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REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

Electroacoustics – Audiometric equipment –
Part 1: Equipment for pure-tone and speech audiometry

IEC 60645-1:2017-03 RLV(en)

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ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 1: Equipment for pure-tone and speech audiometry

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

International Standard IEC 60645-1 has been prepared by IEC technical committee 29: Electroacoustics.

This fourth edition cancels and replaces the third edition, published in 2012, and the first edition IEC 60645-2, published in 1993. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

This edition now includes the requirements for both pure-tone (prior edition of IEC 60645-1) and speech audiometers (prior edition of IEC 60645-2) into a single document. The technical requirements in this edition remain similar to the intent of the prior two documents, but now eliminate technical and editorial contradictions caused by two separate standards with different review cycles applying to an audiometer.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
29/927/FDIS	29/941/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts in the IEC 60645 series, published under the general title *Electroacoustics – Audiometric equipment*, can be found on the IEC website.

Future standards in this series will carry the new general title as cited above. Titles of existing standards in this series will be updated at the time of the next edition.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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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. The IEC 60645 series consists of a number of parts. IEC 60645-1 is the first in the series and covers the requirements for both pure-tone and speech audiometers.

This standard describes ~~equipment~~ the performance requirements for pure-tone audiometers, which ~~is~~ are designed for the measurement of hearing in the frequency range from 125 Hz to 16 kHz, and speech audiometers, which are designed for performing live or recorded speech audiometry.

~~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.~~

When speech signal facilities are provided by an audiometer, performance requirements are given for both live voice and recorded speech material. Although live voice speech audiometry may not be capable of meeting the requirements of this standard, it is widely practiced, particularly with children, and therefore a specification is included in order to ensure as high a degree of reliability as possible. This standard does not specify the speech material that is used for test purposes or the required acoustic properties of the test room.[1]

Speech audiometers use earphones or loudspeakers to present signals to the test subject. In this standard, specifications of the performance characteristics of speech audiometers and relevant calibration and test methods are given with respect to both a free-field equivalent output level method and an uncorrected ear simulator or acoustic coupler output level method.

In order to relate earphone listening to sound field listening, the concept of a free-field equivalent output level of an earphone, as described in IEC 60268-7, is used for specification and measurement purposes.

Although it is recognised that bone vibrators are used for speech audiometry purposes, their performance can be extremely variable when using speech signals. Therefore only known "good practice" specifications for bone conduction using speech signals are provided to promote consistency when this capability is provided.

The test requirements to demonstrate audiometer conformity are now specified separately. Conformance to the performance specification 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~~ when a measured deviation from a design goal equals or does not exceed the corresponding acceptance limit(s), and the laboratory has demonstrated that the associated uncertainty of measurement equals or does not exceed the maximum permitted uncertainty 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.~~ The requirements for an audiometer are essentially the same as in the previous editions of IEC 60645-1 and IEC 60645-2.

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1 These requirements are specified in ISO 8253-1.

~~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 and speech 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, and those designed to perform psychoacoustic tests using speech material.

The object of this standard is to ensure:

a) that tests of hearing in the frequency range 125 Hz to 16 kHz on a given human ear, performed with different pure-tone 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 a means of presenting speech material to a subject in a standardized manner is provided. This will ensure that tests of hearing using a specific speech signal and a specific manner of signal presentation, when performed with different audiometers which comply with this standard, give substantially the same results;

d) that audiometers are classified according to the range of test signals they ~~generate~~ present, according to the mode of operation or according to ~~the complexity of the range of auditory functions they test~~ their presumed primary application.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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 60268-7, *Sound system equipment – Part 7: Headphones and earphones*

IEC 60268-17, *Sound system equipment – Part 17: Standard volume indicators*

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~~ disturbances – Requirements and tests*

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

IEC 61260-1, *Electroacoustics – Octave-band and fractional-octave-band filters – Part 1: Specifications*

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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
equipment for pure-tone audiometry
pure-tone audiometer
instrument for the measurement of hearing for pure tones and in particular of 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 presentation and recording of results are performed manually

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

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

3.4
equipment for speech audiometry
speech audiometer
instrument for the measurement of hearing ~~for~~ using 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 kHz to 16 kHz

Note 1 to entry: The frequency 8 kHz 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 and model 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 type

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 on a specified mechanical coupler for a specified configuration and model 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: Some parts of the ISO 389 series specify reference equivalent threshold levels for the age group 18 years to 30 years inclusive.

3.13
close-coupled sensitivity
at a given frequency, the quotient of the sound pressure level generated by the earphone in an ear simulator or acoustic coupler and the voltage applied to the terminals of the earphone

3.14
close-coupled sensitivity level
ten times the logarithm to the base ten of the quotient of the squared close-coupled sensitivity by the squared reference sensitivity, expressed as 1 Pa/V

3.15
free-field sensitivity
at a given frequency and for at least 10 otologically normal subjects, the quotient of the sound pressure level of a frontally incident plane progressive sound wave (0° sound incident) and of that voltage of equal frequency which is applied to the terminals of the earphone in order that

the subjects, on average, judge the sound wave and the sound produced by the earphone as equally loud, with both sounds being received in the same ear

Note 1 to entry: Test methods are described in IEC 60268-7. Though the loudness comparison may be performed binaurally, the resulting sensitivity is that of a single earphone.

3.16
free-field sensitivity level
ten times the logarithm to the base ten of the quotient of the squared free-field sensitivity to the squared reference sensitivity, expressed as 1 Pa/V

Note 1 to entry: Free-field sensitivity and free-field sensitivity level of a bone vibrator are defined in a corresponding way.

3.17
free-field equivalent earphone output level
for a speech audiometer, the sound pressure level generated by an earphone corrected by the difference between the close-coupled and the free-field sensitivity levels of the earphone

3.18
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

3.19
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 for determining thresholds of hearing are specified in ISO 8253-1~~:2010~~.

3.20
hearing level for speech
for a specified speech signal and a specified manner of signal presentation, the speech level minus the appropriate reference speech recognition threshold level

3.21
speech signal
test signal generated by a natural human or synthetic voice

3.22
speech level
sound pressure level or vibratory force level of the speech signal as measured in an appropriate ear simulator, acoustic coupler or mechanical coupler or in a sound field with specified frequency weighting and specified time weighting

3.23
speech recognition threshold level
SRT level
for a given test subject, a specified speech signal and a specified manner of signal presentation, the lowest speech level at which the speech recognition score is equal to 50 %

3.24
reference SRT level
for a specified speech signal and a specified manner of signal presentation, the median value of the speech recognition threshold levels of a sufficiently large number of otologically normal test subjects, of both sexes, aged between 18 years and 25 years inclusive and for whom the test material is appropriate

3.25
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.

3.26
acoustic coupler
device for measuring the acoustic output of sound sources where the sound pressure level 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.

3.27
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.

3.28
masking
process by which the threshold of hearing of a sound is raised by the presence of another (masking) sound

3.29
effective masking level
level of a specified masking sound which is numerically equal to that hearing level to which the pure-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 effective masking (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 3.18), i.e. it is a measure of sound on a physical scale, independent of the particular ear under test.

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

3.30
speech weighted noise
weighted random noise for the masking of speech

3.31
effective masking level for speech
level of a specified masking sound which is numerically equal to that hearing level for speech to which the speech recognition threshold level for a specified speech signal for a notional normal hearing 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 effective masking (ISO 389-1 and ISO 389-4).

4 Requirements ~~for specific types of fixed frequency~~ by type and class of audiometer

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

Speech audiometers are specified as two classes, and the requirements for minimum facilities are given in Table 1.

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]~~
~~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.~~

Facility	Pure-tone types					Speech class	
	Type 1 Advanced clinical/ research	Type 2 Clinical	Type 3 Basic diagnostic	Type 4 Screening monitoring	EHF [g] Extended high-frequency	Class A	Class B
Transducers							
– two earphones	X	X	X	X	X	X[d]	X[d]
– two insert earphones	X						
– two loud speakers or electrical outputs [e]	X	X				X	
– bone conduction	X	X	X			X	
Hearing levels and Test frequencies (see Table 2)	X	X	X	X	X	X	X
Output level control	X	X	X	X	X	X	X
Masking level control	X	X	X		X	X	X
Test signal switching							
– presentation/interruption	X	X	X	X[b]	X	X	X
– pulsed tone	X	X			X		
– frequency modulation (FM)	X	X					
Reference tone [c]							
– alternate presentation	X	X					
– simultaneous presentation	X						
Speech input							
– signal level indicator	X	X				X	X
– acoustical or visual monitor for speech test material						X	X
– integrated playback device or input for external signal	X[f]	X[f]				X[f]	X[f]
– microphone for live voice testing						X	
– operator and subject speech communication						X	
Masking							
– narrow-band noise	X	X	X		X		
– speech spectrum noise						X	X
Routing of masking							
– contralateral earphone	X	X	X		X	X	X
– ipsilateral earphone	X					X	
– loudspeaker or electrical output [e]	X	X				X	
– bone vibrator	X					X	
Subject response system	X	X	X	X[a]	X		
Signal indicator	X	X			X	X	X
Monitoring of test signal	X					X	X
Talk-forward system	X	X				X	
Talk-back system	X					X	

[a] Not mandatory for manual audiometers.

[b] Not mandatory for automatic-recording audiometers.

[c] The minimum requirement is for presentation of reference tones of the same frequency as the test tones.

[d] Free-field equivalent is not mandatory but is recommended. Where this is provided the audiometer shall be additionally designated as speech class E. The audiometer will therefore be class A-E or class B-E.

[e] The manufacturer shall specify how conformity with this standard is to be achieved if the power amplifier and loudspeakers are not supplied with the audiometer.

[f] The replay device is not always supplied by the manufacturer of the audiometer.

[g] The extended high-frequency range (EHF) is optional for all four types of pure tone audiometers.

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 (HL).

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~~ Measured reference equivalent threshold sound pressure levels may differ significantly at 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~~ calibration at the site of the user under their typical ambient pressure and temperature conditions should be undertaken. In circumstances where the calibration site and the user site do not share similar ambient conditions, appropriate corrections for environmental effects should be applied as recommended by the manufacturer.

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.

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

5.5.3 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. 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 ISO 8253-1:2010, Table 4 (see the 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 and between any combination of transducers

The following measurements shall be completed by the manufacturer as part of an audiometer design validation to ensure the intended requirements of 5.7 are met in any combination of transducers. Testing shall be conducted for crosstalk, breakthrough or leakage between or from all transducers, for example: earphones, insert earphones, bone vibrator, loudspeakers, or monitors. Any unwanted sound present in any non-active transducer shall be less than 0 dB HL. This shall be measured in one-third-octave bands throughout the full test capability provided by the audiometer. The unwanted sound present in any one-third-octave band shall not exceed the reference sound pressure levels or force levels, specific for each non active transducer measured. Measurements shall be made electrically.

This requirement shall be met with all selected active transducers signals switched on, set to a hearing level of 60 dB or maximum output whichever is lower. The electrical indirect measurement method shall be used to validate performance as described in 13.4.1.

5.7.3 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~~ signal 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 as well as a subjective method of verifying performance ~~are~~ shall be employed as described in 13.4.1.

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

5.7.4 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~~ may affect the ~~validity~~ reliability of the bone conduction measurement. The manufacturer shall also state the possible extent of this ~~impairment~~ affect. A method to show conformity with this requirement is given in 13.4.2.

5.7.5 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~~ This 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 a patient activated switch, an output selection switch or a detent on the frequency switch that might emit noise ~~when the subject is not actually being tested~~, but will not influence the test results.

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 Speech signals

6.1.1 Speech signal general requirements

The manufacturer shall state the characteristics and acceptance limits of the signals provided. Speech audiometers shall provide the minimum range of hearing levels as indicated in the appropriate column of Table 2.

For the results of earphone speech audiometry using class A-E and B-E audiometers to be comparable to those of loudspeaker sound-field testing, or to the results from using different types of transducer, sound-field equivalent measurement conditions shall be used to specify and test the characteristics of the speech audiometer.

For class A and class B audiometers where there is no requirement to maintain such comparability, the uncorrected earphone measurement conditions shall be used to specify and test the characteristics of the speech audiometer.

For acceptance limits for using uncorrected earphone measurement conditions, see 6.3.2.

6.1.2 Free-field equivalent earphone output level

For class A-E and B-E audiometers, the output sound pressure level and overall frequency response of the speech audiometer, including the earphone, shall be specified in terms of free-field equivalent sound pressure level. The basic method for measuring the free-field equivalent sound pressure level of earphones is described in IEC 60268-7.

NOTE Routine calibrations can be performed using an ear simulator or acoustic coupler and applying correction figures for the difference between the free-field sensitivity level and the close-coupled sensitivity level for the type of earphone under test.

6.1.3 Uncorrected earphone output level

For class A and B audiometers, the output sound pressure level and overall frequency response of the speech audiometer, including the earphone, shall be specified in terms of the uncorrected sound pressure level measured in an ear simulator according to IEC 60318-1 or IEC 60318-4 or an acoustic coupler according to IEC 60318-3 or IEC 60318-5. The manufacturer shall specify the method of measurement and the employed ear simulator or acoustic coupler.

6.1.4 Loudspeaker output level

The output sound pressure level and overall frequency response of the speech audiometer including the loudspeaker shall be specified as measured in a sound field at a minimum distance of 1 m on the reference axis of the loudspeaker.

NOTE the performance measured under reference conditions might not apply in conditions other than in a sound field and at a distance of 1 m.

6.1.5 Bone vibrator output level

For class A-E and B-E audiometers, the output vibratory force level and overall frequency response of the speech audiometer including the bone vibrator shall be specified in terms of free-field equivalent sound pressure level. If corresponding data for the type of bone vibrator used does not exist, the characteristics shall be specified in terms of uncorrected vibratory force level measured on a mechanical coupler complying with IEC 60318-6.

6.1.6 Speech signal frequency response

For the reference conditions given in 6.1.4, and the signals as specified in 13.6, the output sound pressure level generated by the loudspeaker shall be within the following acceptance limits:

Using one-third-octave-band filters the sound pressure level generated by the loudspeaker with any test signal centered around the centre frequency of the filter in the frequency range from 250 Hz to 4 kHz shall not differ by more than ± 5 dB from the average sound pressure level of all test signals in this range. For any test signal between 4 kHz and 6,3 kHz the acceptance limit is ± 8 dB.

Acceptance limits outside the frequency range given above shall be specified by the manufacturer.

If loudspeakers are not provided, the frequency response requirements of 6.3.2 for earphones shall be met.

6.1.7 Calibration signal

The specifications and test methods for speech audiometers are based on the assumption that the calibration signal level of the recorded speech material is the same as the average level of the speech material when measured in a specified manner.

The calibration signal shall be either a speech weighted noise, as specified in 6.5.3, or as specified in ISO 8253-3. If a different calibration signal is used, its characteristics shall be specified by the provider of the speech test material.

