BS EN 60645-1:2015

BSI Standards Publication

Electroacoustics — Audiometric equipment

Part 1: Equipment for pure-tone audiometry

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National foreword

This British Standard is the UK implementation of EN 60645-1:2015. It is identical to IEC 60645-1:2012. It supersedes BS EN 60645-1:2001 and BS EN 60645-4:1995, which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EPL/29, Electroacoustics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone audiometry (IEC 60645-1:2012)

Électroacoustique - Appareils audiométriques - Partie 1: Appareils pour l'audiométrie tonale (IEC 60645-1:2012)

Akustik - Audiometer - Teil 1: Reinton-Audiometer (IEC 60645-1:2012)

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Foreword

The text of document 29/754/FDIS, future edition 3 of IEC 60645-1, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60645-1:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2015-08-05
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2017-11-05

This document supersedes EN 60645-1:2001 and EN 60645-4:1995.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This standard covers the Principle Elements of the Safety Objectives for Electrical Equipment Designed for Use within Certain Voltage Limits (LVD - 2006/95/EC).

Endorsement notice

The text of the International Standard IEC 60645-1:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 61260	NOTE	Harmonized as EN 61260.
ISO 389-9	NOTE	Harmonized as EN ISO 389-9.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Publication	Year	Title	EN/HD	Year
IEC 60268-3	-	Sound system equipment - Part 3: Amplifiers	EN 60268-3	-
IEC 60318-1	-	Electroacoustics - Simulators of human head and ear - Part 1: Ear simulator for the measurement of supra-aural and circumaural earphones	EN 60318-1	-
IEC 60318-3	-	Electroacoustics - Simulators of human head and ear - Part 3: Acoustic coupler for the calibration of supra-aural earphones used in audiometry	EN 60318-3	-
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 means of ear inserts	EN 60318-4	-
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	EN 60318-5	-
IEC 60318-6	-	Electroacoustics - Simulators of human head and ear - Part 6: Mechanical coupler for the measurements on bone vibrators	EN 60318-6	-
IEC 60601-1	-	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	-
IEC 60601-1-2	-	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	-
IEC 60645-2	-	Audiometers - Part 2: Equipment for speech audiometry	EN 60645-2	-
IEC 61672-1	-	Electroacoustics - Sound level meters - Part 1: Specifications	EN 61672-1	-

Publication	Year	Title	EN/HD	Year
ISO 266	-	Acoustics - Preferred frequencies	EN ISO 266	-
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	EN ISO 389-1	-
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	EN ISO 389-2	-
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	EN ISO 389-3	-
ISO 389-4	1994	Acoustics - Reference zero for the calibration of audiometric equipment - Part 4: Reference levels for narrow-band masking noise	EN ISO 389-4	1998
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	EN ISO 389-5	-
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	EN ISO 389-7	-
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	EN ISO 389-8	-
ISO 4869-1	-	Acoustics - Hearing protectors - Part 1: Subjective method for the measurement of sound attenuation	EN 24869-1	-
ISO 8253-1	2010	Acoustics - Audiometric test methods - Part 1: Pure-tone air and bone conduction audiometry	EN ISO 8253-1	2010
ISO 8253-2	-	Acoustics - Audiometric test methods - Part 2: Sound field audiometry with pure-tone and narrow-band test signals	EN ISO 8253-2	-
ISO 8253-3	-	Acoustics - Audiometric test methods - Part 3: Speech audiometry	EN ISO 8253-3	-

CONTENTS

INTRODUCTION

Developments in the field of hearing measurements for diagnostic, hearing conservation and rehabilitation purposes have resulted in the availability of a wide range of audiometers. In addition it is possible to consider the audiometer in terms of a set of functional units which can be specified independently. By specifying these functional units it is then possible to specify the performance of other audiometric equipment which use these units. IEC 60645 series consists of a number of parts. IEC 60645-1 is the first in the series and covers the requirements for pure tone audiometers.

This standard describes equipment which is designed for the measurement of hearing in the frequency range from 125 Hz to 16 000 Hz.

Due to the development of the later parts of IEC 60645, no reference is now made in part 1 to the use of broad-band noise for masking. Requirements for broad-band masking noise now only relate to its use with speech signals as described in IEC 60645-2.

The test requirements to demonstrate conformity are now specified separately. Conformance to the specifications in this standard is demonstrated only when the result of a measurement, extended by the actual expanded uncertainty of measurement of the testing laboratory, lies fully within the tolerances specified in this standard. The tolerances that are to be met by the manufacturer of an audiometer are essentially the same as in the first edition of IEC 60645-1, while the tolerances as applicable to the testing of the audiometer are increased by U_{max} compared with those of the previous edition.

IEC 60645 series consists of the following parts:

IEC 60645-1, *Electroacoustics – Audiometric equipment – Part 1: Equipment for pure-tone audiometry*

IEC 60645-2, *Audiometers – Part 2: Equipment for speech audiometry*

IEC 60645-3, *Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration*

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

IEC 60645-5, *Electroacoustics – Audiometric equipment – Part 5: Instruments for the measurement of aural acoustic impedance/admittance*

IEC 60645-6, *Electroacoustics – Audiometric equipment – Part 6: Instruments for the measurement of otoacoustic emissions*

IEC 60645-7, *Electroacoustics – Audiometric equipment – Part 7: Instruments for the measurement of auditory brainstem responses*

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 1: Equipment for pure-tone audiometry

1 Scope

This part of IEC 60645 specifies general requirements for audiometers and particular requirements for pure-tone audiometers designed for use in determining hearing threshold levels, relative to standard reference threshold levels established by means of psychoacoustic test methods.

The object of this standard is to ensure:

a) that tests of hearing in the frequency range 125 Hz to 16 000 Hz on a given human ear, performed with different audiometers which comply with this standard shall give substantially the same results;

b) that the results obtained represent a valid comparison between the hearing of the ear tested and the reference threshold of hearing;

c) that audiometers are classified according to the range of test signals they generate, according to the mode of operation or according to the complexity of the range of auditory functions they test.

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.

IEC 60268-3, *Sound system equipment – Part 3: Amplifiers*

IEC 60318-1, *Electroacoustics – Simulators of human head and ear – Part 1: Ear simulator for the measurement of supra-aural and circumaural earphones*

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 means of ear inserts*

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 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60645-2, *Audiometers – Part 2: Equipment for speech audiometry*

IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

ISO 266, *Acoustics – Preferred frequencies*

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

ISO 389-4:1994, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 4: Reference levels for narrow-band masking noise*

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*

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 4869-1, *Acoustics – Hearing protectors – Part 1: Subjective method for the measurement of sound attenuation*

ISO 8253-1:2010, *Acoustics – Audiometric test methods – Part 1: Pure-tone air and bone conduction audiometry*

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

ISO 8253-3, *Acoustics – Audiometric test methods – Part 3: Speech audiometry*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
equipment for pure-tone audiometry
pure-tone audiometer
instrument for the measurement of hearing for pure tones and in particular the threshold of hearing

Note 1 to entry The pure-tone audiometer may be either of a fixed or continuous sweep frequency type.

3.2
manual audiometer
audiometer in which signal presentations and recording of results are performed manually

3.3
automatic-recording audiometer
audiometer in which signal presentations, hearing level variation, frequency selection or frequency variation, and recording of subject's responses are implemented automatically

Note 1 to entry Hearing level change is under subject's control and is recorded automatically.

