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ISO 389-9

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Acoustics — Reference zero for the calibration of audiometric equipment —

Part 9:

Preferred test conditions for the determination of reference hearing threshold levels

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

Partie 9: Conditions d'essai préconisées pour la détermination des niveaux liminaires d'audition de référence



Reference number ISO 389-9:2009(E)

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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.

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 389-9 was prepared by Technical Committee ISO/TC 43, Acoustics.

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 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

ISO/TC 43, *Acoustics*, is responsible for the production of International Standards specifying human hearing thresholds for use in the calibration of audiometric equipment. The Committee bases its work on data from independent laboratories throughout the world. Unfortunately, problems have existed in the past in trying to relate the data from experiments carried out by different laboratories in different parts of the world, all of which have had the same objective, but which lacked a common set of criteria for subject selection, methods of test and reporting of data, etc.

ISO/TC 43 has developed this part of ISO 389 in order to collate the data that is being, or will be, produced in the future, and to encourage other laboratories to participate in these activities. The test conditions are aimed at providing guidance to researchers to ensure that the collation of future work is made easier, which in turn ought to lead to a more rapid production of relevant standards.

Acoustics — Reference zero for the calibration of audiometric equipment —

Part 9:

Preferred test conditions for the determination of reference hearing threshold levels

1 Scope

This part of ISO 389 specifies test conditions for determining the hearing thresholds of subjects for the purpose of establishing standardized values for reference hearing threshold levels.

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 amendments) applies.

ISO 389-1:1998, Acoustics — Reference zero for the calibration of audiometric equipment — Part 1: Reference equivalent threshold sound pressure levels for pure tones and supra-aural earphones¹⁾

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 earphones¹⁾

ISO 389-3, Acoustics — Reference zero for the calibration of audiometric equipment — Part 3: Reference equivalent threshold force levels for pure tones and bone vibrators

ISO 389-6, Acoustics — Reference zero for the calibration of audiometric equipment — Part 6: Reference threshold of hearing for test signals of short duration

ISO 389-7, Acoustics — Reference zero for the calibration of audiometric equipment — Part 7: Reference threshold of hearing under free-field and diffuse-field listening conditions

ISO 389-8, Acoustics — Reference zero for the calibration of audiometric equipment — Part 8: Reference equivalent threshold sound pressure levels for pure tones and circumaural earphones

ISO 8253-1:—²⁾, Acoustics — Audiometric test methods — Part 1: Basic pure-tone air and bone conduction threshold audiometry

ISO 8253-2:—³⁾, Acoustics — Audiometric test methods — Part 2: Sound field audiometry with pure tone and narrow-band test signals

¹⁾ Under revision.

²⁾ To be published. (Revision of ISO 8253-1:1989)

³⁾ To be published. (Revision of ISO 8253-2:1992)

ISO/IEC Guide 98-3, Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)

IEC 60318-1, Electroacoustics — Simulators of human head and ear — Part 1: Ear simulator for the calibration of supra-aural and circumaural earphones 4)

IEC 60318-3, Electroacoustics — Simulators of human head and ear — Part 3: Acoustic coupler for the calibration of supra-aural earphones used in audiometry

IEC 60318-4, Electroacoustics — Simulators of human head and ear — Part 4: Occluded-ear simulator for the measurement of earphones coupled to the ear by ear inserts 5)

IEC 60318-5, Electroacoustics — Simulators of human head and ear — Part 5: 2 cm³ coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts

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

IEC 60645-1:2001, Electroacoustics — Audiological equipment — Part 1: Pure-tone audiometers

IEC 60645-3:2007, Electroacoustics — Audiometric equipment — Part 3: Test signals of short duration

IEC 60645-4, Audiometers — Part 4: Equipment for extended high-frequency audiometry

Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8253-1 and ISO 389-6 apply.

Test conditions

Test subjects 4.1

- At least 25 subjects shall participate, both males and females, preferably represented in equal numbers.
- 4.1.2 The subjects shall be in the age range 18 years to 25 years inclusive.
- The subjects shall be otologically normal, i.e. be in a normal state of health, be free from all signs or symptoms of ear disease and from obstructing wax in the ear canals, and have no history of undue exposure to noise, exposure to potentially ototoxic drugs or familial hearing loss. Minimum information to be collected is given in Annex A.
- Tympanometry shall be performed at the beginning of each test session. Hearing threshold measurements shall be performed only if a middle ear pressure in the range \pm 50 daPa has been obtained.

Maximum ambient noise levels 4.2

4.2.1 The acoustic environment in which the test subjects are located during testing shall fulfil the requirements given in ISO 8253-1:—, 11.1 and 11.2 for measurement of hearing levels down to -10 dB with a maximum uncertainty of +2 dB due to ambient noise. The requirements for 8 kHz shall also be applied to the one-third-octave bands from 10 kHz to 16 kHz.

