apparatus for measuring vibrotactile perception threshold

A.1 Introduction

This annex describes tests for verifying the performance of apparatus for measuring vibrotactile perception threshold (VPT). The information is intended to assist the user in fulfilling the requirements of 4.10. Tests are described that can be used in the field, in a clinical setting or in a laboratory. A self-test of the VPT measurement apparatus is recommended for each day it is used.

Tests are described for the electrical and mechanical components of a measurement system and for the psychophysical algorithm employed in the measurement procedure. The measurement system and algorithm shall be in compliance with the provisions of this part of ISO 13091. It is recommended that the correct functioning of the apparatus be verified before commencing VPT measurements, when the apparatus is physically moved to a different location, or as required by the user. The tests described in this annex, and their intended use, are summarized in Table A.1. The results of the tests should be reported with the results of VPT measurements.

Table A.1 — Summary of tests

Test	Clause	Recommended tests			
		Initial set-up of apparatus	After relocation of apparatus	Periodic calibration	Before or after measurements
Contact force or skin indentation	A.2	X	X	X	—
Baseline vibration	A.3	X	—	X	—
Hardware	A.4	—	—	X	—
Algorithm	A.5	—	—	X	—
System check	A.6	X	X	X	X

The system check is intended to employ only the VPT measurement system itself, preferably implemented as a built-in “self-test”. The test checks only the electromechanical performance of the apparatus. Tests for verifying the performance of components of the measurement system can require additional laboratory instrumentation.

In order to evaluate the results of the tests described in this annex, the vibration sensor and signal-conditioning means within the VPT measurement apparatus need to have been calibrated for sensitivity and frequency response traceable to national standards, as required by this part of ISO 13091. A sensor and signal-conditioning means capable of recording acceleration levels from 60 dB to 150 dB (ref. 10^{-6} m/s^2), or accelerations from 10^{-3} m/s^2 to 31,6 m/s^2, and frequencies from 2,5 Hz to 200 Hz are required to measure VPTs at all magnitudes and frequencies specified in this part of ISO 13091. VPT measurement apparatus designed to operate over a range of frequencies less than that specified in this part of ISO 13091 may require a smaller range of magnitudes, the lower limit of which is related to the VPTs of healthy persons at those frequencies (see ISO 13091-2). In addition, the output of the sensor and conditioning means should not contain spurious signals of magnitude comparable to the signals resulting from the tests described in this annex. Instrument baseline vibration is a primary source of spurious signals and should be measured as described in A.3, and taken into account when evaluating the results of tests of the hardware or measurement algorithm.

Any laboratory instrumentation (e.g. voltmeter, oscilloscope, spectrum analyser) shall have been calibrated in accordance with the specifications provided by the manufacturer.

A.2 Verification of contact force or skin indentation

Separate tests are described for measurement systems employing the following:

— a beam balance;

— direct control of contact force;

— skin indentation, and

— a surround.

These tests should be performed during initial set-up of the apparatus, during periodic calibration, when the apparatus is physically moved to a different location, and as required by the user.

For measurement systems employing a beam balance to impose a contact force between the stimulator probe tip and the skin, the ability of the balance to impose the required force at the probe tip shall be established.

The ability of the balance beam to swing freely (i.e. without excess friction in the bearings) should first be demonstrated when the stimulating probe is not in contact with the skin. For this test, the beam can first be balanced (e.g. for a linear beam, positioned horizontally). For beams with a preset contact force (i.e. off balance), a suitable mass shall be applied to bring the beam into balance. A test of excess friction can be obtained by first loading, and then unloading, the beam with an off-balance mass provided to impose the desired contact force. Under these conditions the beam should swing back to its initial equilibrium position when the off-balance mass is removed. Failure of the beam to return to its initial position could result from excess bearing friction. A measure of the error in application of the contact force would then be obtained by applying additional masses to return the beam to its initial equilibrium position. This test should be performed without a subject.