3.4
equipment for speech audiometry
speech audiometer
instrument for the measurement of hearing for speech test material

3.5
air conduction
transmission of sound through the external and middle ear to the inner ear

3.6
bone conduction
stimulation of the inner ear mediated primarily by mechanical vibration of the cranial bones

3.7
extended high frequency
EHF
audiometric test frequency in the range from 8 000 Hz to 16 000 Hz

Note 1 to entry The frequency 8 000 Hz is considered both as the highest frequency in the conventional range and as the lowest frequency of the extended high-frequency range.

3.8
otologically normal person
person in a normal state of health who is free from all signs and symptoms of ear disease and from obstructing wax in the ear canal and has no history of undue exposure to noise, to potentially ototoxic drugs, or of familial hearing loss

3.9
equivalent threshold sound pressure level
monaural earphone listening
for a given ear, at a specified frequency, for a specified type of earphone and for a stated force of application of the earphone to a human ear, the sound pressure level set up by the earphone in a specified ear simulator or acoustic coupler when the earphone is activated by that electrical input which, with the earphone applied to the ear concerned, would correspond to the threshold of hearing

3.10
equivalent threshold force level
monaural listening
for a given ear, at a specified frequency, for a specified configuration of bone vibrator on a specified mechanical coupler, the force level set up by the bone vibrator in a specified mechanical coupler when the bone vibrator is activated by that voltage which, with the bone vibrator applied to the mastoid prominence or to the forehead, would correspond to the threshold of hearing

Note 1 to entry This definition requires the non-test ear to be masked in accordance with ISO 389-4.

3.11
reference equivalent threshold sound pressure level
RETSPL
at a specified frequency, the median, mean or modal value of the equivalent threshold sound pressure levels 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 ear simulator or acoustic coupler for a specified earphone

Note 1 to entry Values of RETSPL are specified in ISO 389-1, ISO 389-2, ISO 389-5 and ISO 389-8.

Note 2 to entry Some parts of the ISO 389 series specify reference equivalent threshold levels for the age group 18 years to 30 years inclusive.

3.12
reference equivalent threshold force level
RETFL
at a specified frequency, the mean value of the equivalent threshold force levels 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 Mean values of reference equivalent threshold force levels are specified in ISO 389-3.

Note 2 to entry In some parts of the ISO 389 series an age range of 18 years to 30 years have been used.

3.13
hearing level of a pure tone
HL
at a specified frequency, for a specific type of transducer and for a specified manner of application, the sound pressure level or the vibratory force level set up by the transducer in a specified ear simulator, acoustic coupler or mechanical coupler minus the appropriate RETSPL or RETVFL

3.14
hearing threshold level for pure tones
at a specified frequency, the threshold of hearing at that frequency expressed as hearing level

Note 1 to entry Methods of determining thresholds of hearing are specified in ISO 8253-1:2010.

3.15
ear simulator
device for measuring the acoustic output of sound sources where the sound pressure is measured by a calibrated microphone coupled to the source so that the overall acoustical impedance of the device approximates that of the normal human ear at a given location and in a given frequency band

Note 1 to entry Two types of ear simulator are specified in IEC 60318-1 and IEC 60318-4.

3.16
acoustic coupler
device for measuring the acoustic output of sound sources where the sound pressure is measured by a calibrated microphone coupled to the source by a cavity of predetermined shape and volume which does not necessarily approximate the acoustical impedance of the normal human ear

Note 1 to entry Two types of acoustic coupler are specified in IEC 60318-3 and IEC 60318-5.

3.17
mechanical coupler
device designed to present a specified mechanical impedance to a vibrator applied with a specified static force and equipped with a mechano-electric transducer to enable the

alternating force level at the surface of contact between the vibrator and the mechanical coupler to be determined

Note 1 to entry A mechanical coupler is specified in IEC 60318-6.

3.18
masking
process by which the threshold of hearing of a sound is raised by the presence of another (masking) sound

3.19
effective masking level
level of a specified masking sound which is numerically equal to that hearing level to which the tone threshold of the notional normal person would be raised by the presence of that masking sound

Note 1 to entry The notional normal person is one whose hearing conforms to the standards for threshold and for masking efficiency (ISO 389-1, ISO 389-2, ISO 389-4 and ISO 389-8).

Note 2 to entry Effective masking is thus analogous to hearing level (see 3.14), i.e. it is a measure of sound on a physical scale, independent of a particular ear under test.

Note 3 to entry Reference values for effective masking are given in ISO 389-4.

4 Requirements for specific types of fixed frequency audiometer

Four different types of audiometers are specified by the requirements for minimum mandatory facilities in Table 1. Other facilities are not precluded. The four types relate to their presumed primary application.

Table 1 – Minimum facilities for fixed-frequency audiometers

Facility	Type 1 Advanced clinical/research	Type 2 Clinical	Type 3 Basic diagnostic	Type 4 Screening/ monitoring
Air conduction				
– two earphones	X	X	X	X
– additional insert earphone	X			
Bone conduction	X	X	X	
Hearing levels and test frequencies (see Table 2 and Table 3)				
Narrow-band masking noise	X	X	X	
Input for external signals	X	X		
Tone switching				
– tone presentation	X	X	X	X [a]
– tone interruption	X	X		X [b]
– pulsed tone	X	X		
Routing of masking				
– contralateral earphone	X	X	X	
– ipsilateral earphone	X			
– bone vibrator	X			
Reference tone [c]				
– alternate presentation	X	X		
– simultaneous presentation	X			
Subject's response system	X	X	X	X [b]

Facility	Type 1 Advanced clinical/research	Type 2 Clinical	Type 3 Basic diagnostic	Type 4 Screening/ monitoring
Electrical signal output	X	X		
Signal indicator	X	X		
Audible monitoring of test signal				
– pure tones and noise	X			
– external input	X			
Speech communication				
– operator to subject	X	X		
– subject to operator	X			
NOTE The extended high-frequency range (EHF range) is optional for all four types of audiometers.				
[a] Not mandatory for automatic recording audiometers, except for calibration purposes.				
[b] Not mandatory for manual audiometers.				
[c] The minimum requirement is for presentation of reference tones of the same frequency as the test tones.				

5 General requirements

5.1 General safety requirements

Audiometers shall conform to IEC safety requirements (see IEC 60601-1) except where otherwise specified in this standard.

5.2 Acoustic safety requirements

As audiometers are capable of producing sound pressure levels that could cause hearing damage, a non-auditory warning indication to the operator is required for all settings above 100 dB hearing level.

5.3 Environmental conditions

The specifications shall be met for combinations of temperature within the range of 15°C to 35°C, relative humidity within the range of 30 % to 90 % and ambient pressure within the range of 98 kPa to 104 kPa.

The actual values of the environmental parameters at the time of calibration shall be stated.

NOTE Reference equivalent threshold sound pressure levels may differ significantly with ambient pressures outside the above range. Therefore recalibration around the nominal ambient pressure at the site of the user should be undertaken in those circumstances where the calibration site and the user site do not share similar ambient conditions.

