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Acoustics — Reference zero for the calibration of audiometric equipment —

Part 3:

Reference equivalent threshold vibratory force levels for pure tones and bone vibrators (standards.iteh.ai)

Acoustique — Zéro de référence pour l'étalonnage d'équipements audiométriques 016

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Reference number ISO 389-3:2016(E)

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<u>ISO 389-3:2016</u> https://standards.iteh.ai/catalog/standards/sist/7ae96236-e603-4534-96b6-120c1157db86/iso-389-3-2016



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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ASO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 43, *Acoustics*.

This second edition cancels and replaces the first edition (ISO 389-3:1994), which has been technically revised. It also incorporates the Technical Corrigendum ISO 389-3:1994/Cof 3:1995.

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ISO 389 consists of the following parts, under the general title *Acoustics* — *Reference zero for the calibration of audiometric equipment*:

- Part 1: Reference equivalent threshold sound pressure levels for pure tones and supra-aural earphones
- Part 2: Reference equivalent threshold sound pressure levels for pure tones and insert earphones
- Part 3: Reference equivalent threshold vibratory force levels for pure tones and bone vibrators
- Part 4: Reference levels for narrow-band masking noise
- Part 5: Reference equivalent threshold sound pressure levels for pure tones in the frequency range 8 kHz to 16 kHz
- Part 6: Reference threshold of hearing for test signals of short duration
- Part 7: Reference threshold of hearing under free-field and diffuse-field listening conditions
- Part 8: Reference equivalent threshold sound pressure levels for pure tones and circumaural earphones
- Part 9: Preferred test conditions for the determination of reference hearing threshold levels

Introduction

Each part of ISO 389 specifies a specific reference zero for the calibration of audiometric equipment. ISO 389-1, ISO 389-2 and ISO 389-8 are applicable to audiometric equipment for the transmission of pure tones by air conduction.

For clinical diagnostic and other audiometric purposes, it is often necessary to compare the measured hearing threshold levels of a person for sound transmitted to the inner ear by the air-conduction and bone-conduction pathways, respectively. Bone-conducted sound is provided for this purpose by an electromechanical vibrator applied to the mastoid prominence or to the forehead of the person under test.

The reference zero for the calibration of audiometric equipment for air conduction is defined in ISO 389-1, ISO 389-2 and ISO 389-8 in terms of reference equivalent threshold sound pressure levels (RETSPL), i.e. threshold sound pressure levels produced in an ear simulator or acoustic coupler of specified characteristics by supra-aural, circumaural or insert earphones of various patterns, when excited electrically at a level corresponding to the threshold of hearing of young otologically normal persons. Similarly, this part of ISO 389 provides a reference zero for bone-conduction audiometry in terms of reference equivalent threshold vibratory force levels (RETVFL), i.e. the vibratory force levels produced by a bone vibrator on a specified mechanical coupler when the vibrator is excited electrically at a level corresponding to the threshold of hearing of young otologically normal persons. In some countries, the preferred location is the mastoid prominence; in other countries, the forehead location is used in addition to the mastoid prominence. Different RETVFL values are valid for each of the two positions (see <u>Annex C</u>).

For bone-conduction measurements, it is necessary to specify the static force of application of the vibrator to the test subject and to the mechanical coupler, as well as certain geometrical features of the vibrator tip. In addition, it is usually necessary to apply masking noise to the ear not under test, since excitation of the cranial bones by the vibrator may be heard by that ear instead of (or in addition to) the ear intended for the test. An appropriate specification of the masking noise is, therefore, required as an adjunct to the reference equivalent threshold vibratory force levels, and such a specification is given in this part of ISO 389. Due to the so-called "occlusion effect" whereby the wearing of the transducer needed to provide the (air-conducted) masking noise causes a lowering of the bone-conduction threshold of hearing of the ear receiving the masking signal, it is necessary for the level of masking noise to be raised to cancel out the occlusion effect and provide adequate masking of the ear not under test. The specification of masking noise given in this part of ISO 389 is based on the procedures used in the experimental investigations from which the reference zero of this part of ISO 389 is derived.