6.1.8 Live voice microphone frequency response

The microphone frequency response shall meet the requirements specified in 6.1.6 or if loudspeakers are not provided, the frequency response requirements of 6.3.2 for earphones shall be met. The manufacturer shall state how the microphone is to be used (for example, angle of incidence) to meet these requirements.

6.1.9 Scale reference and output level

Scales referring to sound pressure level shall include a reference position of 20 dB. Scales referring to hearing level shall include a reference position of 0 dB. Relative to its reference position, the output level control shall cover at least a range from -10 dB to 80 dB for loudspeaker output and -10 dB to 100 dB for earphone output levels.

NOTE A sound pressure level of 20 dB corresponds approximately to a common reference speech recognition threshold level for easily recognizable test material presented monaurally.

6.1.10 Distortion requirements for speech signals

6.1.10.1 Earphone output

The total harmonic distortion of the earphone output shall meet the requirements of 6.2.3 but shall be measured using a pure-tone signal which is + 9 dB above the reference indication of the signal level indicator.

6.1.10.2 Loudspeaker output

The total harmonic distortion of the signal generated by the loudspeaker shall not exceed 3 %. This shall be measured with the same input conditions as in 6.1.10.1, but at an output sound pressure level of 80 dB. The total harmonic distortion shall be less than 10 % at 100 dB output sound pressure level for the same frequencies

6.1.10.3 Bone vibrator output

The total harmonic distortion of the bone vibrator output shall meet the requirements of 6.2.3.

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

Frequency in Hz	Hearing levels (HL) in dB [a] The minimum hearing level shall be –10 dB.						
	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.~~							
Extended high frequency audiometers (EHF) – All types [c]							
*8 000	100						
9 000	90						
*10 000	90						
11 200	80						
*12 500	70						
14 000	70						
*16 000	60						
Speech signals [b]							
	Class A			Class B			
	Air	Bone	Loudspeaker	Air			
	100	60	80	100			

[a] Sound field / loudspeaker outputs within the range of 250 Hz to 6 000 Hz shall be within 20 dB of those for air, for each instrument type.

[b] For the SPL range requirements for speech signals when provided, see 6.1.9.

[c] The minimum hearing level for all EHF audiometers shall be -10 dB HL or lower at frequencies above 8 kHz.

* Mandatory test signal frequencies for extended high frequency audiometers.

6.2 Pure tones

6.2.1 Frequency range and hearing level range

6.2.1.1 General requirements

The manufacturer shall state the characteristics and acceptance limits of the signals provided.

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.

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.

~~6.1.1.2 EHF test signals~~

EHF test signals in the frequency range from 8 kHz to 16 kHz shall ~~be~~ include the one-sixth-octave frequencies as specified in ISO 266. Their frequencies and corresponding hearing level ranges are presented in Table 2. The following EHF test signal frequencies are mandatory: 8 kHz, 10 kHz, 12,5 kHz and 16 kHz.

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.~~	

6.2.1.2 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.~~

6.2.2 Frequency ~~accuracy~~ acceptance limits

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

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~~ %.

6.2.3 Total harmonic distortion

The maximum total harmonic distortion shall not exceed the values given in Table 3.

Table 3 – Maximum permissible acoustic total harmonic distortion, for supra-aural, circumaural, insert earphones and bone vibrators

	Air conduction			Bone conduction		
Frequency range in Hz [a]	125 to 200	250 to 400	500 to 8 000	250 to 400	500 to 800	1 000 to 4 000
Hearing level [b] in dB	75	90	110	20	50	60
Total harmonic distortion in %	~~3~~ 2,5	~~3~~ 2,5	~~3~~ 2,5	~~6~~ 5,5	~~6~~ 5,5	~~6~~ 5,5

NOTE For speech signals requirements see 6.1.10.

[a] These ranges relate to the one-third-octave centre frequencies.

[b] 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.

6.2.4 Rate of frequency change

Where automatic recording facilities include a continuous sweep frequency, at least one of the rates of frequency change available shall be one octave per minute ±~~25~~ 20 %. If an automatic-recording audiometer provides fixed frequencies, a minimum period of 30 s shall be allowed at each frequency.

6.2.5 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~~ an acceptance limit 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~~ an acceptance limit of ±~~15~~ 10 % 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~~ an acceptance limit of ±~~15~~ 10 % of its stated value.

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

6.3 External signal sources

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.~~

All external inputs, which involve the use of speech signals or other complex signals in addition to pure tones, are considered in the following clause's 6.3.2, 6.3.3,6.3.4,6.3.5 and 6.3.6.

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 or acoustic coupler 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~~ acceptance limit is $^{+4}_{-11}$ dB and above 4 kHz the ~~tolerance~~ acceptance limit is $^{+4}_{-6}$ dB.

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

6.3.3 Playback device input

The audiometer, in conjunction with its playback device input and an electrical source specified by the manufacturer, shall fulfill the requirements of 6.1.6 for speech signals use.

6.3.4 Signal-to-noise ratio for playback device input

At an output level control setting of 70 dB and with the level of the calibration signal set to the reference indication of the signal level indicator, the voltage level at any transducer input terminal, measured with frequency weighting A according to IEC 61672-1, shall be at least 45 dB higher than that obtained when the playback system is stopped in a pause mode. The manufacturer shall specify how conformity with this requirement is to be achieved if the playback system is not supplied with the speech audiometer.

NOTE this test includes measurement of the performance of the playback system, the audiometer and any external amplifiers.

6.3.5 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.

6.3.6 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.

6.4 Operator and test subject speech communication

6.4.1 General

The requirements for operator to test subject and test subject to operator communication are dependent upon the type of testing to be performed. Where these functions are provided for pure-tone audiometry only, the requirements of 6.4.2 and 6.4.3 shall be met. Where these functions are provided for performing live voice speech audiometry 6.4.4 shall be met and, when the test procedure requires the subject to provide a vocal response, 6.4.5 shall be met.

The components and installation methods used for these functions can differ in many aspects. However, it is known that the performance of these functions may significantly influence test reliability. If a specific configuration or installation is required to ensure appropriate performance, this shall be stated by the manufacturer in the instruction manual.

6.4.2 Operator to test subject speech communication (talk-forward)

This facility shall allow speech communication from the operator to the test subject under normal test conditions. It should be possible to present the operator's voice to the test subject via the transducers being used for that specific test.

The level of the ~~speech signal~~ operator's voice presented to the test subject should be controlled to prevent any effect on the reliability of test results and to prevent the introduction of distortion, for example from signal clipping.

An indicator shall be provided to show when this function is active.

6.4.3 Test subject to operator speech communication (talk-back)

This facility shall allow speech communication from the test subject to the operator under normal test conditions. The microphone used by the test subject shall be positioned so that it accurately relays the test subject's voice to the operator and provides both frequency response and signal to noise characteristics which will ensure that the operator can reliably hear the test subject when they are speaking at a normal conversational level and are located at the test position for that particular test.

6.4.4 Operator to test subject speech communication for live voice speech audiometry

The level of the operator's voice presented to the test subject should be controlled to prevent any effect on the reliability of test results. A level indicator shall be provided so that the operators can monitor their own voice level to ensure that an appropriate speech level is being presented to the test subject and to prevent the introduction of distortion, for example from signal clipping.

The position of the microphone relative to the mouth of the operator (live voice talker) shall be specified by the manufacturer. With the microphone located at this position, the overall frequency response of the operator to test subject speech communication system, when using a loudspeaker as the test transducer shall meet the relevant requirements of 6.1.6, and shall meet the requirements of 6.3.2 when using earphones as the test transducer.

6.4.5 Test subject to operator speech communication for vocal response speech audiometry

The position of the microphone relative to the mouth of the test person shall be specified by the manufacturer. For sound-field speech audiometry this position may be specified relative to the test reference point (ISO 8253-3).

With the microphone located at this position, and with a sound source located at the position of the test subject's mouth in their absence, the overall frequency response of test subject to operator speech communication system when using a loudspeaker to monitor the test subject's response, shall meet relevant requirements of 6.1.6.

When using earphones to monitor the test subject's response the earphone output, measured in an appropriate ear simulator or acoustic coupler as specified by the manufacturer, shall meet the relevant requirements of 6.3.2.

6.5 Masking sound

6.5.1 General

For audiometers which provide masking sound, all measurements of the masking sound shall be made in the same ear simulator, acoustic coupler 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.~~

For speech signals it is considered that the appropriate masking noise is speech weighted noise.

Alternatively, modulated noise may be used.

6.5.2 Narrow-band noise

Where narrow-band masking is required, the noise band shall be centred geometrically around the test frequency. The band limits for the masking noise are given in Table 4.

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 outside these three octaves it shall be at least ~~35~~ 36 dB below the level at the centre frequency. Measurements are required in the range from 31,5 kHz 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, acoustic couplers 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 4 – Narrow-band masking noise: upper and lower cut-off frequencies for a sound pressure spectrum density level of –3 dB ~~referred~~ referenced 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 (for 11 200 Hz and above to four)

6.5.3 Speech weighted noise

Audiometers that provide speech signals shall provide a weighted random noise for the masking of speech. For the loudspeaker output and the reference conditions in 6.1.4 the spectrum band-limited spectrum level of the weighted random noise as measured acoustically in the sound field shall be constant from 125 Hz to 1 kHz and shall fall at 12 dB/octave from 1 kHz to 6 kHz. For frequencies above 6 kHz the spectrum level shall not exceed the level at 6 kHz. These characteristics shall meet the acceptance limits given in 6.1.6.

For the uncorrected earphone sound pressure level output, the same specifications shall be met when measured in an ear simulator or acoustic coupler. For the free-field equivalent earphone sound pressure level output, correction figures representing the frequency dependent difference between the free-field sensitivity level and the close-coupled sensitivity level for the type of earphone used shall be added to the measured ear simulator or acoustic coupler sound pressure levels before applying the acceptance limits.

6.5.4 Other masking sound

If other types of masking sound (such as modulated noise) are provided the manufacturer shall specify the frequency spectrum and use.

7 Transducers

7.1 Types of transducers

The types of transducers used in ~~pure-tone~~ audiometry consist of different types of earphones (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 of pure-tone and speech signal level controls

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

For speech signals it shall be clearly marked as to whether the scale refers to sound pressure level or hearing level. For class A-E and B-E audiometers, the scale shall refer to sound pressure levels (SPL). For class A and B audiometers, the scale shall refer to hearing level if a hearing level according to its definition is available for the signal and measurement conditions used.

Scales referring to sound pressure level shall include a reference position (zero marking) of 20 dB. Scales referring to the hearing level (HL) shall include a reference position (zero marking) of 0 dB. Relative to its reference position, the output level control shall cover at least the range from –10 dB to 80 dB for loudspeaker output and -10 dB to 100 dB for earphone output levels.

NOTE 1 A sound pressure level of 20 dB corresponds approximately to a common reference speech recognition threshold level for easily recognizable test material presented monaurally.

NOTE 2 Adjusting the reference level for speech audiometers for known national differences in speech reception thresholds with differing languages is common practice.

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 response time characteristics of the level indicator shall be that of a VU meter specified in IEC 60268-17 when speech signals are used. For other 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.~~

For speech signals, the level indicator shall have a reference position indicating the level to which an appropriate applied reference or calibration signal shall be adjusted.

Manual signal level adjustment and/or monitoring may not be applicable for particular tests using fixed signal sources (e.g. speech test material internally stored in the speech audiometer) or automatic level adjustment. In this case, the manufacturer shall specify the appropriate signal level adjustment and/or monitoring method.

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 specified ear simulator or acoustic coupler as used for the calibration of pure tones, with the hearing level control set at the 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 acceptance limits

When one signal channel is connected to the earphone, the sound pressure level produced minus the reference equivalent threshold level shall ~~not differ by~~ be no more than ± ~~3,7~~ 3,0 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~~ 5,0 dB at frequencies up to and including ~~8~~ 16 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~~ 4,0 dB in the frequency range 250 Hz to 4 kHz and by ± ~~7,0~~ 5,0 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~~ 1,0 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~~ these levels shall not differ by more than ± 2,0 dB, and at frequencies above 8 kHz and up to 16 kHz ~~a tolerance of ± 3,5 dB is required~~ these levels

shall not differ by more than ± 3,0 dB. 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~~ Signal level control

8.4.1 Manual audiometers

~~A hearing~~ For pure tones, the signal level control shall have only one scale, hearing level (HL) and one reference zero point which is common for all frequencies. ~~Indicator readings of hearing~~ The signal level control 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.

For speech signals, the signal level control shall be clearly marked as to whether the scale refers to sound pressure level or hearing level (HL) for speech.

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~~ acceptance limit shall be ± ~~25~~ 20 %.

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

8.4.3 ~~Accuracy of~~ Signal level control acceptance limits

~~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).~~

The measured difference in output level between two successive indications of signal level or hearing level (HL) which are not more than 5 dB apart shall not deviate from the indicated difference by more than three-tenths of the indicated interval measured in dB or by more than 1 dB, whichever is smaller.

The maximum accumulated deviation from attenuator linearity at any indicated signal level or hearing level (HL) dial setting shall not exceed 1,5 dB from the referenced starting point.

Linearity shall be measured relative to the output sound pressure level, or vibratory force level, produced with the audiometer hearing level control set to the level used for calibration. Step deviation (difference from indicated value) and accumulated deviation (overall deviation) can then be determined at any setting as stated in 8.3.

8.5 Masking sound level control

8.5.1 General

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

8.5.2 Masking sound 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 ISO 389-4:1994, Table 1, the mean values of columns 1 and 2 of ISO 389-4:1994, Table 1, shall be used.

NOTE For EHF instruments the narrow-band masking level ~~may~~ can be derived from ISO 389-4:1994, Table 1, presenting data for one-third-octave ~~bandwidth~~ bands. An approximation would be to ~~increase the reference equivalent threshold sound pressure levels by 5 dB~~ use a 5 dB addition to the reference equivalent threshold sound pressure levels.

b) For speech weighted noise the masking sound level control can be specified in terms of sound pressure level (re 20 μPa) or effective masking sound level. It shall be clearly marked whether the scale refers to sound pressure level or effective masking sound level.

c) For other types of sound the masking sound level control shall be calibrated in sound pressure level as measured with the earphone on the same ear simulator or acoustic coupler 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.

8.5.3 ~~Accuracy of~~ Masking sound level acceptance limits

The level of the masking sound produced by an earphone shall not differ from the indicated value by more than ~~$^{+6}_{-4}$~~ +5,0 / -3,0 dB.

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

NOTE Due to the time-varying nature of ~~narrow-band~~ masking signals 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 sound level range

Pure-tone 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, in steps of 5 dB or less.

For speech signal masking sound, the masking sound level control shall, relative to its reference position, cover at least a range from 0 dB to 80 dB for the loudspeaker and earphone output level in steps of 5 dB or less.