5.4 Warm-up time

The performance requirements shall be met after the stated warm-up time has elapsed and after any setting up adjustments have been carried out in accordance with the manufacturer's instructions. The minimum warm-up time shall be specified by the manufacturer but shall not exceed 10 min when the audiometer has been kept at the ambient temperature of the test environment.

5.5 Power supply variation

5.5.1 Interruption of power supply

If any interruption of the power supply occurs for up to 5 s, the audiometer shall revert to a condition that will neither endanger the subject's hearing, nor yield invalid results.

5.5.2 Mains operation

The specifications shall be met when any long term deviation in mains supply voltage or frequency, in combination, is the least favourable within the limits of ± 10 % of the stated mains supply voltage and ± 5 % of the stated mains frequency.

5.5.3 Battery operation

The manufacturer shall specify the limits of battery voltage within which the specifications shall be met. A suitable indicator shall be provided to ensure that the battery voltage is within the specified limits. The specification of the audiometer shall be met at all battery voltages within the specified limits.

5.5.4 Other power supplies

If the audiometer is powered by means other than by mains or battery, the manufacturer shall state the type of power supply, its characteristics and tolerances within which the specifications of the audiometer shall be met.

5.6 Electromagnetic compatibility

During, and as a result of, any EMC immunity testing, under the EMC test conditions according to IEC 60601-1-2, the unwanted sound from any air conduction transducer shall not exceed a hearing level corresponding to 80 dB. Subclause 13.3 provides methods for showing conformity.

5.7 Unwanted sound

5.7.1 General

Objective acoustical measurements (see 13.4) may be impracticable for testing for the presence of unwanted sound from the audiometer. Therefore, subjective tests shall be performed using at least two otologically normal test subjects whose hearing threshold levels shall not exceed 10 dB for the test frequencies 250 Hz to 8 kHz. The test room for subjective tests shall meet the requirements of Table 4 of ISO 8253-1:2010, (see right hand column of table). For EHF audiometers these tests shall cover frequencies up to the highest frequency available.

NOTE For the frequency range above 8 kHz test rooms according to ISO 8253-1:2010 have shown in practice to provide sufficiently low ambient noise levels.

5.7.2 Unwanted sound from an earphone

Unwanted sound from an earphone may arise from electrical signals generated in a variety of ways within the audiometer when the tone switch is “OFF”. An unwanted tone (commonly called breakthrough or cross talk) may also occur in the non-test earphone when the test tone is “ON”. Specific requirements and an indirect electrical measurement method and a subjective method of verifying performance are described in 13.4.1.

An unwanted tone may also occur in the earphone due to the tone switch not being completely effective. Requirements for the tone switch are described in 8.6.

5.7.3 Unwanted sound from a bone vibrator

The manufacturer shall state at which test frequencies the bone vibrator might radiate sound to such an extent that the sound reaching the test ear by air conduction through the unoccluded ear canal might impair the validity of the bone conduction measurement. The manufacturer shall also state the possible extent of this impairment. A method to show conformity with this requirement is given in 13.4.2.

5.7.4 Unwanted sound radiated by an audiometer

Where audiometers are intended to be used with the subject in the same room, any sound due to the operation of the audiometer controls during the actual listening test, radiation from the audiometer, or radiation from any part of a computer system used in conjunction with the audiometer, shall be inaudible at each hearing level setting up to and including 50 dB. A method to show conformity with this requirement is given in 13.4.3.

NOTE The limitation on noise coming from controls applies to any noise that could furnish the patient with a clue which might influence the test results. It is not intended to apply to a mechanism such as an output selection switch or a detent on the frequency switch that might emit noise when the subject is not actually being tested.

5.8 Testing of automatic-recording audiometers

Automatic-recording audiometers shall be provided with means to adequately control the signals for the purpose of measuring the characteristics of the audiometer.

5.9 Interface connections

No unintentional change of the audiometer's calibration shall be possible via any interface.

6 Test signals

6.1 Pure tones

6.1.1 Frequency range and hearing level range

6.1.1.1 General

Fixed frequency audiometers shall have test frequencies for which the minimum range of hearing level values is indicated in the appropriate column of Table 2 for supra-aural earphones and bone vibrators. For Type 1 audiometers using circumaural or insert earphones, the maximum hearing levels may be 10 dB less than the tabulated values over the frequency range 500 Hz to 8 kHz. Additional frequencies up to 8 kHz may be used where RETSPL values are given in the ISO 389 series.

Table 2 – Minimum number of frequencies to be provided and the minimum range of values of hearing level for fixed frequency audiometers

Hearing levels in dB [a]							
Frequency in Hz	Type 1		Type 2		Type 3		Type 4
	Air	Bone	Air	Bone	Air	Bone	Air
125	70	–	60	–	–	–	–
250	90	45	80	45	70	35	70
500	120	60	110	60	100	50	70
750	120	60	–	–	–	–	–
1 000	120	70	110	70	100	60	70
1 500	120	70	110	70	–	–	–
2 000	120	70	110	70	100	60	70
3 000	120	70	110	70	100	60	70
4 000	120	60	110	60	100	50	70
6 000	110	50	100	–	90	–	70
8 000	100	–	90	–	80	–	–

[a] Maximum hearing level to be at least equal to the tabulated values. Minimum hearing level to be –10 dB or lower.

6.1.1.2 EHF test signals

EHF test signals in the frequency range from 8 000 Hz to 16 000 Hz shall be the one-sixth-octave frequencies as specified in ISO 266. Their frequencies and corresponding hearing level ranges are presented in Table 3. The following EHF test signal frequencies are mandatory: 8 000 Hz, 10 000 Hz, 12 500 Hz and 16 000 Hz.

NOTE Some EHF instruments have the capability of going up to 20 kHz, but at present no standardized reference threshold data are available

Table 3 – Minimum range of values of hearing level for EHF audiometers

Frequency in Hz	Hearing levels in dB [a]
* 8 000	100
9 000	90
* 10 000	90
11 200	80
* 12 500	70
14 000	70
* 16 000	60
a Minimum hearing levels to be -10 dB or lower for all frequencies.	
* Mandatory test signal frequencies.	

6.1.1.3 Test signal level range for earphones

The minimum hearing level shall be -10 dB or lower.

NOTE 1 Due to the large spread of hearing threshold levels in normal hearing subjects at the highest frequencies a minimum hearing level of -10 dB is not sufficient to reach threshold in many subjects. Consequently, a minimum hearing level of less than -10 dB is recommended.

NOTE 2 No requirement is given for the range of output for loudspeakers and bone vibrators.

For sweep frequency audiometers, the range of frequencies and hearing levels shall be at least equal to those given in Table 2 for fixed frequency audiometers.

6.1.2 Frequency accuracy

For fixed frequency audiometers, the frequencies shall be equal to the stated values within the following tolerances:

Type 1 and 2: ± 1,5 %

Type 3 and 4: ± 2,5 %

For continuous sweep frequency audiometers, the frequency of the test tone shall agree with the value indicated on the audiogram within ± 5,5 %.

6.1.3 Total harmonic distortion

The maximum total harmonic distortion shall not exceed the values given in Table 4.

Table 4 – Maximum permissible acoustic total harmonic distortion, for supra-aural, circumaural, insert earphones and bone vibrators

	Air conduction			Bone conduction		
Frequency range in Hz	125 to 200	250 to 400	500 to 8 000	250 to 400	500 to 800	1 000 to 4 000
Hearing level[a] in dB	75	90	110	20	50	60
Total harmonic distortion in %	3	3	3	6	6	6

[a] Or maximum output level of the audiometer, whichever is lower. For circumaural and insert earphones the hearing level shall be 10 dB less than the levels specified in the table.