⁴⁾ To be published. (Revision of IEC 60318-1:1998 and IEC 60318-2:1998)

⁵⁾ To be published. (Revision of IEC 60711:1981)

- **4.2.2** For typical current supra-aural earphones with sound attenuation as given in ISO 8253-1:—, Table 3, conformance with the requirement of 4.2.1 means that noise levels shall be at least 10 dB below the levels given in ISO 8253-1:—, Table 2.
- **4.2.3** If the sound attenuation provided by the actual earphone differs from the values given in ISO 8253-1:—, Table 3, the maximum permissible level of noise shall be modified accordingly.
- **4.2.4** For sound field audiometry, the acoustic environment shall fulfil the requirement given in ISO 8253-2:—, Clause 6.

4.3 Test procedure

Monaural pure-tone hearing threshold levels shall be determined according to ISO 8253-1. Binaural hearing threshold levels shall be determined according to ISO 8253-2. Either the bracketing or ascending method shall be used. Each subject shall have at least one training session with two or three selected test signals.

5 Audiometric equipment

5.1 General

The audiometric equipment, which is used for control of stimulus gating and stimulus level and for execution of the test procedure, shall fulfill the relevant requirements of IEC 60645-1 (for air- and bone-conduction puretone signals and masking), IEC 60645-3 (only for signals of short duration) and IEC 60645-4 (only for extended high-frequency signals). Special care shall be taken to avoid detection by the test subjects of any sounds coinciding with the tone and attenuator switching.

Calibration of test equipment shall be performed at regular intervals to ensure that levels are within those specified in the prevailing data. ISO 8253-1:—, Clause 12 specifies three stages of maintenance and calibration procedures, and a stage B periodic objective test is required at regular intervals.

5.2 Transducers

5.2.1 General

The many different transducers used in hearing threshold measurements will require special attention. Air-conduction and bone-conduction transducers as well as loudspeakers for sound field measurements are involved. For air-conduction transducers, supra-aural, circumaural and insert earphones are used, and the first two of these will require special attention related to headband force. The use of a correct ear simulator or microphone will also have to be controlled. Relevant International Standards are available for this field (see 5.2.2).

5.2.2 Classes of transducers

These include:

- a) supra-aural earphones, which shall meet the specifications given in ISO 389-1:1998, 4.2 or 4.3;
- b) circumaural earphones, which shall meet the specifications given in ISO 389-8;
- c) insert earphones, which shall meet the specifications given in ISO 389-2;
- d) bone vibrators, which shall meet the specifications given in ISO 389-3;
- e) loudspeakers for sound field measurements according to ISO 389-7.

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5.2.3 Calibration

Calibration of supra-aural earphones shall be performed on an ear simulator according to IEC 60318-1 or on an acoustic coupler according to IEC 60318-3.

Calibration of circumaural earphones shall be performed on an ear simulator according to IEC 60318-1.

If other adapters are used for circumaural earphones, data should be provided to demonstrate their equivalency.

Calibration of insert earphones shall be performed on an ear simulator according to IEC 60318-4 or an acoustic coupler according to IEC 60318-5.

Calibration of bone vibrators shall be performed on a mechanical coupler according to IEC 60318-6.

5.2.4 Force of application, height of headband

Different types of earphones and bone vibrators require different values of force of application to the ear or mastoid and to the ear simulator. The values refer to the force exerted by the headband when the opposing faces of the ear cushions are separated by 145 mm. This same separation is also required between the bone vibrator and the opposite end of its headband for mastoid application. The earphone or bone vibrator shall be applied to the ear simulator with the nominal static force of the same value, not including the weight of the transducer itself.

For supra-aural earphones, specification for the height of the headband is found in 13.8.1 of IEC 60645-1:2001.

5.2.5 Fitting

Experimenter-supervised fitting of supra- and circumaural earphones shall be undertaken followed by adjustment by the test subject to maximum loudness of an 8 kHz test tone. For insert earphones, only experimenter fitting shall be undertaken. The bone vibrator shall be positioned so that the largest possible area of the tip is in contact with the skull. If placed on the mastoid, the vibrator shall be positioned behind and as near as possible to the pinna, without touching it. After positioning the bone vibrator on the subject, place the masking earphone on the ear not under test. Care shall be taken that the headbands of the two transducers do not interfere with one another.