8.6 ~~Tone~~ Signal switching

8.6.1 ~~Tone~~ Signal switch for manual audiometers

Manual audiometers shall be provided with a ~~tone~~ switch for the presentation or the interruption of the test ~~tone~~ signal. The switch and its associated circuitry shall be such that the subject will respond to the test ~~tone~~ signal rather than to the mechanical noise (see 5.7.5) 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.

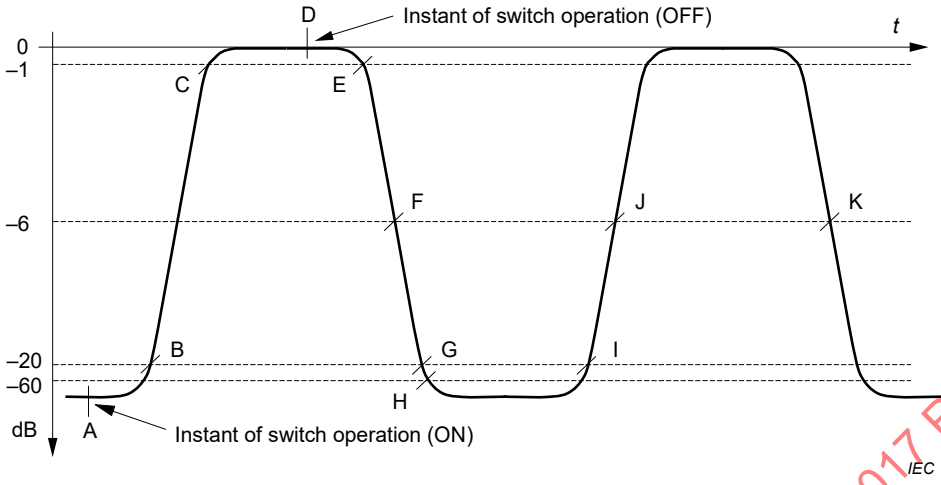


Figure 1 – Rise/fall envelope of test tones

8.6.5 Subject's response system

The subject's response system is a means by which the tester is made aware that the subject has responded to the test signal and controls an appropriate function in the audiometer.

~~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~~ The subject's response system shall be constructed in such a manner as to enable easy and reliable operation by one hand without generating ~~any~~ acoustical sound or electrical interference that might result in a hearing threshold level measurement error.

8.6.6 Subject's response time for automated test procedures

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

9 Reference tone

9.1 General

The following requirements 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 known 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~~ 8 kHz.

9.3.2 Intervals

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

The control normally intended for the masking sound level may be used as the reference tone level control provided 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 level expressed in dB (see 8.4).

9.3.4 ~~Accuracy~~ Acceptance limits

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~~ 3,0 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~~ 5,0 dB, and for frequencies up to 16 kHz (where available) the deviation shall be within ±~~6,5~~ 6,0 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, ISO 8253-2 and ISO 8253-3).

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

Calibration adjustments should be protected either physically (e.g. an internal switch) or by password or other means to prevent any unintended change of calibration. Calibration information stored electronically shall be subject to verification routines to ensure integrity.

Table 5 gives the types of transducer, the standards which specify the appropriate reference equivalent threshold levels and the ear simulator, reference coupler, mechanical coupler, 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~~ covered by 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.

NOTE 1 ISO 389-9 provides details of preferred test conditions for the determination of reference hearing threshold levels.

If an earphone, whose reference equivalent threshold levels are given for an ear simulator, is to be calibrated on an acoustic coupler, ~~validated correction values for the specific type of earphone shall be applied~~ the manufacturer shall provide the reference equivalent threshold levels for the specific type of earphone and specific type of coupler to be used. In this case the calibration of the earphone will not meet the requirements of ISO 389-1 and this shall be documented in the associated calibration report. Calibration of an earphone in this manner shall be restricted to Stage B calibration as defined in ISO 8253-1.

NOTE 2 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 5 – ~~Reference~~ Standards ~~for obtaining audiometric zero~~ specifying reference equivalent threshold levels

Type of transducer	Reference equivalent threshold ~~values~~ levels	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~~ shall state the output characteristics, including the impedance, the frequency response and the voltage available across 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 6 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 6 – 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 – unmasked, forehead		
Bone conduction – masked, 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 one-sixth 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 kHz 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 a measured deviation from the stated requirement equals or does not exceed the acceptance limits for that requirement provided also that the uncertainty of the measurement used to assess conformance does not exceed the maximum permitted uncertainty (U_{max}) in Table 7. When measurements are not appropriate, conformance shall be demonstrated by other means, for example visual inspection (e.g. Clause 15) or examination of supporting documentation (e.g. Clause 5).

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~~ meet the requirements of 6.2.3.

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 ± 1) kPa and (104 ± 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~~ meet the requirements of 6.2.3.

13.3 Electromagnetic compatibility

Electromagnetic compatibility shall be tested and demonstrated.

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°.

c) The ambient acoustic noise in the EMC testing space shall be below 55 dB SPL 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 % of the bandwidth being measured. 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 and IEC 60601-1-2.

To avoid possible effects of electromagnetic fields on the measuring microphone an acoustic tube should be inserted between the audiometer earphone, together with a suitable adapter, or loudspeaker and the measuring microphone in order to remove it from the higher level test field.

NOTE Because of the changes a mechanical coupler would cause in the electromagnetic field this device cannot be used to measure the output of bone vibrators in an electromagnetic field. A suitable method has not been developed.

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~~ test 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 6.2.3 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 or acoustic coupler 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~~ may affect the reliability 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 Microphone for live voice speech testing

Conformity with the specification in 6.1.6 speech microphone frequency response shall be performed under free-field conditions using test signals of a constant sound pressure level (re 20 μPa) of 80 dB filtered from white noise by one-third-octave filters according to IEC 61260-1 centered at the preferred one-third-octave frequencies according to ISO 266.

13.7 Signal accuracy

13.7.1 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 or acoustic coupler. 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.

13.7.2 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 or acoustic coupler. Alternatively, the transducer may be replaced by a dummy electrical load which simulates the transducer at the test frequency.

13.8 Masking sound

13.8.1 Narrow-band noise

Conformity with 6.5.2 shall be demonstrated up to 3,15 kHz by measuring the spectrum of the masking noise acoustically using the same ear simulator or acoustic coupler 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 or acoustic coupler.

13.8.2 Masking sound 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 pressure level at a hearing level setting of 70 dB at all available frequencies and with the same ear simulator or acoustic coupler as used for the measurement of pure tones.

13.9 Headbands

13.9.1 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 are given in Table 7.

13.9.2 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~~ acceptance limit for the dimensions is ± 5 mm.

13.9.3 Bone vibrator headband

For demonstrating conformity, the spacing of the bone vibrator and the opposite end of the headband shall meet the requirements of 13.9.2, except for forehead placement where the spacing shall be 190 mm with ~~a tolerance~~ the acceptance limit of ± 5 mm.

14 Maximum permitted expanded uncertainty of measurements U_{max}

Table 7 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 7 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 7, the measurement shall not be used to demonstrate conformance to the requirements of this standard. Please see Annex A for further guidance in the application of Table 7.

Table 7 – Values of U_{max} for basic measurements

Measured quantity	Relevant sub clause number	Basic U_{max}
Sound pressure level 125 Hz to 4 kHz	8.3, 9.3.4	0,7 dB
Sound pressure level 5 kHz to 8 kHz	8.3, 9.3.4	1,2 dB
Sound pressure level 9 kHz to 16 kHz	8.3, 9.3.4	1,5 dB
Frequency	6.2.2	0,5 %
Total harmonic distortion	6.2.3	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	6.2.4	5 %
Repetition rate	6.2.5	5 %
Frequency deviation	6.2.5	5 %
Frequency response	6.3.2	1,0 dB
~~Masking cut-off frequencies~~	~~6.4.2~~	~~1 %~~
Narrow-band masking noise cut-off frequencies	6.5.2	1 %
Masking –36 dB level	6.5.2	1,0 dB
Frequency response speech weighted noise	6.5.3	1 %
Level of speech weighted noise	6.5.3	1,5 dB
Speech signal frequency response	6.1.6	1,5 dB
Live voice microphone frequency response	6.1.8	1,5 dB
Masking sound level 125 Hz to 4 kHz	8.5.3	1,0 dB
Force level 250 Hz to 4 kHz	8.3	1,5 dB
Force level greater than 4 kHz	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~~ 0,5 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)~~, the serial number of the instrument and conform with regulatory and safety marking requirements. ~~An individual instrument identification shall also be marked on the test signal transducers.~~ In addition, the instrument and/or transducers shall be marked with specific identification; to ensure they are used together.

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 and class (see Table 1) ~~for which the instrument complies with this standard and~~, the number and year of this standard which the instrument claims to comply, and all applicable regulatory and safety requirements, 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, reference coupler, mechanical coupler or measurement method 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 sounds provided (see 6.5 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~~ acceptance limits 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~~ radiated by the bone vibrator and means to obtain the correct test results

m) For speech classes A-E and B-E audiometers, for the type of earphone provided and for each preferred frequency in the range from 125 Hz to 6,3 kHz, the difference between the free-field sensitivity level and the close-coupled sensitivity level of the earphone for test signals consisting of one-third-octave bands of white noise centered at these frequencies.

n) Reference calibration level; the manual shall contain a warning that only recorded speech material with a stated relationship with the calibration signal should be used. If the speech and calibration signal are not at the same level the method of calibration shall be described. If the level of the calibration signal and the average level of the speech material are different, calibration and test methods should be modified as recommended by the producer of the speech test material.

o) Information about the time window for subject's response for automated test procedures according to 8.6.6.

p) For battery operated instruments: type of battery, means of checking the battery and method of replacement, expected battery life time.

q) Maintenance and calibration procedures and schedules. ISO 8253-1~~:2010~~, ISO 8253-2 and ISO 8253-3 give appropriate information.

r) 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.

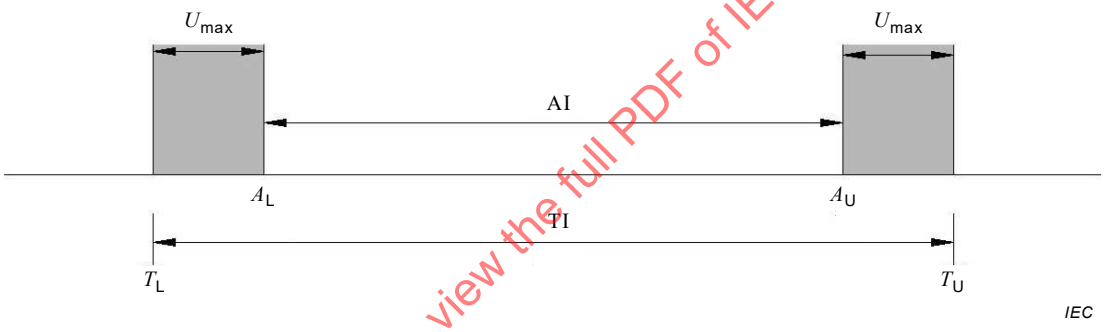
Annex A
(informative)

Relationship between tolerance interval, corresponding acceptance interval and the maximum permitted uncertainty of measurement

This part of IEC 60645, in common with other IEC standards, uses adaptations of the guidelines from ISO/IEC Guide 98-4, *Uncertainty of measurement – Part 4: Role of measurement uncertainty in conformity assessment* (equivalent to guidance document JCGM 106 from the Joint Committee for Guides in Metrology), as the basis for demonstration of conformance of an instrument to the specifications given in this document.

ISO/IEC Guide 98-4 describes guarded acceptance in terms of tolerance intervals, acceptance intervals and uncertainties of measurement.

To promote clarity for users and testing laboratories, the IEC has adopted a policy whereby tolerance limits around design goals are not explicitly stated, but can be determined if required from the specified acceptance limits for allowed deviations from a design goal and the corresponding specified maximum permitted uncertainty of measurement, by using the illustration in Figure A.1.



Key

A I	Acceptance interval
T I	Tolerance interval
U_{max}	Guard band for the maximum permitted uncertainty of measurement for a 95% coverage interval
A_L	Lower acceptance limit
A_U	Upper acceptance limit
T_L	Lower tolerance limit
T_U	Upper tolerance limit

Figure A.1 – Relationship between tolerance interval, corresponding acceptance interval and the maximum permitted uncertainty of measurement

The limits of an acceptance interval are associated with the acceptance interval and not with the guard band for the maximum permitted uncertainty of measurement. Hence a measured deviation equal to a limit of an acceptance interval demonstrates conformance to a specification, providing also that the uncertainty of the measurement from the laboratory performing a test does not exceed the specified maximum permitted uncertainty.

Bibliography

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

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

[2] 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*

IEC 60645-1

Edition 4.0 2017-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Electroacoustics – Audiometric equipment – Part 1: Equipment for pure-tone and speech audiometry

Électroacoustique – Appareils audiométriques – Partie 1: Appareils pour l'audiométrie tonale et vocale

IEC 60645-1:2017-03(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 1: Equipment for pure-tone and speech audiometry

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60645-1 has been prepared by IEC technical committee 29: Electroacoustics.

This fourth edition cancels and replaces the third edition, published in 2012, and the first edition IEC 60645-2, published in 1993. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

This edition now includes the requirements for both pure-tone (prior edition of IEC 60645-1) and speech audiometers (prior edition of IEC 60645-2) into a single document. The technical requirements in this edition remain similar to the intent of the prior two documents, but now eliminate technical and editorial contradictions caused by two separate standards with different review cycles applying to an audiometer.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
29/927/FDIS	29/941/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts in the IEC 60645 series, published under the general title *Electroacoustics – Audiometric equipment*, can be found on the IEC website.

Future standards in this series will carry the new general title as cited above. Titles of existing standards in this series will be updated at the time of the next edition.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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. The IEC 60645 series consists of a number of parts. IEC 60645-1 is the first in the series and covers the requirements for both pure-tone and speech audiometers.

This standard describes the performance requirements for pure-tone audiometers, which are designed for the measurement of hearing in the frequency range from 125 Hz to 16 kHz, and speech audiometers, which are designed for performing live or recorded speech audiometry.

When speech signal facilities are provided by an audiometer, performance requirements are given for both live voice and recorded speech material. Although live voice speech audiometry may not be capable of meeting the requirements of this standard, it is widely practiced, particularly with children, and therefore a specification is included in order to ensure as high a degree of reliability as possible. This standard does not specify the speech material that is used for test purposes or the required acoustic properties of the test room.[1]

Speech audiometers use earphones or loudspeakers to present signals to the test subject. In this standard, specifications of the performance characteristics of speech audiometers and relevant calibration and test methods are given with respect to both a free-field equivalent output level method and an uncorrected ear simulator or acoustic coupler output level method.