Use of this reference zero to calibrate audiometers will ensure that measured bone-conduction hearing threshold levels of persons with unimpaired hearing or with hearing losses of purely sensorineural type (i.e. having unimpaired outer and middle ear function) will be compatible with the air-conduction hearing threshold levels of the same persons when using the reference zero of ISO 389-1, ISO 389-2 or ISO 389-8, respectively. Although exact equivalence of air-conduction and bone-conduction thresholds for any individual in these classes cannot be expected, due to biological variability of sound transmission through the external and middle ear and through the cranial bones, this part of ISO 389 will ensure that systematic deviations averaged over groups of such persons are reduced to a practical minimum.

This part of ISO 389 is based on an assessment of technical data provided by laboratories in three countries using methods of threshold testing which, in the respects described, were essentially uniform. Examination of the data showed that the experimental results were consistent. It has, therefore, been possible to standardize a reference zero by means of RETVFL values which are to be used for all bone vibrators used in audiometry having similar characteristics to those used by the laboratories. The systematic uncertainties introduced by this deliberate simplification will be small in comparison to the usual step size of hearing level controls in clinical audiometers (5 dB).

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Acoustics — Reference zero for the calibration of audiometric equipment —

Part 3: **Reference equivalent threshold vibratory force levels for pure tones and bone vibrators**

1 Scope

This part of ISO 389 specifies the following data applicable to the calibration of bone vibrators for pure-tone bone-conduction audiometry:

- a) reference equivalent threshold vibratory force levels (RETVFL), corresponding to the threshold of hearing of young otologically normal persons by bone-conduction audiometry;
- b) essential characteristics of the bone vibrator and the method of coupling to the test subject, and to the mechanical coupler;
- c) essential characteristics of the masking noise and the baseline masking noise level applied to the ear not under test.

Guidance on the practical application of this part of ISO 389 in the calibration of audiometers is given in <u>Annex B</u>.

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RETVFL is the vibratory force level transmitted to a mechanical coupler of specified characteristics by a vibrator when applied to the mechanical coupler under stated conditions of test and when energized at the voltage level corresponding to the normal threshold of hearing for location on the mastoid prominence.

NOTE 1 Values for the differences in reference equivalent threshold vibratory force levels between location on the forehead and mastoid are included for information in <u>Annex C</u>.

NOTE 2 Recommended procedures for carrying out bone-conduction audiometry are specified in ISO 8253-1.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 389-1, Acoustics — Reference zero for the calibration of audiometric equipment — Part 1: Reference equivalent threshold sound pressure levels for pure tones and supra-aural earphones

ISO 389-2, Acoustics — Reference zero for the calibration of audiometric equipment — Part 2: Reference equivalent threshold sound pressure levels for pure tones and insert earphones

ISO 389-4, Acoustics — Reference zero for the calibration of audiometric equipment — Part 4: Reference levels for narrow-band masking noise

IEC 60318-6, *Electroacoustics — Simulators of human head and ear — Part 6: Mechanical coupler for the measurement of bone vibrators*

3 Terms and definitions

For the purposes of this document, the definitions given in ISO 389-1 and ISO 389-2, and the following terms and definitions apply.

3.1

bone conduction

transmission of sound to the inner ear primarily by means of mechanical vibration of the cranial bones

3.2

bone vibrator

electromechanical transducer intended to produce the sensation of hearing by vibrating the cranial bones

3.3

vibratory force level

ten times the logarithm to base ten of the ratio of the mean square vibratory force by the square of the reference force, 1 μN

Note 1 to entry: The vibratory force level is expressed in decibels (dB).