For example, the accuracy and repeatability of the contact force applied by the beam balance could be obtained by allowing the probe tip to contact a suitable scale, and then repeatedly applying and removing the off-balance mass provided to impose the desired contact force. A contact force of 0,15 N, which is recommended for a 4 mm diameter probe, corresponds to an off-balance mass of 15 g. An accuracy of ± 0,09 N is given in 4.6.3 for this contact force.

For measurement systems that directly monitor or control the contact force, the accuracy and repeatability of the contact force shall be established. This test should be performed without a subject.

For example, the accuracy and repeatability of the contact force could be obtained by applying a series of masses to the probe tip, and observing the force indicated by the measurement system to be the desired contact force. If the apparatus introduces a contact force without indication to the user, a different test method may be necessary and may require a calibrated force measurement system.

For measurement systems with probes that directly indent the skin, such as by means of an electromechanical positioning device, the accuracy and repeatability of the positioning system shall be established. This test should be performed with a subject present so that the probe tip can indent the skin surface.

For example, a test of skin indentation could be performed using a probe with side markings (e.g. circumferential grooves) indicating the distance from the probe tip. When the fingertip of a subject is positioned for conducting threshold measurements, the skin indentation resulting from application of the contact force or from activating the positioning device can be observed visually.

For measurement systems with a surround (method B), the compliance of the surround force with the range allowed in this part of ISO 13091 should be established.

For example, if the apparatus indicates to the subject when the surround contact force is appropriate, the accuracy of the force displayed could be established, in the absence of a subject, by placing a series of masses on the surround. The range of surround contact force specified in this part of ISO 13091 corresponds to masses from 70 g to 230 g. If the apparatus introduces a surround contact force without indication to the user, a different test method may be necessary and may require a calibrated force measurement system.

A.3 Instrument baseline vibration

The instrument baseline vibration recorded by the VPT measurement apparatus, which can result, for example, from floor vibration at the measurement site or from electrical noise generated within the instrumentation, or a combination of both, should be measured during initial set-up, calibration and after relocation of the apparatus. The baseline vibration, both real and apparent, produced by the measurement apparatus at each frequency employed for the tests described in A.4 to A.6 shall be at least 10 dB less than the intended acceleration level, or no more than one-third the intended acceleration. The baseline vibration shall be measured with sufficient bandwidth to include all recommended stimulation frequencies in Table 3 for the mechanoreceptor type selected (i.e. from 3,15 Hz to 5,0 Hz for SAI, from 20 Hz to 31,5 Hz for FAI and from 100 Hz to 160 Hz for FAII).

A test for the magnitude of the instrument baseline vibration can be performed by the VPT measurement apparatus itself when there is no electrical input to the stimulator, no subject present, and the probe tip is not in contact with an external surface. Under these conditions, the acceleration at the sensor as amplified and detected by the built-in electronics of the VPT measurement apparatus becomes the instrument baseline vibration.

NOTE Instrument baseline vibration at any frequency at which VPTs are mediated by a given mechanoreceptor type masks thresholds at all frequencies mediated by that receptor type. The measurement procedure provided only approximates this condition, and does not account for masking by baseline vibration at frequencies outside the range used for stimulation. An improvement to the procedure, for circumstances in which low-frequency out-of-band baseline vibration is suspected, is to extend the measurement bandwidth to include lower frequencies (e.g. to from 20 Hz to 160 Hz for FAII mechanoreceptors).

A.4 Verification of performance of measurement hardware

The conduct of a VPT measurement requires the stimulator to produce appropriate mechanical motions at the probe tip, and the sensor to record appropriately the magnitude of the stimulus. Tests for verifying the electromechanical and electronic performances of these aspects of the sensor, stimulator and signal-conditioning circuits are described in this clause. It is assumed that the sensor and signal-conditioning means have been calibrated (see A.1) and the instrument baseline vibration is acceptable (see A.3). The tests should be performed during calibration of the apparatus, and as required by the user.