In order to relate earphone listening to sound field listening, the concept of a free-field equivalent output level of an earphone, as described in IEC 60268-7, is used for specification and measurement purposes.

Although it is recognised that bone vibrators are used for speech audiometry purposes, their performance can be extremely variable when using speech signals. Therefore only known “good practice” specifications for bone conduction using speech signals are provided to promote consistency when this capability is provided.

The test requirements to demonstrate audiometer conformity are now specified separately. Conformance to the performance specification in this standard is demonstrated when a measured deviation from a design goal equals or does not exceed the corresponding acceptance limit(s), and the laboratory has demonstrated that the associated uncertainty of measurement equals or does not exceed the maximum permitted uncertainty specified in this standard. The requirements for an audiometer are essentially the same as in the previous editions of IEC 60645-1 and IEC 60645-2.

[1] These requirements are specified in ISO 8253-1.

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 1: Equipment for pure-tone and speech audiometry

1 Scope

This part of IEC 60645 specifies general requirements for audiometers designed for use in determining hearing threshold levels, relative to standard reference threshold levels established by means of psychoacoustic test methods, and those designed to perform psychoacoustic tests using speech material.

The object of this standard is to ensure:

a) that tests of hearing in the frequency range 125 Hz to 16 kHz on a given human ear, performed with different pure-tone audiometers which comply with this standard, 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 a means of presenting speech material to a subject in a standardized manner is provided. This will ensure that tests of hearing using a specific speech signal and a specific manner of signal presentation, when performed with different audiometers which comply with this standard, give substantially the same results;

d) that audiometers are classified according to the range of test signals they present, according to the mode of operation or according to their presumed primary application.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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 60268-7, *Sound system equipment – Part 7: Headphones and earphones*

IEC 60268-17, *Sound system equipment – Part 17: Standard volume indicators*

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 disturbances – Requirements and tests*

IEC 61260-1, *Electroacoustics – Octave-band and fractional-octave-band filters – Part 1: Specifications*

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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
equipment for pure-tone audiometry
pure-tone audiometer
instrument for the measurement of hearing for pure tones and in particular of 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 presentation and recording of results are performed manually

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

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

3.4
equipment for speech audiometry
speech audiometer
instrument for the measurement of hearing using speech 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 kHz to 16 kHz

Note 1 to entry: The frequency 8 kHz 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, 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 and model 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 type

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 on a specified mechanical coupler for a specified configuration and model 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: Some parts of the ISO 389 series specify reference equivalent threshold levels for the age group 18 years to 30 years inclusive.

3.13
close-coupled sensitivity
at a given frequency, the quotient of the sound pressure level generated by the earphone in an ear simulator or acoustic coupler and the voltage applied to the terminals of the earphone

3.14
close-coupled sensitivity level
ten times the logarithm to the base ten of the quotient of the squared close-coupled sensitivity by the squared reference sensitivity, expressed as 1 Pa/V

3.15
free-field sensitivity
at a given frequency and for at least 10 otologically normal subjects, the quotient of the sound pressure level of a frontally incident plane progressive sound wave (0° sound incident) and of that voltage of equal frequency which is applied to the terminals of the earphone in order that the subjects, on average, judge the sound wave and the sound produced by the earphone as equally loud, with both sounds being received in the same ear

Note 1 to entry: Test methods are described in IEC 60268-7. Though the loudness comparison may be performed binaurally, the resulting sensitivity is that of a single earphone.

3.16
free-field sensitivity level
ten times the logarithm to the base ten of the quotient of the squared free-field sensitivity to the squared reference sensitivity, expressed as 1 Pa/V

Note 1 to entry: Free-field sensitivity and free-field sensitivity level of a bone vibrator are defined in a corresponding way.

3.17
free-field equivalent earphone output level
for a speech audiometer, the sound pressure level generated by an earphone corrected by the difference between the close-coupled and the free-field sensitivity levels of the earphone

3.18
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

3.19
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 for determining thresholds of hearing are specified in ISO 8253-1.

3.20
hearing level for speech
for a specified speech signal and a specified manner of signal presentation, the speech level minus the appropriate reference speech recognition threshold level

3.21
speech signal
test signal generated by a natural human or synthetic voice

3.22
speech level
sound pressure level or vibratory force level of the speech signal as measured in an appropriate ear simulator, acoustic coupler or mechanical coupler or in a sound field with specified frequency weighting and specified time weighting

3.23
speech recognition threshold level
SRT level
for a given test subject, a specified speech signal and a specified manner of signal presentation, the lowest speech level at which the speech recognition score is equal to 50 %

3.24
reference SRT level
for a specified speech signal and a specified manner of signal presentation, the median value of the speech recognition threshold levels of a sufficiently large number of otologically normal test subjects, of both sexes, aged between 18 years and 25 years inclusive and for whom the test material is appropriate

3.25
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.

3.26
acoustic coupler
device for measuring the acoustic output of sound sources where the sound pressure level 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.

3.27
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.

3.28
masking
process by which the threshold of hearing of a sound is raised by the presence of another (masking) sound

3.29
effective masking level
level of a specified masking sound which is numerically equal to that hearing level to which the pure-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 effective masking (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 3.18), i.e. it is a measure of sound on a physical scale, independent of the particular ear under test.

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

3.30
speech weighted noise
weighted random noise for the masking of speech

3.31
effective masking level for speech
level of a specified masking sound which is numerically equal to that hearing level for speech to which the speech recognition threshold level for a specified speech signal for a notional normal hearing 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 effective masking (ISO 389-1 and ISO 389-4).

4 Requirements by type and class of audiometer

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

Speech audiometers are specified as two classes, and the requirements for minimum facilities are given in Table 1.

Table 1 – Minimum facilities for audiometers

Facility	Pure-tone types					Speech class	
	Type 1 Advanced clinical/ research	Type 2 Clinical	Type 3 Basic diagnostic	Type 4 Screening monitoring	EHF [g] Extended high-frequency	Class A	Class B
Transducers							
– two earphones	X	X	X	X	X	X[d]	X[d]
– two insert earphones	X						
– two loud speakers or electrical outputs [e]	X	X				X	
– bone conduction	X	X	X			X	
Hearing levels and Test frequencies (see Table 2)	X	X	X	X	X	X	X
Output level control	X	X	X	X	X	X	X
Masking level control	X	X	X		X	X	X
Test signal switching							
– presentation/interruption	X	X	X	X[b]	X	X	X
– pulsed tone	X	X			X		
– frequency modulation (FM)	X	X					
Reference tone [c]							
– alternate presentation	X	X					
– simultaneous presentation	X						
Speech input							
– signal level indicator	X	X				X	X
– acoustical or visual monitor for speech test material						X	X
– integrated playback device or input for external signal	X[f]	X[f]				X[f]	X[f]
– microphone for live voice testing						X	
– operator and subject speech communication						X	
Masking							
– narrow-band noise	X	X	X		X		
– speech spectrum noise						X	X
Routing of masking							
– contralateral earphone	X	X	X		X	X	X
– ipsilateral earphone	X					X	
– loudspeaker or electrical output [e]	X	X				X	
– bone vibrator	X					X	
Subject response system	X	X	X	X[a]	X		
Signal indicator	X	X			X	X	X
Monitoring of test signal	X					X	X
Talk-forward system	X	X				X	
Talk-back system	X					X	

[a] Not mandatory for manual audiometers.

[b] Not mandatory for automatic-recording audiometers.

[c] The minimum requirement is for presentation of reference tones of the same frequency as the test tones.

[d] Free-field equivalent is not mandatory but is recommended. Where this is provided the audiometer shall be additionally designated as speech class E. The audiometer will therefore be class A-E or class B-E.

[e] The manufacturer shall specify how conformity with this standard is to be achieved if the power amplifier and loudspeakers are not supplied with the audiometer.

[f] The replay device is not always supplied by the manufacturer of the audiometer.

[g] The extended high-frequency range (EHF) is optional for all four types of pure tone audiometers.

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 (HL).

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.

Measured reference equivalent threshold sound pressure levels may differ significantly at ambient pressures outside the above range. Therefore calibration at the site of the user under their typical ambient pressure and temperature conditions should be undertaken. In circumstances where the calibration site and the user site do not share similar ambient conditions, appropriate corrections for environmental effects should be applied as recommended by the manufacturer.

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.

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

5.5.3 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. 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 ISO 8253-1:2010, Table 4 (see the 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 have shown in practice to provide sufficiently low ambient noise levels.

5.7.2 Unwanted sound from and between any combination of transducers

The following measurements shall be completed by the manufacturer as part of an audiometer design validation to ensure the intended requirements of 5.7 are met in any combination of transducers. Testing shall be conducted for crosstalk, breakthrough or leakage between or from all transducers, for example: earphones, insert earphones, bone vibrator, loudspeakers, or monitors. Any unwanted sound present in any non-active transducer shall be less than 0 dB HL. This shall be measured in one-third-octave bands throughout the full test capability provided by the audiometer. The unwanted sound present in any one-third-octave band shall not exceed the reference sound pressure levels or force levels, specific for each non active transducer measured. Measurements shall be made electrically.

This requirement shall be met with all selected active transducers signals switched on, set to a hearing level of 60 dB or maximum output whichever is lower. The electrical indirect measurement method shall be used to validate performance as described in 13.4.1.

5.7.3 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 signal 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 as well as a subjective method of verifying performance shall be employed as described in 13.4.1.

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

5.7.4 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 may affect the reliability of the bone conduction measurement. The

manufacturer shall also state the possible extent of this affect. A method to show conformity with this requirement is given in 13.4.2.

5.7.5 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.

This 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 a patient activated switch, an output selection switch or a detent on the frequency switch that might emit noise, but will not influence the test results.

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 Speech signals

6.1.1 Speech signal general requirements

The manufacturer shall state the characteristics and acceptance limits of the signals provided. Speech audiometers shall provide the minimum range of hearing levels as indicated in the appropriate column of Table 2.

For the results of earphone speech audiometry using class A-E and B-E audiometers to be comparable to those of loudspeaker sound-field testing, or to the results from using different types of transducer, sound-field equivalent measurement conditions shall be used to specify and test the characteristics of the speech audiometer.

For class A and class B audiometers where there is no requirement to maintain such comparability, the uncorrected earphone measurement conditions shall be used to specify and test the characteristics of the speech audiometer.

For acceptance limits for using uncorrected earphone measurement conditions, see 6.3.2.

6.1.2 Free-field equivalent earphone output level

For class A-E and B-E audiometers, the output sound pressure level and overall frequency response of the speech audiometer, including the earphone, shall be specified in terms of free-field equivalent sound pressure level. The basic method for measuring the free-field equivalent sound pressure level of earphones is described in IEC 60268-7.

NOTE Routine calibrations can be performed using an ear simulator or acoustic coupler and applying correction figures for the difference between the free-field sensitivity level and the close-coupled sensitivity level for the type of earphone under test.

6.1.3 Uncorrected earphone output level

For class A and B audiometers, the output sound pressure level and overall frequency response of the speech audiometer, including the earphone, shall be specified in terms of the uncorrected sound pressure level measured in an ear simulator according to IEC 60318-1 or IEC 60318-4 or an acoustic coupler according to IEC 60318-3 or IEC 60318-5. The manufacturer shall specify the method of measurement and the employed ear simulator or acoustic coupler.

6.1.4 Loudspeaker output level

The output sound pressure level and overall frequency response of the speech audiometer including the loudspeaker shall be specified as measured in a sound field at a minimum distance of 1 m on the reference axis of the loudspeaker.

NOTE the performance measured under reference conditions might not apply in conditions other than in a sound field and at a distance of 1 m.

6.1.5 Bone vibrator output level

For class A-E and B-E audiometers, the output vibratory force level and overall frequency response of the speech audiometer including the bone vibrator shall be specified in terms of free-field equivalent sound pressure level. If corresponding data for the type of bone vibrator used does not exist, the characteristics shall be specified in terms of uncorrected vibratory force level measured on a mechanical coupler complying with IEC 60318-6.

6.1.6 Speech signal frequency response

For the reference conditions given in 6.1.4, and the signals as specified in 13.6, the output sound pressure level generated by the loudspeaker shall be within the following acceptance limits:

Using one-third-octave-band filters the sound pressure level generated by the loudspeaker with any test signal centered around the centre frequency of the filter in the frequency range from 250 Hz to 4 kHz shall not differ by more than ± 5 dB from the average sound pressure level of all test signals in this range. For any test signal between 4 kHz and 6,3 kHz the acceptance limit is ± 8 dB.

Acceptance limits outside the frequency range given above shall be specified by the manufacturer.

If loudspeakers are not provided, the frequency response requirements of 6.3.2 for earphones shall be met.

6.1.7 Calibration signal

The specifications and test methods for speech audiometers are based on the assumption that the calibration signal level of the recorded speech material is the same as the average level of the speech material when measured in a specified manner.

The calibration signal shall be either a speech weighted noise, as specified in 6.5.3, or as specified in ISO 8253-3. If a different calibration signal is used, its characteristics shall be specified by the provider of the speech test material.

6.1.8 Live voice microphone frequency response

The microphone frequency response shall meet the requirements specified in 6.1.6 or if loudspeakers are not provided, the frequency response requirements of 6.3.2 for earphones shall be met. The manufacturer shall state how the microphone is to be used (for example, angle of incidence) to meet these requirements.

6.1.9 Scale reference and output level

Scales referring to sound pressure level shall include a reference position of 20 dB. Scales referring to hearing level shall include a reference position of 0 dB. Relative to its reference position, the output level control shall cover at least a range from -10 dB to 80 dB for loudspeaker output and -10 dB to 100 dB for earphone output levels.

NOTE A sound pressure level of 20 dB corresponds approximately to a common reference speech recognition threshold level for easily recognizable test material presented monaurally.

6.1.10 Distortion requirements for speech signals

6.1.10.1 Earphone output

The total harmonic distortion of the earphone output shall meet the requirements of 6.2.3 but shall be measured using a pure-tone signal which is + 9 dB above the reference indication of the signal level indicator.

6.1.10.2 Loudspeaker output

The total harmonic distortion of the signal generated by the loudspeaker shall not exceed 3 %. This shall be measured with the same input conditions as in 6.1.10.1, but at an output sound pressure level of 80 dB. The total harmonic distortion shall be less than 10 % at 100 dB output sound pressure level for the same frequencies

6.1.10.3 Bone vibrator output

The total harmonic distortion of the bone vibrator output shall meet the requirements of 6.2.3.

Table 2 – Minimum number of frequencies to be provided and the minimum range of values of hearing level for type and class of audiometer

Frequency in Hz	Hearing levels (HL) in dB [a] The minimum hearing level shall be –10 dB.						
	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		
Extended high frequency audiometers (EHF) – All types [c]							
*8 000	100						
9 000	90						
*10 000	90						
11 200	80						
*12 500	70						
14 000	70						
*16 000	60						
Speech signals [b]							
	Class A			Class B			
	Air	Bone	Loudspeaker	Air			
	100	60	80	100			

[a] Sound field / loudspeaker outputs within the range of 250 Hz to 6 000 Hz shall be within 20 dB of those for air, for each instrument type.