3.4

mechanical coupler

device for calibrating bone vibrators, designed to present a specified mechanical impedance to a bone vibrator applied with a specified static force, and equipped with an electromechanical transducer to enable the vibratory force level at the surface contact between a bone vibrator and mechanical coupler to be determined **iTeh STANDARD PREVIEW**

Note 1 to entry: A mechanical coupler is specified in IEC 60318-6. en ai)

3.5

equivalent threshold vibratory force level ISO 389-3:2016

vibratory force level for a given early at a specified frequency; for a specified configuration of bone vibrator and for a stated force of application of the bone vibrator to the human mastoid prominence, set up by the bone vibrator on a specified mechanical coupler when the bone vibrator is actuated by that voltage which, with the bone vibrator applied to the mastoid prominence concerned, would correspond to the threshold of hearing

Note 1 to entry: The term is relevant for monaural listening only.

3.6

reference equivalent threshold vibratory force level RETVFL

mean value of the equivalent threshold vibratory force levels at a specified frequency, of a sufficiently large number of ears of otologically normal persons, of both sexes, aged between 18 years and 25 years inclusive, expressing the threshold of hearing in a specified mechanical coupler for a specified configuration of bone vibrator

Note 1 to entry: The term was formerly referred to by the acronym RETFL.

3.7

hearing level

vibratory force level (or sound pressure level) at a specified frequency, for a specified model of transducer and for a specified manner of application, produced by the transducer in a specified mechanical coupler (or ear simulator or acoustic coupler) minus the appropriate reference equivalent threshold vibratory force level (or reference equivalent threshold sound pressure level) for bone conduction or air conduction, as applicable

Note 1 to entry: By extension, this definition may be applied to a narrow band of noise.

3.8

occlusion effect

increase in level of a bone-conducted signal reaching the inner ear when an earphone or earplug is placed over, or at the entrance to the ear canal, thereby forming an enclosed air volume in the external ear

Note 1 to entry: The effect depends on the type of earphone or earplug used and is greatest at low frequencies.

Note 2 to entry: This is expressed in decibels (dB).

3.9

masking

<process> process by which the threshold of hearing of a sound is raised by the presence of another (masking) sound

3.10

masking

<quantity> amount by which the hearing threshold level is so raised

Note 1 to entry: This is expressed in decibels.

3.11

baseline masking level

level, expressed as hearing level of a band of noise delivered by air conduction for the purpose of masking, in the presence of which a pure tone at the centre frequency of the noise band and at a hearing level of 35 dB is just audible, on the basis of 50 % detection in repeated trials by an otologically normal person, having a hearing threshold level of 0 dB by air conduction for that pure tone

Note 1 to entry: The value of 35 dB for the pure-tone test stimulus has been adopted arbitrarily as lying within the range used in experimental studies on which this part of ISO 389 is based. It does not imply a recommendation to adopt this level of masking noise in clinical practice.

Note 2 to entry: The relationship between the levels of a masking noise and a pure tone just masked by the presence of this noise is specified in ISO 389-47 db86/iso-389-3-2016

Note 3 to entry: The term was formerly called "datum level of masking noise" in the earlier edition of this part of ISO 389.

Note 4 to entry: By extension, this definition may be applied to a narrow band of noise.

3.12

critical bandwidth

bandwidth of a frequency band of sound, being a portion of a continuous noise spectrum of wider bandwidth, which effectively masks a tone coinciding with the centre frequency of the band

3.13

vibrotactile threshold level

vibratory force level at which a person gives a predetermined percentage of correct detection responses on repeated trials due to the sensation of vibration on the skin

Note 1 to entry: A 50 % correct detection rate is often used.

3.14

white noise

noise, having a power spectral density that is essentially independent of frequency

4 Reference equivalent threshold vibratory force levels (RETVFL)

Reference equivalent threshold vibratory force levels for location of the bone vibrator on the mastoid prominence are given in <u>Table 1</u>. They are derived from determinations of the threshold of hearing by

bone conduction of otologically normal persons as measured on the mastoid prominence, under the conditions described in <u>Clause 5</u> (see <u>Annex A</u>).