5.3 Test signals

5.3.1 General requirements for pure-tone signals

- **5.3.1.1** The maximum permissible deviation from the nominal frequency shall be 0,1 %.
- **5.3.1.2** Each tone shall be presented monaurally with a duration of 1 s to 2 s and the tone switching shall meet the requirements of IEC 60645-1:2001, 8.6.

5.3.2 Requirements for frequency range 125 Hz to 8 kHz

5.3.2.1 Pure tones of the following audiometric frequencies shall be used:

125 Hz, 250 Hz, 500 Hz, 750 Hz, 1 000 Hz, 1 500 Hz, 2 000 Hz, 3 000 Hz, 4 000 Hz, 6 000 Hz, 8 000 Hz.

The order of test frequencies should preferably start with 1 kHz, continuing upwards, then repeating 1 kHz and finally measuring from 750 Hz downwards.

The order of test frequencies may be randomized.

Optional additional one-third-octave frequencies according to ISO 266 may be used.

5.3.2.2 At any frequency, the dynamic range of test tone levels shall be at least \pm 30 dB, relative to the expected average equivalent threshold sound pressure level.

5.3.3 Requirements for frequency range 8 kHz to 16 kHz

5.3.3.1 Pure tones of the following preferred frequencies according to IEC 60645-4 shall be used:

8 kHz, 9 kHz, 10 kHz, 11,2 kHz, 12,5 kHz, 14 kHz, 16 kHz.

The order of test frequencies may be randomized.

Optional additional frequencies above 16 kHz may be used.

5.3.3.2 At any frequency up to 14 kHz, the dynamic range of test tone levels shall be at least \pm 30 dB relative to the expected average equivalent threshold sound pressure level. At 16 kHz the corresponding range should be at least \pm 40 dB.

5.3.4 Requirements for sound field audiometry

- **5.3.4.1** Specifications for sound field audiometry are found in ISO 8253-2 and imply binaural listening to test signals presented as sound pressure levels from loudspeakers.
- **5.3.4.2** Test signals shall consist of pure tones, narrowbands of noise or frequency-modulated tones.
- **5.3.4.3** The acoustical characteristics of the sound field are determined by the choice of test signal, by the number and acoustical properties of the loudspeakers used, as well as by the acoustical characteristics of the test room.

5.3.5 Requirements for signals of short duration

- **5.3.5.1** Clicks as well as tone bursts shall be used as single stimuli and as groups of stimuli with a repetition rate of 20/s. Each group shall have a duration of 1 s to 2 s and envelope rise and fall times as specified in IEC 60645-1:2001, 8.6. Stimulation shall be monaural.
- **5.3.5.2** Clicks should preferably have an electric waveform according to IEC 60645-3:2007, 5.2. The waveform consists of a reference pulse (single monophasic square wave) having the following specifications: the duration shall be 100 μ s \pm 10 μ s; rise and fall times shall be less than 25 μ s. The click polarity as verified acoustically shall be specified.
- NOTE For this verification to be reliable, the polarity of the measurement system has to be known, as commercial microphones, preamplifiers and measuring amplifiers can give rise to phase shifts.

Other waveforms, if stated, may also be used.

5.3.5.3 Reference tone bursts should preferably have an electric waveform according to IEC 60645-3:2007, 5.3. This has linear rise and fall times of 1,6 periods of the modulated frequency and a duration of three periods. The total number of periods in the reference tone burst is five. Each tone shall start in the same phase from a zero crossing. The modulated frequencies used shall be stated.

Other waveforms, if stated, may also be used.

At frequencies where measurements are made for tone bursts, measurements shall also be made with longer tones (1 s to 2 s), using the same equipment (earphone, ear simulator, etc.) and the same test procedure.

5.3.5.4 Stimuli should preferably be presented by means of any of the types of transducers listed in 5.2.2. Other types of earphones may be used if reproducible calibration can be obtained.

Reporting of data 6

- For pure-tone signals as specified in 5.3.1 to 5.3.3, the results shall be given as equivalent threshold sound pressure levels for a stated and standardized ear simulator or as equivalent threshold vibratory force levels for a mechanical coupler.
- 6.2 For sound field audiometry according to 5.3.4, results shall be given as threshold sound pressure levels.
- 6.3 For signals of short duration according to 5.3.5, results shall be given as peak-to-peak equivalent signal levels representing either the equivalent threshold sound pressure levels for supra-aural, circumaural and insert earphones, the threshold sound pressure levels for sound field audiometry, or the equivalent threshold vibratory force levels for bone vibrators. All results shall be referenced to a specified ear simulator, mechanical coupler or specific instrumentation for sound field measurements. For longer tones according to 5.3.1, results shall be given in accordance with 6.1 or 6.2.
- 6.4 Data shall be reported for each individual subject, including
- monaural hearing threshold results for the actual test stimuli, or binaural in the case of free field testing,
- other relevant information obtained, such as age and gender of the subject and the results of the tympanometry.
- In addition, median values of the results shall be given for the total group, together with the expanded measurement uncertainty for a coverage probability of 95 % in accordance with ISO/IEC Guide 98-3, and for subgroups such as male and female subjects or different age ranges, e.g. 18 years to 21 years and 22 years to 25 years.
- Transducers and the relevant calibration procedure shall be described in detail, including manufacturer, type, version and cushion. Details shall be given of the fitting of the transducer on test subjects and to the ear simulator, including the applied force.
- A frequency response curve of the transducers as measured on the stated ear simulator, or in free field for loudspeakers, shall be provided. For signals of short duration the acoustic waveforms shall be given as measured in the actual calibration system.
- Any other relevant information shall be reported, such as audiometric equipment used, attenuator step 6.8 size and test procedure.