[b] For the SPL range requirements for speech signals when provided, see 6.1.9.

[c] The minimum hearing level for all EHF audiometers shall be -10 dB HL or lower at frequencies above 8 kHz.

* Mandatory test signal frequencies for extended high frequency audiometers.

6.2 Pure tones

6.2.1 Frequency range and hearing level range

6.2.1.1 General requirements

The manufacturer shall state the characteristics and acceptance limits of the signals provided.

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.

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.

EHF test signals in the frequency range from 8 kHz to 16 kHz shall include the one-sixth-octave frequencies as specified in ISO 266. Their frequencies and corresponding hearing level ranges are presented in Table 2. The following EHF test signal frequencies are mandatory: 8 kHz, 10 kHz, 12,5 kHz and 16 kHz.

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

6.2.1.2 Test signal level range for earphones

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

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.

6.2.2 Frequency acceptance limits

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

Type 1 and 2: ± 1 %

Type 3 and 4: ± 2 %

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

6.2.3 Total harmonic distortion

The maximum total harmonic distortion shall not exceed the values given in Table 3.

Table 3 – Maximum permissible acoustic total harmonic distortion, for supra-aural, circumaural, insert earphones and bone vibrators

	Air conduction			Bone conduction		
Frequency range in Hz [a]	125 to 200	250 to 400	500 to 8 000	250 to 400	500 to 800	1 000 to 4 000
Hearing level [b] in dB	75	90	110	20	50	60
Total harmonic distortion in %	2,5	2,5	2,5	5,5	5,5	5,5

NOTE For speech signals requirements see 6.1.10.

[a] These ranges relate to the one-third-octave centre frequencies.

[b] 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.

6.2.4 Rate of frequency change

Where automatic recording facilities include a continuous sweep frequency, at least one of the rates of frequency change available shall be one octave per minute ± 20 %. If an automatic-recording audiometer provides fixed frequencies, a minimum period of 30 s shall be allowed at each frequency.

6.2.5 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 an acceptance limit of ± 3 % 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 an acceptance limit of ± 10 % 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 an acceptance limit of ± 10 % of its stated value.

6.3 External signal sources

6.3.1 Signals

All external inputs, which involve the use of speech signals or other complex signals in addition to pure tones, are considered in the following clause's 6.3.2, 6.3.3,6.3.4,6.3.5 and 6.3.6.

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 or acoustic coupler 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 acceptance limit is $^{+4}_{-11}$ dB and above 4 kHz the acceptance limit is $^{+4}_{-6}$ dB.

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

6.3.3 Playback device input

The audiometer, in conjunction with its playback device input and an electrical source specified by the manufacturer, shall fulfill the requirements of 6.1.6 for speech signals use.

6.3.4 Signal-to-noise ratio for playback device input

At an output level control setting of 70 dB and with the level of the calibration signal set to the reference indication of the signal level indicator, the voltage level at any transducer input terminal, measured with frequency weighting A according to IEC 61672-1, shall be at least 45 dB higher than that obtained when the playback system is stopped in a pause mode. The manufacturer shall specify how conformity with this requirement is to be achieved if the playback system is not supplied with the speech audiometer.

NOTE this test includes measurement of the performance of the playback system, the audiometer and any external amplifiers.

6.3.5 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.

6.3.6 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.

6.4 Operator and test subject speech communication

6.4.1 General

The requirements for operator to test subject and test subject to operator communication are dependent upon the type of testing to be performed. Where these functions are provided for pure-tone audiometry only, the requirements of 6.4.2 and 6.4.3 shall be met. Where these functions are provided for performing live voice speech audiometry 6.4.4 shall be met and, when the test procedure requires the subject to provide a vocal response, 6.4.5 shall be met.

The components and installation methods used for these functions can differ in many aspects. However, it is known that the performance of these functions may significantly influence test reliability. If a specific configuration or installation is required to ensure appropriate performance, this shall be stated by the manufacturer in the instruction manual.

6.4.2 Operator to test subject speech communication (talk-forward)

This facility shall allow speech communication from the operator to the test subject under normal test conditions. It should be possible to present the operator's voice to the test subject via the transducers being used for that specific test.

The level of the operator's voice presented to the test subject should be controlled to prevent any effect on the reliability of test results and to prevent the introduction of distortion, for example from signal clipping.

An indicator shall be provided to show when this function is active.

6.4.3 Test subject to operator speech communication (talk-back)

This facility shall allow speech communication from the test subject to the operator under normal test conditions. The microphone used by the test subject shall be positioned so that it accurately relays the test subject's voice to the operator and provides both frequency response and signal to noise characteristics which will ensure that the operator can reliably hear the test subject when they are speaking at a normal conversational level and are located at the test position for that particular test.

6.4.4 Operator to test subject speech communication for live voice speech audiometry

The level of the operator's voice presented to the test subject should be controlled to prevent any effect on the reliability of test results. A level indicator shall be provided so that the operators can monitor their own voice level to ensure that an appropriate speech level is being presented to the test subject and to prevent the introduction of distortion, for example from signal clipping.

The position of the microphone relative to the mouth of the operator (live voice talker) shall be specified by the manufacturer. With the microphone located at this position, the overall frequency response of the operator to test subject speech communication system, when using a loudspeaker as the test transducer shall meet the relevant requirements of 6.1.6, and shall meet the requirements of 6.3.2 when using earphones as the test transducer.

6.4.5 Test subject to operator speech communication for vocal response speech audiometry

The position of the microphone relative to the mouth of the test person shall be specified by the manufacturer. For sound-field speech audiometry this position may be specified relative to the test reference point (ISO 8253-3).

With the microphone located at this position, and with a sound source located at the position of the test subject's mouth in their absence, the overall frequency response of test subject to operator speech communication system when using a loudspeaker to monitor the test subject's response, shall meet relevant requirements of 6.1.6.

When using earphones to monitor the test subject's response the earphone output, measured in an appropriate ear simulator or acoustic coupler as specified by the manufacturer, shall meet the relevant requirements of 6.3.2.

6.5 Masking sound

6.5.1 General

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

For pure tones, it is considered that the appropriate masking noise is narrow-band noise.

For speech signals it is considered that the appropriate masking noise is speech weighted noise.

Alternatively, modulated noise may be used.

6.5.2 Narrow-band noise

Where narrow-band masking is required, the noise band shall be centred geometrically around the test frequency. The band limits for the masking noise are given in Table 4.

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 outside these three octaves it shall be at least 36 dB below the level at the centre frequency. Measurements are required in the range from 31,5 kHz 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, acoustic couplers 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 4 – Narrow-band masking noise: upper and lower cut-off frequencies for a sound pressure spectrum density level of –3 dB referenced 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 (for 11 200 Hz and above to four)

6.5.3 Speech weighted noise

Audiometers that provide speech signals shall provide a weighted random noise for the masking of speech. For the loudspeaker output and the reference conditions in 6.1.4 the spectrum band-limited spectrum level of the weighted random noise as measured acoustically in the sound field shall be constant from 125 Hz to 1 kHz and shall fall at 12 dB/octave from 1 kHz to 6 kHz. For frequencies above 6 kHz the spectrum level shall not exceed the level at 6 kHz. These characteristics shall meet the acceptance limits given in 6.1.6.

For the uncorrected earphone sound pressure level output, the same specifications shall be met when measured in an ear simulator or acoustic coupler. For the free-field equivalent earphone sound pressure level output, correction figures representing the frequency dependent difference between the free-field sensitivity level and the close-coupled sensitivity level for the type of earphone used shall be added to the measured ear simulator or acoustic coupler sound pressure levels before applying the acceptance limits.

6.5.4 Other masking sound

If other types of masking sound (such as modulated noise) are provided the manufacturer shall specify the frequency spectrum and use.

7 Transducers

7.1 Types of transducers

The types of transducers used in audiometry consist of different types of earphones (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 of pure-tone and speech signal level controls

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

For speech signals it shall be clearly marked as to whether the scale refers to sound pressure level or hearing level. For class A-E and B-E audiometers, the scale shall refer to sound pressure levels (SPL). For class A and B audiometers, the scale shall refer to hearing level if a hearing level according to its definition is available for the signal and measurement conditions used.

Scales referring to sound pressure level shall include a reference position (zero marking) of 20 dB. Scales referring to the hearing level (HL) shall include a reference position (zero marking) of 0 dB. Relative to its reference position, the output level control shall cover at least the range from –10 dB to 80 dB for loudspeaker output and -10 dB to 100 dB for earphone output levels.

NOTE 1 A sound pressure level of 20 dB corresponds approximately to a common reference speech recognition threshold level for easily recognizable test material presented monaurally.

NOTE 2 Adjusting the reference level for speech audiometers for known national differences in speech reception thresholds with differing languages is common practice.

8.2 Signal indicator

If a signal indicator is provided (see Table 1) to allow the level of the 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 response time characteristics of the level indicator shall be that of a VU meter specified in IEC 60268-17 when speech signals are used. For other signals the manufacturer shall state the characteristics of the signal indicator, i.e. time weighting, dynamic range and rectifier characteristics.

For speech signals, the level indicator shall have a reference position indicating the level to which an appropriate applied reference or calibration signal shall be adjusted.

Manual signal level adjustment and/or monitoring may not be applicable for particular tests using fixed signal sources (e.g. speech test material internally stored in the speech audiometer) or automatic level adjustment. In this case, the manufacturer shall specify the appropriate signal level adjustment and/or monitoring method.

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 specified ear simulator or acoustic coupler as used for the calibration of pure tones, with the hearing level control set at the stated value and the input activated by a specified signal of stated level which brings the monitor indicator to its reference indication.

8.3 Sound pressure level and vibratory force level acceptance limits

When one signal channel is connected to the earphone, the sound pressure level produced minus the reference equivalent threshold level shall be no more than ± 3,0 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 ± 5,0 dB at frequencies up to and including 16 kHz.

Similarly the force level produced by the bone vibrator minus the reference equivalent threshold force level shall not differ by more than ± 4,0 dB in the frequency range 250 Hz to 4 kHz and by ± 5,0 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 ± 1,0 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 these levels shall not differ by more than ± 2,0 dB and at frequencies above 8 kHz and up to 16 kHz these levels shall not differ by more than ± 3,0 dB. 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 Signal level control

8.4.1 Manual audiometers

For pure tones, the signal level control shall have only one scale, hearing level (HL) and one reference zero point which is common for all frequencies. The signal level control 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.

For speech signals, the signal level control shall be clearly marked as to whether the scale refers to sound pressure level or hearing level (HL) for speech.

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 acceptance limit shall be ± 20 %.

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

8.4.3 Signal level control acceptance limits

The measured difference in output level between two successive indications of signal level or hearing level (HL) which are not more than 5 dB apart shall not deviate from the indicated difference by more than three-tenths of the indicated interval measured in dB or by more than 1 dB, whichever is smaller.

The maximum accumulated deviation from attenuator linearity at any indicated signal level or hearing level (HL) dial setting shall not exceed 1,5 dB from the referenced starting point.

Linearity shall be measured relative to the output sound pressure level, or vibratory force level, produced with the audiometer hearing level control set to the level used for calibration. Step deviation (difference from indicated value) and accumulated deviation (overall deviation) can then be determined at any setting as stated in 8.3.

8.5 Masking sound level control

8.5.1 General

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

8.5.2 Masking sound 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 ISO 389-4:1994, Table 1, the mean values of columns 1 and 2 of ISO 389-4:1994, Table 1, shall be used.

NOTE For EHF instruments the narrow-band masking level can be derived from ISO 389-4:1994, Table 1, presenting data for one-third-octave bands. An approximation would be to use a 5 dB addition to the reference equivalent threshold sound pressure levels.

b) For speech weighted noise the masking sound level control can be specified in terms of sound pressure level (re 20 μPa) or effective masking sound level. It shall be clearly marked whether the scale refers to sound pressure level or effective masking sound level.

c) For other types of sound the masking sound level control shall be calibrated in sound pressure level as measured with the earphone on the same ear simulator or acoustic

coupler 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.

8.5.3 Masking sound level acceptance limits

The level of the masking sound produced by an earphone shall not differ from the indicated value by more than +5,0 / -3,0 dB.

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

NOTE Due to the time-varying nature of masking signals 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 sound level range

Pure-tone 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, in steps of 5 dB or less.

For speech signal masking sound, the masking sound level control shall, relative to its reference position, cover at least a range from 0 dB to 80 dB for the loudspeaker and earphone output level in steps of 5 dB or less.

8.6 Signal switching

8.6.1 Signal switch for manual audiometers

Manual audiometers shall be provided with a switch for the presentation or the interruption of the test signal. The switch and its associated circuitry shall be such that the subject will respond to the test signal rather than to the mechanical noise (see 5.7.5) 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 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 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.

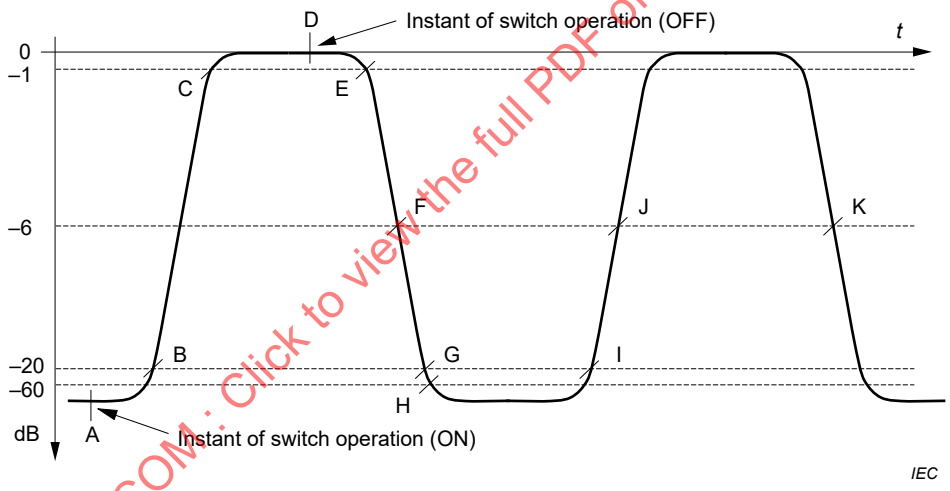


Figure 1 – Rise/fall envelope of test tones

8.6.5 Subject’s response system

The subject’s response system is a means by which the tester is made aware that the subject has responded to the test signal and controls an appropriate function in the audiometer.

The subject’s response system shall be constructed in such a manner as to enable easy and reliable operation by one hand without generating acoustical sound or electrical interference that might result in a hearing threshold level measurement error.