6.1.4 Rate of frequency change

Where automatic recording facilities include a continuous sweep frequency, at least one of the rate of frequency changes available shall be one octave per minute ± 25 %. If an automatic recording audiometer provides fixed frequencies, a minimum period of 30 s shall be allowed at each frequency.

6.2 Frequency modulation

If frequency modulated tones are provided they shall have the following characteristics:

a) Carrier frequency.

   The carrier frequency shall be chosen from the audiometric test frequencies specified in Table 2 with a tolerance of ± 3,5 % of the stated value.

b) Waveform of modulating signal.

   The waveform of the modulating signal shall be either sinusoidal or triangular with symmetrical rising and falling portions on a linear or on a logarithmic frequency scale.

   If the modulating waveform is sinusoidal, its total harmonic distortion shall not exceed 5 %. If it is triangular, its ramps shall not deviate from a linear form by more than 5 % of its amplitude. For a triangular waveform, the duration of the rising and falling portions shall not differ by more than 10 %.

c) Repetition rate of modulating signal.

   The repetition rate of the modulating signal shall be within the range of 4 Hz to 20 Hz with a tolerance of ± 15 % of its stated value.

d) Frequency deviation.

   The frequency deviation shall be in the range from ± 2,5 % to ± 12,5 % of the carrier frequency with a tolerance of ± 15 % of its stated value.

The manufacturer shall state the characteristics and tolerances of the signals provided.

6.3 External signal source

6.3.1 Signals

Audiometers may involve the use of speech signals or other complex signals in addition to, or instead of pure tones. IEC 60645-2 specifies equipment for speech audiometry and ISO 8253-3 specifies techniques for speech audiometry. This standard does not specify the parameters required for speech audiometry or for the use of complex signals.

6.3.2 Frequency response

For a constant voltage applied to the external input socket, the output sound pressure level generated by the earphone, as measured in the same ear simulator as used for the calibration

of the audiometer, shall not differ by more than ± 4 dB from the average sound pressure level of all test signals in the frequency range 250 Hz to 4 kHz. For any signal in the range below 250 Hz the tolerance is $^{+4}_{-11}$ dB and above 4 kHz the tolerance is $^{+4}_{-6}$ dB.

For the bone vibrator output, the manufacturer shall specify the frequency response and tolerances in the frequency range from 250 Hz to 4 kHz.

6.3.3 Electrical sensitivity

The manufacturer shall specify the electrical sensitivity of the external input in terms of the voltage of a stated input signal required for a stated output sound pressure level, when the signal indicator is at its reference position.

6.3.4 Reference level for external signal source

The external signal shall be capable of being monitored by a signal indicator (see 8.2). The reference level shall be stated when the signal indicator is at its reference position.

6.3.5 Operator to subject speech communication

A facility shall allow speech communication from the operator to the test subject under normal testing conditions. The level of the speech signal should be controlled to prevent any effect on the reliability of the test results.

6.3.6 Subject to operator speech communication

A facility shall allow speech communication from the test subject to the operator under normal test conditions.

6.4 Masking sound

6.4.1 General

For audiometers which provide masking sound, all measurements of the masking sound shall be made in the same ear simulator or mechanical coupler as is used in the pure-tone measurements.

As this standard only specifies requirements for pure tones, it is considered that the appropriate masking noise is narrow-band noise. IEC 60645-2 specifies masking noise for speech signals when this facility is incorporated in a pure-tone audiometer.

6.4.2 Narrow-band noise

Where narrow-band masking is required, the noise band shall be centred geometrically around the test frequencies. The band limits for the masking noise are given in Table 5. Outside these band limits the sound pressure spectrum density level of the noise shall fall at a rate of at least 12 dB per octave for at least three octaves and shall be at least 35 dB below the level at the centre frequency. Measurements are required in the range from 31,5 Hz to 10 kHz for instruments limited to 8 kHz. For EHF instruments measurements are required up to 20 kHz.

Due to limitations of transducers, ear simulators and mechanical couplers, measurements of the bandwidth at 4 kHz and above may not accurately describe the spectrum of the masking noise. Therefore at centre frequencies above 3,15 kHz measurements shall be made electrically across the transducer terminals.

Table 5 – Narrow-band masking noise: upper and lower cut-off frequencies for a sound pressure spectrum density level of –3 dB referred to the level at the centre frequency of the band

Centre frequency in Hz	Lower cut-off frequency in Hz		Upper cut-off frequency in Hz	
	Minimum	Maximum	Minimum	Maximum
125	105	111	140	149
160	136	143	180	190
200	168	178	224	238
250	210	223	281	297
315	265	281	354	375
400	336	356	449	476
500	420	445	561	595
630	530	561	707	749
750	631	668	842	892
800	673	713	898	951
1 000	841	891	1 120	1 190
1 250	1 050	1 110	1 400	1 490
1 500	1 260	1 340	1 680	1 780
1 600	1 350	1 430	1 800	1 900
2 000	1 680	1 780	2 240	2 380
2 500	2 100	2 230	2 810	2 970
3 000	2 520	2 670	3 370	3 570
3 150	2 650	2 810	3 540	3 750
4 000	3 360	3 560	4 490	4 760
5 000	4 200	4 450	5 610	5 950
6 000	5 050	5 350	6 730	7 140
6 300	5 300	5 610	7 070	7 490
8 000	6 730	7 130	8 980	9 510
9 000	7 570	8 020	10 100	10 700
10 000	8 410	8 910	11 220	11 890
11 200	9 420	9 980	12 570	13 320
12 500	10 510	11 140	14 030	14 870
14 000	11 770	12 470	15 710	16 650
16 000	13 450	14 250	17 960	19 030

NOTE 1 The bands of noise correspond to one-third octaves as a minimum and one-half octaves as a maximum. At centre frequencies of 400 Hz and above these bands are wider than the critical bands for the same effective masking and thus require an overall sound pressure level greater than critical bands for effective masking by approximately 3 dB (see ISO 389-4). The use of wider bands has the advantage of minimising perceived tonality of masking noise.

NOTE 2 The minimum and maximum lower and upper cut-off frequencies, f_l(min.), f_l(max.), f_u(min.) and f_u(max.), are given by the following formulae (see IEC 61260):

$f_l(\text{min.}) = f_m/2^{1/4}$ $\quad$ $f_l(\text{max.}) = f_m/2^{1/6}$

$f_u(\text{min.}) = f_m \times 2^{1/6}$ $\quad$ $f_u(\text{max.}) = f_m \times 2^{1/4}$

where f_m is the centre frequency.

NOTE 3 The given values are rounded to the first three significant digits.

6.4.3 Other masking sound

If other types of masking sound are provided the manufacturer shall specify the frequency spectrum and use.

7 Transducers

7.1 Type of transducers

The types of transducers used in pure-tone audiometry consist of different types of earphone (supra-aural, circumaural and insert), bone vibrators and loudspeakers.