NOTE 1 It is emphasized that the data given in <u>Table 1</u> are derived from results obtained with different types of bone vibrators having different electromechanical properties, applied to the head in the specified manner. The procedures used to compensate for differences in the masking levels used in the three studies may also have contributed to differences among studies.

NOTE 2 Values for frequencies below 250 Hz are not specified in this part of ISO 389. Results from one laboratory are given for information in <u>Annex D</u>.

5 Test conditions and requirements

5.1 General

5.3

The reference equivalent threshold vibratory force levels apply when the conditions and requirements specified in this Clause are met.

5.2 Bone vibrator

The vibrator shall have a plane, circular tip, of nominal area 175 mm². Any airborne sound which it radiates when in contact with the head of a test subject having unimpaired external and middle ear function shall be low enough in level to provide a margin of 10 dB or more between the true bone-conduction hearing threshold level and a false air-conduction hearing threshold level evoked by the bone vibrator. A method to show conformity with this requirement is given in Annex B.

If this condition is not met directly at all frequencies, the unwanted sound radiation is excluded by inserting an earplug into the external canal of the ear under test at the frequencies which are affected. Due to the occlusion effect, use of the earplug is confined to frequencies above 2 000 Hz.

https://standards.iteh.ai/catalog/standards/sist/7ae96236-e603-4534-96b6-**Fitting of the bone vibrator** 120c1157db86/iso-389-3-2016

A headband shall be used to hold the vibrator on the mastoid prominence with a nominal static force of 5,4 N. The vibrator shall be placed on the mastoid prominence, not touching the pinna, and adjusted so as to remain in a stable position.

Frequency Hz	RETVFL ^a (reference: 1 μN) dB		
250	67,0		
315 ^b	64,0		
400 ^b	61,0		
500	58,0		
630 ^b	52,5		
750c	48,5		
800b	47,0		
1 000	42,5		
1 250b	39,0		
Values rounded to the nearest 0,5 dB.			
Values for these frequencies are derived by interpolation.			

Table 1 — Reference equivalent threshold vibratory force levels (RETVFL) for location of the
vibrator on the mastoid prominence

Frequency Hz	RETVFL ^a (reference: 1 μN) dB			
1 500c	36,5			
1 600 ^b	35,5			
2 000	31,0			
2 500 ^b	29,5			
3 000	30,0			
3 150 ^b	31,0			
4 000	35,5			
5 000c	40,0			
6 000c	40,0			
6 300c	40,0			
8 000c	40,0			
^a Values rounded to the nearest 0,5 dB.				

 Table 1 (continued)

b

Values for these frequencies are derived by interpolation.

Values for these frequencies are derived from the results from one laboratory only.

5.4 Mechanical coupler STANDARD PREVIEW

The mechanical coupler shall comply with the specification in IEC 60318-6.

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Test signal https://standards.iteh.ai/catalog/standards/sist/7ae96236-e603-4534-96b6-5.5

The vibratory force signal produced by the bone vibrator at the excitation level corresponding to <u>Table 1</u>, as measured on the mechanical coupler, shall exhibit total harmonic distortion not exceeding 1 % for fundamental frequencies from 500 Hz to 1 000 Hz, and 2 % for frequencies from 250 Hz to 400 Hz inclusive and from 1 250 Hz upwards.

5.6 Masking noise

The masking noise signal shall be generated according to the specifications given in ISO 389-4, and centred on a test frequency given in <u>Table 1</u>.

5.7 Masking transducer

The masking noise signal shall be delivered to the ear not under test by means of a supra-aural or insert earphone of a pattern conforming to one of the specifications in ISO 389-1 or ISO 389-2, respectively.

5.8 Fitting of masking transducer

If a supra-aural earphone is used for delivering the masking noise, it shall be applied to the ear not under test of the test subject by means of a headband exerting a nominal static force of 4,5 N, and designed not to interfere with the headband holding the bone vibrator which is worn simultaneously. If an insert earphone is used for delivering the masking noise, it shall be applied to the ear not under test as specified in ISO 389-2.