Annex A

(normative)

Questionnaire for hearing tests

1.	Name:			Date of birth:	Gender:	
2.	Have you ever had trouble with your hearing (for example, infections, ear noises, drainage, etc.					
	Yes	No	If yes, pl	ease detail:		
		·				
3.	Have you ever had an operation in your ear?					
	Yes	No	If yes, p	lease detail:		
4.	Have you ever taken drugs, tablets or been given injections that affected your hearing?					
	Yes	No				
5.	5. Have you worked for several years in a place that was very noisy, i.e. where it was communicate?					
	Yes	No	If yes, p	lease detail:		
			_			
6.	Did you wear any hearing protector at that time?					
	Yes	No				
7.	Do you attend pop/rock concerts or discotheques?					
	Never	Once a year	More th	an once a year		
8.	Do you play any musical instrument?					
	Yes	No	If yes, p	lease specify:		
			_			
9.	Do you listen to personal wearable players?					
	Never	Less than 2 hours per week	More th	an 2 hours per wee	k	
10.	10. Have you been exposed to any loud sounds from, e.g. motorbikes, chain-saws, gunf crackers or explosions?					
	Yes	No	If yes, v	what kind and how o	ften:	
			_			
11.	Does/did anyone in your immediate family have a hearing disorder?					
	Yes	No	If yes, p	lease specify:		
			_			
12.	2. Have you ever had a hearing test before?					
	Yes	No	If yes, v	when and where:		
			_			
I agree to the storage of my data and their use in connection with the threshold measurements						
Date:				Signature:		

An answer YES to the following questions should be further explored and might lead to an exclusion from further testing, or results should be deleted from the material: 2, 3, 4, 5, 7 (more than once a year), 8 (rock band, symphony orchestra), 9 (more than 2 hours per week), 10, 11.

Annex B (informative)

Background explanation

For free-field and diffuse-field listening conditions, the threshold values refer to sound pressure levels measured at the position of the subject but without the subject. For earphone listening, the threshold values are equivalent threshold sound pressure levels, which means sound pressure levels measured in an ear simulator, when the earphone is supplied with the voltage corresponding to the threshold. Similarly, for bone vibrators, the values are equivalent threshold vibratory force levels measured as force levels delivered to a mechanical coupler. In any case, values for calibration are given as reference equivalent thresholds, which includes median values of (equivalent) thresholds for specified groups of subjects. Values for the calibration of audiometric equipment have been given in the past in terms of the mean, modal or median values of reference equivalent thresholds, which has led to difficulties in making comparisons. The preferred measures in future will be those of median values.

Developments in audiometry have led to the need for additional information, relating to new types of signals and new types of earphones.

The test conditions in this part of ISO 389 are set out in the form of general requirements that apply to all forms of threshold measurement, and specific requirements that apply to specific frequency ranges and types of test signal.

The qualification criterion for subjects requires a comment. Previously, it has been customary to select subjects with normal hearing, specified by a certain maximum hearing threshold level for the frequency range 125 Hz to 8 kHz. This procedure might lead to an over-selection of the subjects, and the procedure becomes especially questionable when considering reference thresholds for ISO 389-1, in which case the selection criteria would use the values under examination. Therefore, the qualification should only relate to subjects being otologically normal. In order to facilitate a subsequent reworking of data, such as an examination of the distribution of data and a possible exclusion of single subjects, all data should be reported on each individual subject. Thus subjects should not be excluded on the basis of an audiogram (but the audiogram should be reported).

Bibliography

- [1] ISO 266, Acoustics Preferred frequencies
- [2] ISO 389-5, Acoustics Reference zero for the calibration of audiometric equipment Part 5: Reference equivalent threshold sound pressure levels for pure tones in the frequency range 8 kHz to 16 kHz

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