7.2 Headband

A headband shall be provided to hold supra-aural or circumaural earphones or bone vibrators with a nominal static force as specified in the ISO 389 series for that model of transducer. Alternatively, if a transducer requires a different static force to be used, this shall be stated by the manufacturer, and an appropriate headband shall be provided.

7.3 Loudspeaker

Where a loudspeaker is provided for sound-field audiometry the environment in which such audiometry may be undertaken may vary considerably from free-field conditions. ISO 8253-2 describes the characteristics of free-field, diffuse-field and quasi-free-field conditions as well as the procedures and conditions of use for sound-field audiometry. Manufacturers shall describe the test conditions that apply for the measurement of the stated performance of loudspeaker outputs.

8 Signal level control

8.1 Marking

The signal level control shall be identified by the designation “Hearing Level” (HL) or an equivalent national designation.

The zero marking on the hearing level control shall correspond to an output from the transducers which relates to the reference equivalent threshold values given in the relevant parts of ISO 389.

8.2 Signal indicator

If a signal indicator is provided (see Table 1), to allow the level of the external input signal to be monitored for correct operation, the manufacturer shall specify a reading of the signal indicator that is considered to be a reference point for a stated signal. The indicator may also serve to monitor internally generated signals.

The manufacturer shall state the characteristics of the signal indicator, i.e. time weighting, dynamic range and rectifier characteristics. If the indicator is intended to be used with speech signals, the indicator shall meet the requirements of IEC 60645-2.

The indicator shall be connected at a point in the circuit before the hearing level control. Provision shall be made in the amplifier for adjustments of its gain to accommodate a range of 20 dB in the overall level of the signal presented.

The manufacturer shall state the output level as measured on the ear simulator with the hearing level control set at stated value and the input activated by a specified signal of stated level which brings the monitor indicator to its reference indication.

8.3 Accuracy of sound pressure level and vibratory force level

When one signal channel is connected to the earphone, the sound pressure level produced minus the reference equivalent threshold level, shall not differ by more than ± 3,7 dB from the indicated value at any setting of the hearing level dial at indicated frequencies in the range 125 Hz to 4 kHz and by not more than ± 6,2 dB at frequencies up to and including 8 kHz. At higher frequencies this difference shall be within ± 6,5 dB.

Similarly the force level produced by the bone vibrator minus the reference equivalent threshold force level shall not differ by more than ± 5,5 dB in the frequency range 250 Hz to 4 kHz and by ± 7,0 dB at higher frequencies.

If more than one channel for signal and/or noise is connected simultaneously to a single transducer, the output level of either signal (or noise) from the transducer shall not differ by more than ± 1,7 dB from the level obtained when one channel is connected. This requirement shall be met at frequencies from 125 Hz to 4 kHz. At frequencies from 5 kHz to 8 kHz a tolerance of ± 3,2 dB is required, and at frequencies above 8 kHz and up to 16 kHz a tolerance of ± 3,5 dB is required. This shall apply to hearing levels up to 20 dB below the maximum output level.

Sweep frequency audiometers shall meet the requirements above at all appropriate one-third-octave frequencies; the output level shall vary smoothly between these frequencies.

8.4 Hearing level control

8.4.1 Manual audiometers

A hearing level control shall have only one scale and one reference zero point which is common for all frequencies. Indicator readings of hearing level shall be marked in intervals of 5 dB or less, with the 0 dB setting at each frequency corresponding to the reference equivalent threshold level.

8.4.2 Automatic-recording audiometers

For all automatic-recording audiometers a rate of change of 2,5 dB/s shall be provided. If additional rates are provided they shall be at 1,25 dB/s and/or 5 dB/s. The tolerance shall be ± 25 %.

The smallest increment of the hearing level control shall be stated by the manufacturer.

8.4.3 Accuracy of control

The difference (in decibels) between the measured difference and the indicated difference between two successive hearing level settings shall be less than or equal to the smaller of:

- three-tenths of the indicated difference in decibels

or

- 1,5 dB for settings of -10 dB HL to 0 dB HL
- 1,4 dB for settings of 0 dB HL to 45 dB HL
- 1,2 dB for settings of 45 dB HL or greater

(see also 8.3).

8.5 Masking level control

8.5.1 General

The masking level control shall have only one reference zero point that is common for all frequencies. The masking level shall be adjustable in steps of 5 dB or less.

8.5.2 Masking level

a) For narrow-band noise the masking level control shall be calibrated in decibels of effective masking according to ISO 389-4. If the exact bandwidth of the masking noise is not known, within the limits specified in Table 1 of ISO 389-4:1994, the mean values of columns 1 and 2 shall be used;
b) For other types of sound the masking level control shall be calibrated in sound pressure level as measured with the earphone on the same ear simulator as that used for the calibration of pure tones. The manufacturer shall specify the overall sound pressure level and the sound pressure level in one-third-octave bands over the stated frequency range of the masking noise.

For EHF instruments the masking level may be derived from Table 1 in ISO 389-4:1994 presenting data for one-third-octave bandwidth. An approximation would be to increase the reference equivalent threshold sound pressure levels by 5 dB.

8.5.3 Accuracy of masking levels

The level of the masking sound produced by an earphone shall not differ from the indicated value by more than $^{+6}_{-4}$ dB.

The measured difference in output between any two indications of masking level shall meet the requirements of 8.4.3 for pure tones.

NOTE Due to the time-varying nature of the narrow-band masking signal it may be more convenient to route a pure-tone test signal through the masking attenuator (where this facility exists) for measurement purposes.

8.5.4 Masking level range

The masking sound shall be available at levels at least sufficient to mask pure tones, in the same ear, at a hearing level of 60 dB at 250 Hz, 75 dB at 500 Hz and 80 dB from 1 kHz to 4 kHz. The level of the masking sound shall be adjustable over a range from 0 dB hearing level to these levels.

8.6 Tone switching

8.6.1 Tone switch for manual audiometers

Manual audiometers shall be provided with a tone switch for the presentation or the interruption of the test tone. The switch and its associated circuitry shall be such that the subject will respond to the test tone rather than to the mechanical noise (see 5.7.4) or to signal switching transients.

NOTE An audiometer may be equipped with an automatic gating function for controlling the duration and/or repetition rate of a tone pulse.

8.6.2 On/off ratio for manual audiometers

With the switch in the “OFF” position and the hearing level control at 60 dB or below, the output shall be at least 10 dB below the reference equivalent threshold level. At higher

hearing level settings and with the switch still in the “OFF” position, the output shall not rise by more than 10 dB for each 10 dB increase in the hearing level setting above 60 dB.

8.6.3 Rise/fall times for manual audiometers

When the tone switch is moved to the "ON" position the rise time requirements shall be as follows (see Figure 1):

– AC rise time shall not exceed 200 ms;
– BC rise time shall be at least 20 ms;
– between B and C the sound pressure level shall rise in a progressive manner without discontinuities.

When the tone switch is moved to the "OFF" position, the fall time requirements shall be as follows (see Figure 1):

– DH fall time shall not exceed 200 ms;
– EG fall time shall be at least 20 ms;
– between E and G the sound pressure level shall fall in a progressive manner without discontinuities.

At no time during the rise or decay of the tone shall the sound pressure level produced by the earphone attain a value exceeding 1 dB relative to its steady state level in the “ON” position.

NOTE The measurement of AC and DH may require special consideration due to the uncertainty involved.