With the VPT measurement system configured to perform a threshold measurement, the response of the sensor to the motion produced by a preset electrical signal driving the stimulator should be established. No subject is required for this measurement. The stimulating probe should not be in contact with an external surface, and a beam balance, if used, should be unrestrained and in a balanced position. The test consists of the following:

a) producing electrical test signals characteristic of those used to generate the vibrotactile stimuli;

b) applying the test signals to the stimulator;

c) confirming the motions at the probe tip comply with the intended vibration stimuli;

d) confirming the sensor appropriately records the magnitudes of the vibration stimuli.

Continuous and intermittent test signals should be generated for measurement systems that employ intermittent stimulation, to confirm the dynamics of the vibration sensor and conditioning electronics. An r.m.s. voltmeter may be used to verify the vibration magnitude and an oscilloscope to verify the stimulus waveform.

The distortion of the stimulus waveform may be determined with a spectrum analyser. Limits for the total harmonic distortion of the stimulus waveform are given in Table 2.

For example, a test for the r.m.s. acceleration produced by the electrical drive to the stimulator at the driving frequency could be performed by the VPT measurement system itself using the built-in sensor. This requires drive signals with magnitude, frequency and waveform corresponding to stimuli employed for the VPT measurements. Suitable signals for driving the stimulator could be those necessary to produce accelerations at the probe tip sensed by persons with acute sensation (i.e. more sensitive than the mean normative values in ISO 13091-2), e.g. 72 dB (ref. 10^{-6} m/s^2), or $4{,}0 \times 10^{-3}$ m/s^2, at 3,15 Hz, 4 Hz and 5 Hz; 90 dB, or 30×10^{-3} m/s^2, at 20 Hz, 25 Hz and 31,5 Hz; and 100 dB, or 0,1 m/s^2, at 100 Hz, 125 Hz and 160 Hz. The stimuli need to be produced for each frequency at which vibrotactile thresholds are to be obtained.

A.5 Verification of performance of measurement algorithm

The conduct of a VPT measurement relies on the ability of the apparatus to produce and sense the signals necessary to execute the measurement algorithm. A test for verifying this aspect of the stimulator, sensor, signal-conditioning electronics and subject response indicator is described in this clause, and should be conducted after the conditions in A.3 and A.4 have been satisfied. The test should be performed during calibration of the apparatus, and as required by the user.

With the apparatus configured to perform a VPT measurement, the response of the sensor to the motions produced by electrical signals driving the stimulator according to the measurement algorithm should be determined. The test consists of:

a) producing electrical test signals characteristic of those used to generate the vibrotactile stimuli;

b) applying the test signal to the stimulator;

c) allowing a time interval sufficient for the stimulus magnitude to follow the intended algorithm;

d) activating the subject response indicator to reverse the amplitude progression of the test signal;

e) confirming the sensor records changes in the vibration magnitudes expected from the measurement algorithm.

The magnitude shall be recorded for each stimulus if a variant of the up-down algorithm is used, or every second, or less, if the von Békésy algorithm is used.

For example, a test of the measurement algorithm could be performed by the VPT measurement system itself. This requires the apparatus to operate as if a VPT measurement were being performed with a subject present. The probe acceleration is recorded as the stimulus changes and as controlled by the subject response. The acceleration, or acceleration level, shall be recorded for each stimulus with intermittent stimulation, or every second, or less, with continuous stimulation, to confirm that the stimuli follow the prescribed algorithm.

A.6 Self-test of VPT measurement apparatus

The test described in the example of A.4 employing electrical signals of preset magnitude and frequency is suitable for a practical self-test of the VPT measurement apparatus. The test employs stimuli for each frequency at which vibrotactile thresholds are to be obtained. Continuous stimuli should be generated for measurement systems that employ continuous stimulation, and continuous and intermittent stimuli should be generated for measurement systems that employ intermittent stimulation. The r.m.s. acceleration, or acceleration level, detected by the sensor and conditioning electronics for each vibrotactile stimulus should be recorded and tabulated to form the test result. It is recommended that this self-test be performed each day the VPT measurement apparatus is used.