8.6.6 Subject’s response time for automated test procedures

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

9 Reference tone

9.1 General

The following requirements 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 known 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 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 8 kHz.

9.3.2 Intervals

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

The control normally intended for the masking sound level may be used as the reference tone level control provided 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 level expressed in dB (see 8.4).

9.3.4 Acceptance limits

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 ± 3,0 dB of the test tone level for frequencies up to 4 kHz. For frequencies up to 8 kHz the deviation shall be within ± 5,0 dB, and for frequencies up to 16 kHz (where available) the deviation shall be within ± 6,0 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, ISO 8253-2 and ISO 8253-3).

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

Calibration adjustments should be protected either physically (e.g. an internal switch) or by password or other means to prevent any unintended change of calibration. Calibration information stored electronically shall be subject to verification routines to ensure integrity.

Table 5 gives the types of transducer, the standards which specify the appropriate reference equivalent threshold levels and the ear simulator, reference coupler, mechanical coupler, 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 covered by 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.

NOTE 1 ISO 389-9 provides details of preferred test conditions for the determination of reference hearing threshold levels.

If an earphone, whose reference equivalent threshold levels are given for an ear simulator, is to be calibrated on an acoustic coupler, the manufacturer shall provide the reference equivalent threshold levels for the specific type of earphone and specific type of coupler to be used. In this case the calibration of the earphone will not meet the requirements of ISO 389-1 and this shall be documented in the associated calibration report. Calibration of an earphone in this manner shall be restricted to Stage B calibration as defined in ISO 8253-1.

NOTE 2 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 5 – Standards specifying reference equivalent threshold levels

Type of transducer	Reference equivalent threshold levels	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.

The manufacturer shall state the output characteristics, including the impedance, the frequency response and the voltage available across 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 6 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 6 – 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 – unmasked, forehead		
Bone conduction – masked, 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 one-sixth 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 kHz 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 when a measured deviation from the stated requirement equals or does not exceed the acceptance limits for that requirement provided also that the uncertainty of the measurement used to assess conformance does not exceed the maximum permitted uncertainty (U_{max}) in Table 7. When measurements are not appropriate, conformance shall be demonstrated by other means, for example visual inspection (e.g. Clause 15) or examination of supporting documentation (e.g. Clause 5).

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 meet the requirements of 6.2.3.

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 ± 1) kPa and (104 ± 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 meet the requirements of 6.2.3.

13.3 Electromagnetic compatibility

Electromagnetic compatibility shall be tested and demonstrated.

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°.

c) The ambient acoustic noise in the EMC testing space shall be below 55 dB SPL 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 % of the bandwidth being measured. 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 and IEC 60601-1-2.

To avoid possible effects of electromagnetic fields on the measuring microphone an acoustic tube should be inserted between the audiometer earphone, together with a suitable adapter, or loudspeaker and the measuring microphone in order to remove it from the higher level test field.

NOTE Because of the changes a mechanical coupler would cause in the electromagnetic field this device cannot be used to measure the output of bone vibrators in an electromagnetic field. A suitable method has not been developed.

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 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-test 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, 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 6.2.3 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 or acoustic coupler 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 may affect the reliability 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 Microphone for live voice speech testing

Conformity with the specification in 6.1.6 speech microphone frequency response shall be performed under free-field conditions using test signals of a constant sound pressure level (re 20 μPa) of 80 dB filtered from white noise by one-third-octave filters according to IEC 61260-1 centered at the preferred one-third-octave frequencies according to ISO 266.

13.7 Signal accuracy

13.7.1 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 or acoustic coupler. 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.

13.7.2 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 or acoustic coupler. Alternatively, the transducer may be replaced by a dummy electrical load which simulates the transducer at the test frequency.

13.8 Masking sound

13.8.1 Narrow-band noise

Conformity with 6.5.2 shall be demonstrated up to 3,15 kHz by measuring the spectrum of the masking noise acoustically using the same ear simulator or acoustic coupler 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 or acoustic coupler.

13.8.2 Masking sound 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 pressure level at a hearing level setting of 70 dB at all available frequencies and with the same ear simulator or acoustic coupler as used for the measurement of pure tones.

13.9 Headbands

13.9.1 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. The maximum permitted measurement uncertainties are given in Table 7.

13.9.2 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 acceptance limit for the dimensions is ± 5 mm.

13.9.3 Bone vibrator headband

For demonstrating conformity, the spacing of the bone vibrator and the opposite end of the headband shall meet the requirements of 13.9.2, except for forehead placement where the spacing shall be 190 mm with the acceptance limit of ± 5 mm.

14 Maximum permitted expanded uncertainty of measurements U_{max}

Table 7 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 7 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 7, the measurement shall not be used to demonstrate conformance to the requirements of this standard. Please see Annex A for further guidance in the application of Table 7.

Table 7 – Values of U_{max} for basic measurements

Measured quantity	Relevant sub clause number	Basic U_{max}
Sound pressure level 125 Hz to 4 kHz	8.3, 9.3.4	0,7 dB
Sound pressure level 5 kHz to 8 kHz	8.3, 9.3.4	1,2 dB
Sound pressure level 9 kHz to 16 kHz	8.3, 9.3.4	1,5 dB
Frequency	6.2.2	0,5 %
Total harmonic distortion	6.2.3	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	6.2.4	5 %
Repetition rate	6.2.5	5 %
Frequency deviation	6.2.5	5 %
Frequency response	6.3.2	1,0 dB
Narrow-band masking noise cut-off frequencies	6.5.2	1 %
Masking –36 dB level	6.5.2	1,0 dB
Frequency response speech weighted noise	6.5.3	1 %
Level of speech weighted noise	6.5.3	1,5 dB
Speech signal frequency response	6.1.6	1,5 dB
Live voice microphone frequency response	6.1.8	1,5 dB
Masking sound level 125 Hz to 4 kHz	8.5.3	1,0 dB
Force level 250 Hz to 4 kHz	8.3	1,5 dB
Force level greater than 4 kHz	8.3	2,0 dB
Rate of change in level (%)	8.4.2	5 %
Linearity of hearing level control	8.4.3	0,5 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, serial number of the instrument and conform with regulatory and safety marking requirements. In addition, the instrument and/or transducers shall be marked with specific identification; to ensure they are used together.

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 and class (see Table 1), the number and year of this standard which the instrument claims to comply, and all applicable regulatory and safety requirements, 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, reference coupler, mechanical coupler or measurement method 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 sounds provided (see 6.5 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 acceptance limits 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 radiated by the bone vibrator and means to obtain the correct test results

m) For speech classes A-E and B-E audiometers, for the type of earphone provided and for each preferred frequency in the range from 125 Hz to 6,3 kHz, the difference between the free-field sensitivity level and the close-coupled sensitivity level of the earphone for test signals consisting of one-third-octave bands of white noise centered at these frequencies.

n) Reference calibration level; the manual shall contain a warning that only recorded speech material with a stated relationship with the calibration signal should be used. If the speech and calibration signal are not at the same level the method of calibration shall be described. If the level of the calibration signal and the average level of the speech material are different, calibration and test methods should be modified as recommended by the producer of the speech test material.

o) Information about the time window for subject's response for automated test procedures according to 8.6.6.

p) For battery operated instruments: type of battery, means of checking the battery and method of replacement, expected battery life time.

q) Maintenance and calibration procedures and schedules. ISO 8253-1, ISO 8253-2 and ISO 8253-3 give appropriate information.

r) 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.

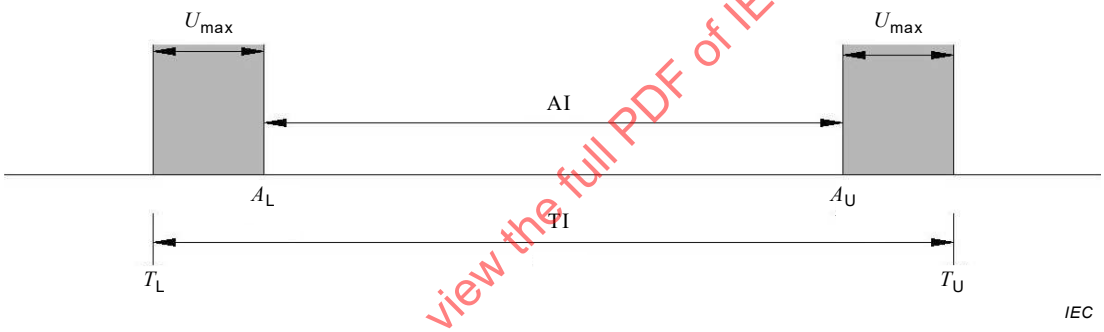
Annex A
(informative)

Relationship between tolerance interval, corresponding acceptance interval and the maximum permitted uncertainty of measurement

This part of IEC 60645, in common with other IEC standards, uses adaptations of the guidelines from ISO/IEC Guide 98-4, *Uncertainty of measurement – Part 4: Role of measurement uncertainty in conformity assessment* (equivalent to guidance document JCGM 106 from the Joint Committee for Guides in Metrology), as the basis for demonstration of conformance of an instrument to the specifications given in this document.

ISO/IEC Guide 98-4 describes guarded acceptance in terms of tolerance intervals, acceptance intervals and uncertainties of measurement.

To promote clarity for users and testing laboratories, the IEC has adopted a policy whereby tolerance limits around design goals are not explicitly stated, but can be determined if required from the specified acceptance limits for allowed deviations from a design goal and the corresponding specified maximum permitted uncertainty of measurement, by using the illustration in Figure A.1.



Key

A I	Acceptance interval
T I	Tolerance interval
U_{max}	Guard band for the maximum permitted uncertainty of measurement for a 95% coverage interval
A_L	Lower acceptance limit
A_U	Upper acceptance limit
T_L	Lower tolerance limit
T_U	Upper tolerance limit

Figure A.1 – Relationship between tolerance interval, corresponding acceptance interval and the maximum permitted uncertainty of measurement

The limits of an acceptance interval are associated with the acceptance interval and not with the guard band for the maximum permitted uncertainty of measurement. Hence a measured deviation equal to a limit of an acceptance interval demonstrates conformance to a specification, providing also that the uncertainty of the measurement from the laboratory performing a test does not exceed the specified maximum permitted uncertainty.

Bibliography

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

[2] 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*

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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ÉLECTROACOUSTIQUE – APPAREILS AUDIOMÉTRIQUES –

Partie 1: Appareils pour l'audiométrie tonale et vocale

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La Norme internationale IEC 60645-1 a été établie par le comité d'études 29 de l'IEC: Electroacoustique.

Cette quatrième édition annule et remplace la troisième édition parue en 2012 et la première édition de l'IEC 60645-2 parue en 1993. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

Cette édition inclut désormais les exigences concernant les audiomètres tonaux (édition précédente de l'IEC 60645-1) et vocaux (édition précédente de l'IEC 60645-2) réunies en un seul document. Les exigences techniques contenues dans cette édition demeurent similaires, dans leur esprit, à celles des deux documents précédents, mais les contradictions éditoriales

et techniques dues à l'existence de deux normes distinctes ayant des cycles de révision différents ont été supprimées.

Le texte de cette Norme internationale est issu des documents suivants:

FDIS	Rapport de vote
29/927/FDIS	29/941/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette norme.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2.

Une liste de toutes les parties de la série IEC 60645, publiées sous le titre général *Electroacoustique – Appareils audiométriques*, peut être consultée sur le site web de l'IEC.

Les futures normes de cette série porteront dorénavant le nouveau titre général cité ci-dessus. Le titre des normes existant déjà dans cette série sera mis à jour lors de la prochaine édition.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives au document recherché. A cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

INTRODUCTION

Les développements dans le domaine des mesures de l'audition à des fins diagnostiques, de préservation ou de réhabilitation de l'ouïe ont entraîné l'apparition sur le marché d'une grande diversité d'audiomètres. En outre, l'audiomètre peut être considéré comme un ensemble d'unités fonctionnelles pouvant être spécifiées séparément. En spécifiant ces unités fonctionnelles, les performances d'autres équipements audiométriques qui utilisent ces unités peuvent alors être spécifiées. La série IEC 60645 est composée de plusieurs parties. L'IEC 60645-1 est la première de la série et elle couvre les exigences concernant les audiomètres tonaux et vocaux.

La présente norme décrit les exigences de performances appliquées aux audiomètres tonaux destinés à la mesure de l'audition dans la plage de fréquences de 125 Hz à 16 kHz, ainsi qu'aux audiomètres vocaux destinés aux techniques audiométriques utilisant la voix naturelle humaine ou la voix enregistrée.

Lorsqu'un audiomètre comporte des dispositifs à signaux vocaux, des exigences de performances sont données pour le matériel vocal utilisant la voix naturelle humaine et la voix enregistrée. Bien que les techniques audiométriques utilisant la voix naturelle humaine puissent ne pas être en mesure de satisfaire aux exigences de la présente norme, elles sont largement pratiquées, en particulier avec les enfants. C'est pourquoi une spécification les concernant a été incluse pour garantir le plus haut degré de fiabilité possible. La présente norme ne spécifie pas le matériel vocal utilisé pour les essais, ni les propriétés acoustiques exigées de la salle d'essai.[1]

Les audiomètres vocaux utilisent des écouteurs ou des haut-parleurs pour présenter les signaux au sujet d'essai. Dans la présente norme, les spécifications des caractéristiques de performances des audiomètres vocaux ainsi que les méthodes d'étalonnage et d'essai appropriées sont données à la fois pour la méthode du niveau de sortie équivalent en champ libre et pour la méthode du niveau de sortie de simulateur d'oreille ou de coupleur acoustique non corrigé.

Afin de relier l'écoute par écouteur à une écoute en champ acoustique, le concept de niveau de sortie équivalent en champ libre d'un écouteur, décrit dans l'IEC 60268-7, est utilisé aux fins de spécification et de mesure.

Bien qu'il soit admis d'utiliser des ossivibrateurs en audiométrie vocale, leurs performances peuvent être extrêmement variables lorsque des signaux vocaux sont utilisés. Par conséquent, seules des spécifications de "bonnes pratiques" bien connues sont données pour la conduction osseuse utilisant des signaux vocaux afin de garantir une certaine cohérence lorsque cette fonction est assurée.

Les exigences d'essai destinées à démontrer la conformité des audiomètres sont à présent spécifiées indépendamment. La conformité aux spécifications de performances de la présente norme est démontrée lorsque l'écart mesuré par rapport à un objectif de conception est inférieur ou égal à la ou aux limites d'acceptation correspondantes et que le laboratoire a démontré que l'incertitude de mesure associée est inférieure ou égale à l'incertitude maximales permise spécifiées dans la présente norme. Les exigences concernant les audiomètres sont essentiellement les mêmes que dans les éditions précédentes de l'IEC 60645-1 et de l'IEC 60645-2.

[1] Ces exigences sont spécifiées dans l'ISO 8253-1.