8.6.4 Automatic pulsed presentation

Where automatic pulsed presentation is made available, the pulse sequence generated shall meet the following requirements (see Figure 1):

– rise time: BC shall be at least 20 ms and shall not exceed 50 ms;
– fall time: EG shall be at least 20 ms and shall not exceed 50 ms;
– rise/fall rates: between B and C and between E and G the sound pressure level shall vary smoothly and without discontinuities;
– "ON" phase: CE shall be at least 150 ms;
– "ON"/"OFF" times: FJ and JK shall each have values of (225 ± 40) ms;
– “ON”/”OFF” ratio: between G and I the output shall remain at least 20 dB below the maximum reached in the “ON” phase CE.

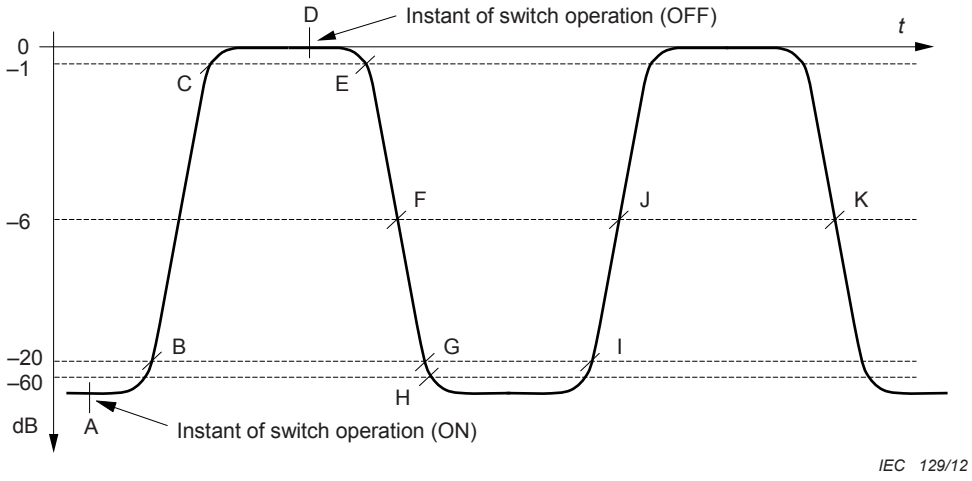

Figure 1 – Rise/fall envelope of test tones

8.6.5 Subject's response time for automated test procedures

The time available for a subject to respond to a test stimulus shall be specified by the manufacturer who shall state the algorithm for the test procedure.

8.6.6 Subject's response system

The subject's response system is a means by which the tester is made aware that the subject has responded to the signal.

Normally the response system is in the form of a hand-held switch which operates a visual indicator on the audiometer. In the case of automatic-recording audiometers, the subject's switch controls an appropriate function in the audiometer, normally the level of the test signal. In this case the switch shall be constructed in such a manner as to enable easy and reliable operation by one hand without generating any sound that might result in a hearing threshold level measurement error.

9 Reference tone

9.1 General

The requirements of Clause 9 apply where means are provided for the alternate or simultaneous presentation of a reference tone and a test tone of the same or different frequency.

The operator shall be able to present the tones conveniently for suitable durations and intervals. In addition to the main hearing level control by which the sound pressure level of the test tone is adjusted, this test mode requires an additional hearing level control by which the level of the reference tone can be set. This latter control is in the following, denoted as the reference tone level control. The requirements with respect to frequency accuracy, distortion, stability, rise and fall of the reference tone are as specified in other relevant clauses of this standard.

9.2 Frequencies

As a minimum, the one-octave frequencies provided in the range 250 Hz to 4 kHz and additionally 6 kHz shall be available as reference tones for air conduction tests.

9.3 Reference tone level control

9.3.1 Range

The reference tone level control shall cover a range from 0 dB hearing level to at least 80 dB hearing level at 250 Hz and to at least 100 dB hearing level at frequencies from 500 Hz to 6 kHz.

9.3.2 Intervals

Either the test tone level or the reference tone level shall be adjustable in intervals of 2,5 dB or less.

The control normally intended for the masking level may be used as the reference tone level control providing the requirements of 9.3.3 to 9.3.5 are met.

9.3.3 Marking

The reference tone level control shall be marked as hearing levels expressed in decibels, see 8.4.

9.3.4 Accuracy

The performance of the reference tone level control shall conform to the requirements of 8.3 and 8.4. Also, for the same hearing level settings and for the same frequency, the sound pressure level of the reference tone shall be within ± 3,7 dB of the test tone level for frequencies up to 4 kHz. For frequencies up to 8 kHz the deviation shall be within ± 6,2 dB, and for frequencies up to 16 kHz (where available) the deviation shall be within ± 6,5 dB.

9.3.5 Operation

Operation of the reference tone level control shall not influence the output of the test tone by more than ± 1 dB.

10 Calibration

References are provided in this clause for the calibration of audiometers using supra-aural earphones, circumaural earphones, insert earphones, bone vibrators and loudspeakers, see ISO 8253-1.

The actual values of the environmental parameters at the time of calibration shall be stated.

Table 6 gives the type of transducer and the appropriate standard reference threshold values and the ear simulator or measurement method to be used to undertake the calibration. The static force obtained with the transducer headband shall also be stated.

For transducers not listed in the ISO 389 series the manufacturer shall state the reference levels, their origins and basis, together with the procedures and equipment to be used for calibration.

If an earphone, whose reference threshold values are given for an ear simulator, is calibrated on an acoustic coupler, validated correction values for the specific type of earphone shall be applied.

NOTE Supra-aural earphones are often used in combination with sound-excluding ear cups. In this case the RETSPL values for supra-aural earphones may no longer be valid.

Table 6 – Reference standards for obtaining audiometric zero

Type of transducer	Reference threshold values	Ear simulator or measurement method
Supra-aural earphone	ISO 389-1	IEC 60318-1 IEC 60318-3
Insert earphone	ISO 389-2, ISO 389-5	IEC 60318-4 IEC 60318-5
Circumaural earphone	ISO 389-5, ISO 389-8	IEC 60318-1
Bone vibrator	ISO 389-3	IEC 60318-6
Loudspeaker	ISO 389-7	ISO 8253-2

11 Electrical output of test signals

An electrical output may be used to provide signals for external equipment such as a power amplifier and loudspeaker for sound field measurements.

The electrical output shall be capable of providing signals from all signal sources available to the audiometer's transducers.

NOTE The manufacturer should state the output characteristics, including the impedance, the frequency response and the voltage available in a specified load under stated conditions.

12 Audiogram format

Where audiometers display or print out hearing threshold levels, they may be presented in tabular form or graphically as an audiogram. For audiograms, one octave on the frequency axis shall correspond to 20 dB on the hearing level axis. Where a graphical presentation of hearing threshold is required, the symbols given in Table 7 should be used. Continuous straight lines should be used to connect the adjacent points for air conduction. Broken lines may be used for bone conduction.

Table 7 – Symbols for the graphical presentation of hearing threshold levels

Test type	Right	Left
Air conduction – unmasked		
Example of no response symbols Air conduction – unmasked		
Air conduction – masked		
Bone conduction – unmasked, mastoid		
Bone conduction – masked, mastoid		
Bone conduction – masked, forehead		
Bone conduction – unmasked, forehead		

If colour is used, red shall be used for the right ear and blue for the left ear symbol and connecting lines.

For measurements limited to the EHF range, the scales shall be such that 1/6 of an octave along the frequency axis corresponds to 10 dB along the hearing level axis.

When presenting the test results graphically in an audiogram covering the range from 125 Hz to 16 000 Hz the format specified in ISO 8253-1:2010, Clause 10 shall be used.

13 Test requirements to demonstrate conformity

13.1 General

Conformance to the requirements of this standard is demonstrated only when the result of a measurement, extended by the actual expanded uncertainty of measurement of the testing laboratory, lies fully within the tolerances specified in this standard. When measurements are not appropriate, conformance shall be demonstrated by other means, for example visual inspection (e.g. 5.2) or examination of supporting documentation (e.g. 5.9).

13.2 Environmental conditions and power supply variation

Conformity with the specifications in 5.3 shall be demonstrated with one sample of each different type of earphone delivered with the audiometer, by measuring frequency, distortion and sound pressure level at 1 kHz indicated frequency, at a hearing level of 100 dB or at the maximum hearing level setting, whichever is lower. Distortion measurements shall be as indicated in 6.1.3.

Environmental tests according to 5.3 shall be performed at the following three combinations of temperature and relative humidity, the ambient pressure being within the range specified in 5.3:

– temperature 15 (± 0,5) °C, relative humidity 30 (± 5) %;

– temperature 23 (± 0,5) °C, relative humidity 50 (± 5) %;

– temperature 35 (± 0,5) °C, relative humidity 90 (± 5) %;

– and one additional combination from within the range specified in 5.3.

For one of the above temperature/relative humidity conditions, the test shall additionally be performed at both 98 kPa (± 1 kPa) and 104 kPa (± 1 kPa), unless objective evidence is available to confirm that ambient pressure has no significant effect.

Conformity with each of the specifications in 5.4 and 5.5 shall be demonstrated with one sample of the type of earphone delivered with the audiometer which can deliver the highest sound pressure level. Conformance shall be demonstrated by measuring frequency, distortion and sound pressure level at 1 kHz indicated frequency, at a hearing level of 100 dB or at the maximum hearing level setting, whichever is lower. Distortion measurements shall be as indicated in 6.1.3.

13.3 Electromagnetic compatibility

a) During the EMC tests, the audiometer shall be equipped with all the accessories and units specified by the manufacturer.

b) The following positions of the audiometer regarding the radiating antenna shall be tested: 0, 90, 180 and 270 degrees.

c) The ambient acoustic noise in the EMC testing space shall be below 55 dB when measured with a one-third-octave filter at 1 kHz.

d) The hearing level control of the audiometer shall be set to its minimum value, the frequency control to 1 kHz and the tone switch to "ON" for the air conduction transducer designated as being the right-hand earphone (if applicable).

e) The EMC tests shall be performed over the frequency range 80 MHz to 2,5 GHz in steps of 1 %. Dwell time for each frequency shall be appropriate to the instrument under test. Testing at a limited number of frequencies does not negate the need to meet the requirements of 5.6.

13.4 Unwanted sound

13.4.1 Unwanted sound from an earphone

Since unwanted sound may result in very low acoustic levels that are difficult to measure, the unwanted sound may be determined indirectly by equivalent electrical measurements. One method is to measure the r.m.s. voltage generated across an appropriate dummy load used in place of the test earphone, using a sound level meter with time weighted F (see IEC 61672-1). A resistance of the same nominal impedance as the earphone, at each test frequency is suitable for this purpose.

a) At a hearing level control setting of 60 dB and with the tone “OFF”, the electrical signal at each frequency within the range 125 Hz to 8 kHz shall be at least 10 dB below the equivalent electrical signal corresponding to the reference equivalent threshold level for the centre-frequency of the one-third-octave band.

b) With the tone "ON", the unwanted signal in the non-test earphone or a substitute dummy load shall be at least 70 dB below the test tone measured with the hearing level control set to 70 dB or greater.

For subjective measurements of unwanted sound from the non-stimulus earphone, no test subject shall detect any sound in the non-stimulus earphone for the frequency range 250 Hz to 6 kHz at any setting of the masking or hearing level controls up to a setting of 70 dB. For frequencies outside this range but within the range 125 Hz to 8 kHz, no test subject shall detect any sound other than the test sound up to a setting of 50 dB. The test shall be conducted in both the “ON” and the “OFF” position of the tone switch.

For higher settings, an external electrical attenuator shall be inserted in the stimulus earphone connection. Tests for compliance at the higher settings shall be made with the external attenuator set to a value equal to the number of decibels above the audiometer hearing level settings minus 70 dB or 50 dB respectively. The opposite earphone shall be disconnected and the audiometer output terminals connected to an appropriate dummy load during the test.

In the EHF range no test subject shall detect any unwanted sound from the transducer coinciding with the presentation of the test tone, even at maximum setting of the hearing level control.

NOTE Many test subjects with almost no hearing ability at 14 kHz and 16 kHz have very good hearing at lower frequencies. This fact is not taken into consideration in 5.7 of this standard.

13.4.2 Unwanted sound from a bone vibrator

The influence on an audiometric test result of sound radiation from the bone vibrator is characterised as follows:

a) first the bone conduction threshold is determined at 2 kHz and above at each frequency provided by the audiometer, in accordance with ISO 8253-1:2010, with the test ear occluded with an earplug which provides a mean attenuation of at least 20 dB at the test frequencies, as measured in accordance with ISO 4869-1;

b) step a) is repeated with the earplug removed;

c) at each frequency, the mean values of the hearing thresholds in a) and b) are calculated.

The influence is regarded as negligible if the mean hearing threshold levels of 16 ears meeting the requirements of 5.7.1 fulfil the requirements that the difference between each pair of mean values shall not exceed 3 dB.

NOTE The maximum permissible total harmonic distortion given in Table 4 may lead to false bone conduction thresholds due to the perception of harmonics of lower test frequencies.

13.4.3 Unwanted sound radiated by an audiometer

The test for the requirements in 5.7.4 shall be made on at least two test subjects meeting the requirements of 5.7.1, wearing a pair of disconnected earphones and located at a distance of 1 m from the audiometer. The electrical output of the audiometer shall be absorbed in a resistive load equal to the impedance of the earphone at 1 kHz; where a bone conduction facility is available, the test shall be repeated with unoccluded ears.

13.5 Total harmonic distortion of test signals

Conformity with the specification in 6.1.3 shall be determined at the hearing levels listed in Table 2 or at the maximum hearing level setting on the audiometer, whichever is the lower, according to the procedure specified in IEC 60268-3, except that measurement of harmonics above 16 kHz is not required.

a) For air conduction, distortion shall be measured acoustically on an ear simulator of the type which is used for the specification of equivalent reference threshold levels.
b) For bone conduction, distortion shall be measured on a mechanical coupler.

Since it is not possible to specify maximum permissible harmonic distortion adequately to ensure that accurate bone conduction results are obtained for all types of hearing losses, the manufacturer shall state at which frequencies and at which hearing levels non-linearity of the bone vibrator provided might impair the validity of bone conduction measurements.

NOTE Due to the limitations of ear simulators and mechanical couplers, measurements of harmonics may not accurately describe the non-linear properties of the system.