ÉLECTROACOUSTIQUE – APPAREILS AUDIOMÉTRIQUES –

Partie 1: Appareils pour l'audiométrie tonale et vocale

1 Domaine d'application

La présente partie de l'IEC 60645 spécifie les exigences générales applicables aux audiomètres destinés à la détermination des seuils d'audition, par rapport aux seuils de référence normalisés établis au moyen de méthodes d'essai psychoacoustiques, ainsi qu'aux audiomètres destinés à la réalisation d'essais psychoacoustiques sur du matériel vocal.

L'objet de la présente norme est de s'assurer:

a) que les essais d'audition effectués sur une oreille humaine donnée dans la plage de fréquences de 125 Hz à 16 kHz avec différents audiomètres tonaux conformes à la présente norme donnent sensiblement les mêmes résultats;

b) que les résultats obtenus constituent une comparaison correcte entre l'audition de l'oreille mesurée et le seuil d'audition de référence;

c) qu'un moyen de présenter un matériel vocal à un sujet de manière normalisée est fourni. Cela permettra de s'assurer que les essais d'audition faisant appel à un signal vocal spécifique et à une manière spécifique de présenter le signal donnent sensiblement les mêmes résultats lorsqu'ils sont pratiqués avec différents audiomètres conformes à la présente norme,

d) que les audiomètres sont classés conformément à la plage de signaux d'essai qu'ils présentent, conformément à leur mode de fonctionnement ou conformément à leur application principale présumée.

2 Références normatives

Les documents suivants cités dans le texte constituent, pour tout ou partie de leur contenu, des exigences du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

IEC 60268-3, *Equipements pour systèmes électroacoustiques – Partie 3: Amplificateurs*

IEC 60268-7, *Equipements pour systèmes électroacoustiques – Partie 7: Casques et écouteurs*

IEC 60268-17, *Equipements pour systèmes électroacoustiques – Partie 17: Indicateurs de volume normalisés*

IEC 60318-1, *Electroacoustique – Simulateurs de tête et d'oreille humaines – Partie 1: Simulateur d'oreille pour la mesure des écouteurs supra-auraux et circumauraux*

IEC 60318-3, *Electroacoustique – Simulateurs de tête et d'oreille humaines – Partie 3: Coupleur acoustique pour l'étalonnage des écouteurs supra-auraux utilisés en audiométrie*

IEC 60318-4, *Electroacoustique – Simulateurs de tête et d'oreille humaines – Partie 4: Simulateur d'oreille occluse pour la mesure des écouteurs couplés à l'oreille par des embouts*

IEC 60318-5, *Electroacoustique – Simulateurs de tête et d'oreille humaines – Partie 5: Coupleur de 2 cm³ pour la mesure des appareils de correction auditive et des écouteurs couplés à l'oreille par des embouts*

IEC 60318-6, *Electroacoustique – Simulateurs de tête et d'oreille humaines – Partie 6: Coupleur mécanique destiné à la mesure des ossivibrateurs*

IEC 60601-1, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*

IEC 60601-1-2, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques —Exigences et essais*

IEC 61260-1, *Electroacoustique – Filtres de bande d'octave et de bande d'une fraction d'octave – Partie 1: Spécifications*

IEC 61672-1, *Electroacoustique – Sonomètres – Partie 1: Spécifications*

ISO 266, *Acoustique – Fréquences normales*

ISO 389-1, *Acoustique – Zéro de référence pour l'étalonnage d'équipements audiométriques – Partie 1: Niveaux de référence équivalents de pression acoustique liminaire pour les écouteurs à sons purs supra-auraux*

ISO 389-2, *Acoustique – Zéro de référence pour l'étalonnage d'équipements audiométriques – Partie 2: Niveaux de référence équivalents de pression acoustique liminaire pour les écouteurs à sons purs et à insertion*

ISO 389-3, *Acoustique – Zéro de référence pour l'étalonnage d'équipements audiométriques – Partie 3: Niveaux de référence équivalents de force liminaire pour les vibrateurs à sons purs et les ossivibrateurs*

ISO 389-4:1994, *Acoustique – Zéro de référence pour l'étalonnage d'équipements audiométriques – Partie 4: Niveaux de référence pour bruit de masque en bande étroite*

ISO 389-5, *Acoustique – Zéro de référence pour l'étalonnage d'équipements audiométriques – Partie 5: Niveaux de référence équivalents de pression acoustique liminaire pour les sons purs dans le domaine de fréquences de 8 kHz à 16 kHz*

ISO 389-7, *Acoustique – Zéro de référence pour l'étalonnage d'équipements audiométriques – Partie 7: Niveau liminaire de référence dans des conditions d'écoute en champ libre et en champ diffus*

ISO 389-8, *Acoustique – Zéro de référence pour l'étalonnage d'équipements audiométriques – Partie 8: Niveaux de référence équivalents de pression acoustique liminaire pour les écouteurs à sons purs circumauraux*

ISO 4869-1, *Acoustique – Protecteurs individuels contre le bruit – Partie 1: Méthode subjective de mesurage de l'affaiblissement acoustique*

ISO 8253-1:2010, *Acoustique – Méthodes d'essais audiométriques – Partie 1: Audiométrie à sons purs en conduction aérienne et en conduction osseuse*

ISO 8253-2, *Acoustique – Méthodes d'essais audiométriques – Partie 2: Audiométrie en champ acoustique avec des sons purs et des bruits à bande étroite comme signaux d'essai*

ISO 8253-3, *Acoustique – Méthodes d'essais audiométriques – Partie 3: Audiométrie vocale*

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions suivants s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

3.1
appareil pour l'audiométrie à sons purs
audiomètre tonal
instrument destiné à la mesure de l'audition pour les sons purs et en particulier à la mesure du seuil d'audition

Note 1 à l'article: L'audiomètre tonal peut être de deux types: à fréquences fixes ou à balayage continu de fréquences.

3.2
audiomètre manuel
audiomètre pour lequel la présentation des signaux ainsi que l'enregistrement des résultats sont effectués manuellement

3.3
audiomètre automatique enregistreur
audiomètre pour lequel la présentation des signaux, la variation du niveau d'audition, le choix ou la variation de la fréquence, ainsi que l'enregistrement des réponses du sujet sont exécutés automatiquement

Note 1 à l'article: La variation du niveau d'audition est commandée par le sujet et enregistrée automatiquement.

3.4
appareil pour l'audiométrie vocale
audiomètre vocal
instrument destiné à la mesure de l'audition à l'aide de matériel vocal

3.5
conduction aérienne
transmission des ondes acoustiques à l'oreille interne par l'intermédiaire de l'oreille externe et de l'oreille moyenne

3.6
conduction osseuse
stimulation de l'oreille interne principalement par l'intermédiaire de la vibration mécanique des os du crâne

3.7
haute fréquence étendue
EHF
fréquence d'essai audiométrique dans la plage de 8 kHz à 16 kHz

Note 1 à l'article: La fréquence de 8 kHz est considérée comme la fréquence la plus élevée de la plage conventionnelle et comme la fréquence la plus basse de la plage haute fréquence étendue.

Note 2 à l'article: L'abréviation "EHF" est dérivée du terme anglais développé correspondant "extended high-frequency".

3.8
individu otologiquement normal
personne en bonne santé, ne présentant pas de signes ou de symptômes de troubles auditifs, dont le conduit auditif externe n'est pas obstrué par du cérumen, qui n'a pas été exposée de façon anormale au bruit ou à des produits potentiellement toxiques pour l'oreille et qui ne présente pas de perte héréditaire d'audition

3.9
niveau équivalent de pression acoustique liminaire
écoute monaurale par écouteur
pour une oreille donnée, à une fréquence spécifiée, pour un type spécifié d'écouteur et pour une force donnée d'application de l'écouteur sur une oreille humaine, niveau de pression acoustique produit par l'écouteur dans un simulateur d'oreille ou un coupleur acoustique spécifié lorsque l'écouteur est excité par l'entrée électrique qui correspondrait au seuil d'audition lorsque l'écouteur est appliqué à l'oreille concernée

3.10
niveau équivalent de force liminaire
écoute monaurale
pour une oreille donnée, à une fréquence spécifiée, pour une configuration et un modèle spécifiés d'ossivibrateur sur un coupleur mécanique spécifié, niveau de force vibratoire produit par l'ossivibrateur sur un coupleur mécanique spécifié, lorsque l'ossivibrateur est excité par la tension qui correspondrait au seuil d'audition lorsque l'ossivibrateur est appliqué sur l'apophyse mastoïde ou sur le front

Note 1 à l'article: Cette définition nécessite que l'oreille non soumise à l'essai soit masquée conformément à l'ISO 389-4.

3.11
niveau de référence équivalent de pression acoustique liminaire
RETSPL
à une fréquence spécifiée, valeur médiane, moyenne ou modale des niveaux équivalents de pression acoustique liminaire pour un nombre suffisamment grand d'oreilles de sujets otologiquement normaux, des deux sexes, âgés de 18 ans à 25 ans inclus, exprimant le seuil d'audition correspondant à un simulateur d'oreille ou à un coupleur acoustique spécifié pour un type d'écouteur spécifié

Note 1 à l'article: Des valeurs du niveau de référence équivalent de pression acoustique liminaire sont spécifiées dans l'ISO 389-1, l'ISO 389-2, l'ISO 389-5 et l'ISO 389-8.

Note 2 à l'article: Certaines parties de la série de normes ISO 389 spécifient les niveaux de référence équivalents liminaires pour les sujets âgés de 18 ans à 30 ans inclus.

Note 3 à l'article: L'abréviation "RETSPL" est dérivée du terme anglais développé correspondant "reference equivalent threshold sound pressure level".

3.12
niveau de référence équivalent de force liminaire
RETFL
à une fréquence spécifiée, valeur moyenne des niveaux équivalents de force liminaire d'un nombre suffisamment grand d'oreilles de sujets otologiquement normaux, des deux sexes, âgés de 18 ans à 25 ans inclus, exprimant le seuil d'audition pour un coupleur mécanique spécifié et pour une configuration et un modèle donnés d'ossivibrateur

Note 1 à l'article: Des valeurs moyennes de niveaux de référence équivalents de force vibratoire liminaire sont spécifiées dans l'ISO 389-3.

Note 2 à l'article: Certaines parties de la série de normes ISO 389 spécifient les niveaux de référence équivalents liminaires pour les sujets âgés de 18 ans à 30 ans inclus.

Note 3 à l'article: L'abréviation "RETFL" est dérivée du terme anglais développé correspondant "reference equivalent threshold force level".

3.13
sensibilité paraphonique
à une fréquence donnée, quotient du niveau de pression acoustique produite par l'écouteur dans un simulateur d'oreille ou un coupleur acoustique par la tension appliquée aux bornes de l'écouteur

3.14
niveau de sensibilité paraphonique
dix fois le logarithme décimal du quotient du carré de la sensibilité paraphonique par le carré de la sensibilité de référence, exprimé sous la forme 1 Pa/V

3.15
sensibilité en champ libre
à une fréquence donnée et pour au moins 10 sujets otologiquement normaux, quotient du niveau de pression acoustique d'une onde sonore progressive plane à incidence frontale (incidence sonore à 0°) par la tension de fréquence équivalente appliquée aux bornes de l'écouteur afin que les sujets, en moyenne, jugent que l'onde sonore et le son produit par l'écouteur ont un niveau équivalent, les deux sons étant reçus dans la même oreille

Note 1 à l'article: Les méthodes d'essai sont définies dans l'IEC 60268-7. Bien que la comparaison de la tonie puisse se faire de manière binaurale, la sensibilité qui en résulte est celle d'un écouteur simple.

3.16
niveau de sensibilité en champ libre
dix fois le logarithme décimal du quotient du carré de la sensibilité en champ libre par le carré de la sensibilité de référence, exprimé sous la forme 1 Pa/V

Note 1 à l'article: La sensibilité en champ libre et le niveau de sensibilité en champ libre d'un ossivibrateur sont définis de manière correspondante.

3.17
niveau de sortie d'écouteur équivalent en champ libre
pour un audiomètre vocal, niveau de pression acoustique produit par un écouteur et corrigé de la différence entre le niveau de sensibilité paraphonique et le niveau de sensibilité en champ libre de l'écouteur

3.18
niveau d'audition pour un son pur
HL
à une fréquence spécifiée, pour un type de transducteur particulier appliqué d'une manière spécifiée, différence entre le niveau de pression acoustique ou de force vibratoire correspondant au signal produit par le transducteur dans un simulateur d'oreille, dans un coupleur acoustique ou dans un coupleur mécanique spécifié, et le niveau de référence équivalent de pression acoustique liminaire ou le niveau de référence équivalent de force liminaire

Note 1 à l'article: L'abréviation "HL" est dérivée du terme anglais développé correspondant "hearing level".

3.19
seuil d'audition pour un son pur
à une fréquence spécifiée, seuil d'audition à cette fréquence exprimé sous forme de niveau d'audition

Note 1 à l'article: Des méthodes de détermination des seuils d'audition sont spécifiées dans l'ISO 8253-1.

3.20
niveau d'audition pour la voix
pour un signal vocal spécifié et une manière spécifiée de présenter le signal, différence entre le niveau vocal et le niveau de référence approprié du seuil de reconnaissance vocale

3.21
signal vocal
signal d'essai produit par un être humain ou une voix synthétique

3.22
niveau vocal
niveau de pression acoustique ou niveau de force vibratoire du signal vocal mesuré dans un simulateur d'oreille, un coupleur acoustique ou un coupleur mécanique approprié, ou bien dans un champ acoustique avec une pondération fréquentielle et une pondération temporelle spécifiées

3.23
niveau du seuil de reconnaissance vocale
niveau SRT
pour un sujet d'essai donné, un signal vocal spécifié et une manière spécifiée de présenter le signal, niveau vocal le plus bas pour lequel le taux de reconnaissance vocale est égal à 50 %

Note 1 à l'article: L'abréviation "SRT" est dérivée du terme anglais correspondant "speech recognition threshold".

3.24
niveau SRT de référence
pour un signal vocal spécifié et une manière spécifiée de présenter le signal, valeur médiane des niveaux de seuil de reconnaissance vocale sur la base d'un nombre suffisamment important de sujets d'essai otologiquement normaux, des deux sexes, âgés de 18 ans à 25 ans inclus et pour lesquels le matériel d'essai est approprié

3.25
simulateur d'oreille
dispositif prévu pour mesurer la sortie acoustique des sources sonores, la pression acoustique étant mesurée par un microphone étalonné couplé à la source de sorte que l'impédance acoustique globale du dispositif soit une approximation de celle de l'oreille humaine normale en un endroit donné et dans une plage de fréquences donnée

Note 1 à l'article: Deux types de simulateurs d'oreilles sont spécifiés dans l'IEC 60318-1 et l'IEC 60318-4.