13.6 Signal accuracy

13.6.1 Accuracy of sound pressure level and vibratory force level

Conformity with the specifications in 8.3 shall be demonstrated on each individual earphone by measuring the output at a hearing level setting of 70 dB or the maximum, whichever is lower, at all available frequencies on a stated ear simulator. For bone vibrators the hearing level setting shall be 30 dB or the maximum, whichever is lower, and measured on a mechanical coupler as described in IEC 60318-6.

13.6.2 Accuracy of hearing level control

The accuracy of the hearing level control shall at least be tested at 1 kHz. If an EHF option is provided an additional test shall be performed at 8 kHz. Whenever possible, measurements for conformity with the requirements in 8.4.3 should be made acoustically. If electrical measurements are made they should be at the input to the transducer attached to an ear simulator. Alternatively, the transducer may be replaced by a dummy electrical load which simulates the transducer at the test frequency.

13.7 Masking sound

13.7.1 Narrow-band noise

Conformity with 6.4.2 shall be demonstrated up to 3,15 kHz by measuring the spectrum of the masking noise acoustically using the same ear simulator as used for the measurement of pure tones. Above 3,15 kHz the measurement shall be made electrically across the terminals of the transducer when placed on the same ear simulator.

13.7.2 Masking level

Conformity with the specification in 8.5.3 shall be demonstrated using a sound level meter that conforms to the class 1 requirements of IEC 61672-1, by measuring the S time-weighted, Z frequency-weighted sound level at a hearing level setting of 70 dB at all available frequencies and with the same ear simulator as used for the measurement of pure tones.

13.8 Headbands

13.8.1 General

The requirements in 7.2 are deemed to be met if the headband static force complies with the specifications of the ISO 389 series (or the manufacturer's specification) for that model of transducer, where the stated tolerances are increased by the maximum permitted measurement uncertainties given in Table 8.

13.8.2 Supra-aural and circumaural earphone headband

For demonstrating conformity, the earphones shall be horizontally separated by 145 mm and the height of the headband shall be adjusted at the same time to produce a vertical distance of 129 mm as measured between the centre (top) of the headband and a line between the centres of the earphones. The tolerance for the dimensions is ± 5 mm.

13.8.3 Bone vibrator headband

For demonstrating conformity, the spacing of the bone vibrator and the opposite end of the headband shall meet the requirements of 13.8.2, except for forehead placement where the spacing shall be 190 mm with a tolerance of ± 5 mm.

14 Maximum permitted expanded uncertainty of measurements U_{max}

The following table specifies the maximum permitted expanded uncertainty for a coverage factor of $k = 2$, associated with the measurements undertaken in this standard. One set of values for U_{max} is given for basic type approval measurements and periodic verification.

The expanded uncertainties of measurement given in Table 8 are the maximum permitted for demonstration of conformance to the requirements of this standard. If the actual expanded uncertainty of a measurement performed by the test laboratory or maintenance service exceeds the maximum permitted value in Table 8, the measurement shall not be used to demonstrate conformance to the requirements of this standard.

Table 8 – Values of U_{max} for basic measurements

Measured quantity	Relevant subclause number	Basic U_{max}
Sound pressure level 125 Hz to 4 000 Hz	8.3, 9.3.4	0,7 dB
Sound pressure level 5 000 Hz to 8 000 Hz	8.3, 9.3.4	1,2 dB
Sound pressure level 9 000 Hz to 16 000 Hz	8.3, 9.3.4	1,5 dB
Frequency	6.1.2, 6.2 a)	0,5 %
Total harmonic distortion	6.1.3	0,5 %
Temperature	5.3, 13.2	0,5 °C
Relative humidity	5.3, 13.2	5 %
Ambient pressure	5.3, 13.2	0,1 kPa
Rate of frequency change	6.1.4	5 %
Narrow-band masking noise cut-off frequencies	6.4.2	1 %
Repetition rate	6.2	5 %
Frequency deviation	6.2	5 %
Frequency response	6.3.2	1,0 dB
Masking cut off frequency	6.4.2	1 %
Masking –36 dB level	6.4.2	1,0 dB
Masking level 125 Hz to 4 000 Hz	8.5.3	1,0 dB
Force level 250 Hz to 4 000 Hz	8.3	1,5 dB
Force level greater than 4 000 Hz	8.3	2,0 dB
Rate of change in level (%)	8.4.2	5 %
Linearity of hearing level control -10 to 0 dB HL	8.4.3	0,5 dB
Linearity of hearing level control 5 dB to 40 dB HL	8.4.3	0,4 dB
Linearity of hearing level control above 40 dB HL	8.4.3	0,2 dB
Rise and fall time	8.6.3, 8.6.4	5 ms
Headband force	7.2	0,3 N

15 Marking and instruction manual

15.1 Marking

The audiometer shall be marked with the name of the manufacturer, the model, the type (see Table 1) and the serial number. An individual instrument identification shall also be marked on the test signal transducers.

The left and right earphones shall be readily identifiable. If the earphones are colour coded the left earphone shall be coded blue and the right earphone red.

15.2 Instruction manual

An instruction manual shall be supplied with the audiometer and shall include at least the information listed below:

a) the type (see Table 1) for which the instrument complies with this standard and a description of the facilities provided and full operating instructions;

b) permissible power supply variations and environmental conditions to ensure conformity with 5.3 and 5.5;

c) description of the correct manner of installing the audiometer for normal use in order to minimise the effect of unwanted sound radiation (see 5.7);

d) identification of the transducers and their reference equivalent threshold levels. The origins of reference levels other than ISO shall be stated together with the ear simulator used for calibration. The static force provided shall be stated. It shall be stated whether the calibration of the bone vibrator refers to mastoid or forehead placement;

e) frequency response characteristics and masking effect of the masking sound provided (see 6.4 and 8.5). The manufacturer shall state the actual bandwidth of the narrow-band masking noise;

f) warm-up time (see 5.4);

g) sensitivities and nominal impedances of all input facilities; available voltage and nominal impedance of all output facilities; pin assignment of all external plug connections;

h) mode of operation and rate of change of sound pressure level of automatic-recording audiometers. For audiometers with continuously variable frequency, the rate of change of frequency shall be given;

i) where frequency modulated signals are provided the manufacturer shall state the following characteristics and tolerances that apply:

   – the frequency of the modulating signal;

   – the modulation waveform, i.e. sine wave or triangular;

   – the modulation range expressed as a percentage of the test frequency;

j) sound attenuation characteristics of the earphones as measured in accordance with ISO 4869-1;

k) maximum hearing level settings provided at each test frequency including limitations in use due to harmonic distortion;

l) effects of airborne sound radiation of the bone vibrator and means to obtain the correct test results;

m) information about the time window for subject’s response for automated test procedures according to 8.6.5;

n) for battery operated instruments: type of battery, means of checking the battery and method of replacement, expected battery life time;

o) maintenance and calibration procedures and schedules. ISO 8253-1:2010 gives appropriate information;

p) EMC warning: a warning shall be given as to the likely effects of radiated electromagnetic fields, particularly from high powered medical devices on the performance of the audiometer.

Bibliography

IEC 61260, *Electroacoustics – Octave-band and fractional-octave-band filters*

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

ISO 389-9, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 9: Preferred test conditions for the determination of reference hearing threshold levels*

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