3.26
coupleur acoustique
dispositif prévu pour mesurer la sortie acoustique des sources sonores, le niveau de pression acoustique étant mesuré par un microphone étalonné, couplé à la source par une cavité de forme et de volume prédéterminés dont l'impédance n'est pas nécessairement une approximation de l'impédance acoustique de l'oreille humaine normale

Note 1 à l'article: Deux types de coupleurs acoustiques sont spécifiés dans l'IEC 60318-3 et l'IEC 60318-5.

3.27
coupleur mécanique
dispositif conçu pour présenter une impédance mécanique spécifiée à un vibrateur appliqué avec une force statique spécifiée, et équipé d'un transducteur mécano-électrique permettant de déterminer le niveau de force vibratoire à la surface de contact entre le vibrateur et le coupleur mécanique

Note 1 à l'article: Un coupleur mécanique est spécifié dans l'IEC 60318-6.

3.28
masquage
processus selon lequel le seuil d'audition d'un son est augmenté en raison de la présence d'un autre son (masquant)

3.29
niveau de masquage effectif
niveau d'un son masquant spécifié numériquement égal au niveau d'audition auquel s'élèverait le seuil d'audition d'un son pur en cas de présence du son masquant, pour une personne réputée normale

Note 1 à l'article: La personne réputée normale est une personne dont l'audition est conforme aux normes pour le seuil et pour l'efficacité du masquage (voir l'ISO 389-1, l'ISO 389-2, l'ISO 389-4 et l'ISO 389-8).

Note 2 à l'article: Le niveau de masquage effectif est donc analogue au niveau d'audition (voir 3.18), c'est-à-dire qu'il correspond à une mesure physique du son, indépendamment de l'oreille à l'essai particulière.

Note 3 à l'article: Des valeurs de référence pour le masquage effectif sont données dans l'ISO 389-4.

3.30
bruit vocal pondéré
bruit aléatoire pondéré du masquage de la voix

3.31
niveau de masquage effectif pour la voix
niveau d'un son masquant spécifié numériquement égal au niveau d'audition pour la voix auquel s'élèverait le seuil de reconnaissance vocale pour un signal vocal spécifié en cas de présence du son masquant, pour une personne présentant une audition normale

Note 1 à l'article: La personne présentant une audition normale est une personne dont l'audition satisfait aux normes en termes de seuil et d'efficacité du masquage (voir l'ISO 389-1 et l'ISO 389-4).

4 Exigences par type et par classe d'audiomètre

Quatre types d'audiomètres tonaux sont spécifiés en fonction des exigences relatives aux dispositifs obligatoires minimaux répertoriés dans le Tableau 1. D'autres dispositifs ne sont pas exclus. Les quatre types correspondent à l'application principale présumée.

Deux classes d'audiomètres vocaux sont spécifiées et les exigences applicables aux dispositifs minimaux sont répertoriées dans le Tableau 1.

Tableau 1 – Dispositifs minimaux des audiomètres

Dispositif	Types tonaux					Classe vocale	
	Type 1 Pratique clinique avancée/ Recherche	Type 2 Pratique clinique	Type 3 Diagnostic fondamental	Type 4 Dépistage et contrôle	EHF [g] Hautes fréquences étendues	Classe A	Classe B
Transducteurs							
– deux écouteurs	X	X	X	X	X	X[d]	X[d]
– deux écouteurs à insertion	X						
– deux haut-parleurs ou sorties électriques [e]	X	X				X	
– conduction osseuse	X	X	X			X	
Niveaux d'audition et fréquences d'essai (voir Tableau 2)	X	X	X	X	X	X	X
Commande de niveau de sortie	X	X	X	X	X	X	X
Commande de niveau du bruit de masquage	X	X	X		X	X	X
Commutation des signaux d'essai							
– présentation/interruption	X	X	X	X [b]	X	X	X
– son pulsé	X	X			X		
– modulation de fréquence (FM)	X	X					
Son de référence [c]							
– présentation alternée	X	X					
– présentation simultanée	X						
Entrée vocale							
– indicateur de niveau du signal	X	X				X	X
– moniteur acoustique ou visuel pour matériel d'essai vocal						X	X
– dispositif de lecture intégré ou entrée de signal externe	X [f]	X [f]				X [f]	X [f]
– microphone pour essais vocaux en voix naturelle						X	
– communication vocale entre l'opérateur et le sujet						X	
Masquage							
– bruit à bande étroite	X	X	X		X		
– bruit dans le spectre vocal						X	X
Application du bruit de masquage							
– écouteur controlatéral	X	X	X		X	X	X
– écouteur ipsilatéral	X					X	
– haut-parleur ou sortie électrique [e]	X	X				X	
– ossivibrateur	X					X	
Dispositif de réponse du sujet	X	X	X	X[a]	X		
Indicateur de signal	X	X			X	X	X
Contrôle du signal d'essai	X					X	X
Système Talk-forward	X	X				X	
Système Talk-back	X					X	

[a] Non obligatoire pour les audiomètres manuels.

[b] Non obligatoire pour les audiomètres automatiques enregistreurs.

[c] L'exigence minimale concerne la présentation de sons de référence de même fréquence que les sons d'essai.

[d] L'équivalent en champ libre n'est pas obligatoire, mais recommandé. Le cas échéant, l'audiomètre doit en outre être conçu en classe vocale E. L'audiomètre relèvera donc de la classe A-E ou B-E.

[e] Le fabricant doit spécifier la façon dont la conformité à la présente norme doit être assurée si l'amplificateur de puissance et les haut-parleurs ne sont pas fournis avec l'audiomètre.

[f] Le dispositif de lecture n'est pas toujours fourni par le fabricant de l'audiomètre.

[g] La plage des hautes fréquences étendues (EHF) est facultative pour les quatre types d'audiomètres tonaux.

5 Exigences générales

5.1 Exigences relatives à la sécurité générale

Sauf spécification contraire dans la présente norme, les audiomètres doivent être conformes aux exigences de l'IEC concernant la sécurité (voir l'IEC 60601-1).

5.2 Exigences relatives à la sécurité acoustique

Etant donné que les audiomètres peuvent produire des niveaux de pression acoustique qui pourraient être dommageables pour l'audition, une indication non auditive doit prévenir l'opérateur pour tous les réglages supérieurs à un niveau d'audition (HL) de 100 dB.

5.3 Conditions d'environnement

Les spécifications doivent être satisfaites pour des combinaisons données de température dans la plage de 15 °C à 35 °C, d'humidité relative dans la plage de 30 % à 90 % et de pression atmosphérique dans la plage de 98 kPa à 104 kPa.

Les valeurs réelles des paramètres d'environnement au moment de l'étalonnage doivent être spécifiées.

Les niveaux de référence équivalents de pression acoustique liminaire mesurés peuvent différer de façon significative lorsque la pression atmosphérique est en dehors de la plage ci-dessus. Il convient donc de procéder à l'étalonnage sur le site de l'utilisateur dans des conditions types de pression et de température ambiantes. Lorsque le site de l'étalonnage et le site de l'utilisateur ne partagent pas des conditions ambiantes similaires, il convient d'appliquer les corrections appropriées aux effets environnementaux selon les recommandations du fabricant.

5.4 Durée de préchauffage

Les exigences de performances doivent être satisfaites lorsque la durée de préchauffage spécifiée s'est écoulée et que tous les réglages préliminaires ont été effectués selon les instructions du fabricant. La durée de préchauffage minimale doit être spécifiée par le fabricant et ne doit pas dépasser 10 min lorsque l'audiomètre a été maintenu à la température ambiante de l'environnement d'essai.

5.5 Variation de l'alimentation

5.5.1 Coupure de l'alimentation

Pour toute interruption de l'alimentation pendant 5 s au maximum, l'audiomètre doit revenir à une condition qui sera sans risque pour l'audition du sujet et ne conduira pas à des résultats erronés.

5.5.2 Fonctionnement sur le secteur

Les spécifications doivent être satisfaites pour tout écart à long terme de la tension ou de la fréquence d'alimentation pour la combinaison la moins favorable comprise dans des limites de ± 10 % pour la tension par rapport à la valeur spécifiée et de ± 5 % pour la fréquence par rapport à la valeur spécifiée.

Pour toute interruption de la tension d'alimentation pendant 5 s au maximum, l'audiomètre doit revenir à une condition qui sera sans risque pour l'audition du sujet et ne conduira pas à des résultats erronés.

5.5.3 Fonctionnement sur batterie

Le fabricant doit spécifier les limites de tension de la batterie à l'intérieur desquelles les spécifications doivent être satisfaites. L'audiomètre doit comporter un indicateur convenable permettant de s'assurer que la tension de la batterie demeure dans les limites spécifiées. Les spécifications de l'audiomètre doivent être satisfaites pour toute tension de batterie comprise à l'intérieur des limites spécifiées.

5.5.4 Autres types d'alimentations

Si l'audiomètre est alimenté par un autre type d'alimentation que le secteur ou une batterie, le fabricant doit spécifier le type d'alimentation, ses caractéristiques ainsi que les tolérances à l'intérieur desquelles les spécifications de l'audiomètre doivent être satisfaites.

5.6 Compatibilité électromagnétique

Pendant et à la suite de tout essai concernant la compatibilité électromagnétique, dans les conditions d'essai de compatibilité électromagnétique conformément à l'IEC 60601-1-2, le son indésirable produit par tout transducteur à conduction aérienne ne doit pas dépasser un niveau d'audition correspondant à 80 dB. Le Paragraphe 13.3 fournit des méthodes permettant de démontrer la conformité.

5.7 Sons indésirables

5.7.1 Généralités

Certaines mesures acoustiques objectives (voir 13.4) peuvent être inapplicables aux essais destinés à détecter la présence de sons indésirables produits par l'audiomètre. En conséquence, des essais subjectifs doivent être effectués avec au moins deux sujets d'essai otologiquement normaux, dont les seuils d'audition ne doivent pas dépasser 10 dB pour les fréquences d'essai comprises entre 250 Hz et 8 kHz. La salle d'essai pour les essais subjectifs doit satisfaire aux exigences de l'ISO 8253-1:2010, Tableau 4 (voir la colonne droite du tableau). Pour les audiomètres fonctionnant dans la plage des hautes fréquences étendues (EHF), ces essais doivent couvrir les fréquences atteignant les niveaux de fréquences disponibles les plus élevés.

NOTE Pour la plage de fréquences dépassant 8 kHz, les salles d'essai conformes à l'ISO 8253-1 ont montré en pratique qu'elles fournissaient des niveaux de bruit ambiant suffisamment faibles.

5.7.2 Sons indésirables émis par et entre une combinaison quelconque de transducteurs

Les mesures suivantes doivent être mises en œuvre par le fabricant dans le cadre de la validation de conception des audiomètres afin de satisfaire aux exigences prévues en 5.7, pour toute combinaison de transducteurs. Des essais doivent être effectués pour la diaphonie, les interférences ou les fuites entre tous les transducteurs (p. ex.: écouteurs, écouteurs à insertion, ossivibrateurs, haut-parleurs ou moniteurs). Tout son indésirable présent dans un transducteur inactif doit être inférieur à 0 dB HL. Elle doit être mesurée par bandes de tiers d'octaves sur l'ensemble des fonctions d'essai fournies par l'audiomètre. Le son indésirable présent dans une bande de tiers d'octave ne doit pas dépasser les niveaux de pression acoustique ou de force de référence spécifiques pour chaque transducteur inactif mesuré. Les mesures doivent être exécutées électriquement.

L'exigence doit être satisfaite avec lorsque les signaux de tous les transducteurs actifs choisis sont en marche, à un niveau d'audition de 60 dB ou à la sortie maximale (la valeur retenue étant la plus faible des deux). La méthode de mesure électrique indirecte doit être utilisée pour valider les performances de la manière décrite en 13.4.1.

5.7.3 Sons indésirables émis par un écouteur

Un écouteur peut émettre des sons indésirables provenant de signaux électriques produits de différentes manières dans l'audiomètre lorsque le commutateur de signal est sur "ARRET". Un son indésirable (appelé communément "interférence" ou diaphonie) peut également être émis dans l'écouteur qui n'est pas soumis à l'essai lorsque le son d'essai est en "MARCHE". Des exigences particulières et une méthode de mesure électrique indirecte ainsi qu'une méthode subjective de vérification des performances doivent être appliquées de la manière décrite en 13.4.1.

Un son indésirable peut également se produire dans l'écouteur en raison d'une efficacité imparfaite du commutateur signal. Les exigences relatives au commutateur de signal sont données en 8.6.

5.7.4 Sons indésirables émis par un ossivibrateur

Le fabricant doit spécifier à quelles fréquences d'essai l'ossivibrateur pourrait rayonner des sons d'une intensité telle que le son atteignant l'oreille à l'essai en conduction aérienne à travers le conduit auditif externe non occlus peut affecter la fiabilité de la mesure en conduction osseuse. Le fabricant doit également spécifier l'étendue possible de cette influence. Une méthode permettant de démontrer la conformité à cette exigence est donnée en 13.4.2.

5.7.5 Sons indésirables rayonnés par un audiomètre

Lorsque les audiomètres sont destinés à être utilisés dans la salle où est placé le sujet, tout son dû au fonctionnement des commandes de l'audiomètre pendant l'essai d'audition réel, au rayonnement émis par l'audiomètre ou au rayonnement émis par un élément d'un système informatique utilisé conjointement avec l'audiomètre doit être inaudible à chaque réglage du niveau d'audition inférieur ou égal à 50 dB. Une méthode permettant de démontrer la conformité à cette exigence est donnée en 13.4.3.

Cette limitation sur le bruit provenant des commandes s'applique à tout bruit, qui pourrait fournir au patient une indication susceptible d'influer sur les résultats d'essai. Il n'est pas prévu de l'appliquer à un mécanisme tel qu'un commutateur activé par le patient, un sélecteur de sortie ou un cran sur le commutateur de fréquence, qui pourrait produire un bruit sans toutefois influencer les résultats d'essai.

5.8 Essais d'audiomètres automatiques enregistreurs

Les audiomètres automatiques enregistreurs doivent être munis de dispositifs permettant de régler les signaux de manière appropriée pour la mesure des caractéristiques de l'audiomètre.

5.9 Liaisons d'interface

L'étalonnage de l'audiomètre ne doit pas pouvoir être modifié de manière non intentionnelle par l'intermédiaire de n'importe quelle interface.

6 Signaux d'essai

6.1 Signaux vocaux

6.1.1 Exigences générales applicables aux signaux vocaux

Le fabricant doit spécifier les caractéristiques et les limites d'acceptation des signaux fournis. Les audiomètres vocaux doivent fournir la plage minimale des niveaux d'audition, indiquée dans la colonne appropriée du Tableau 2.

Pour que les résultats des écouteurs d'audiométrie vocale utilisant des audiomètres des classes A-E et B-E soient comparables à ceux des essais du champ acoustique de haut-parleur ou aux résultats obtenus en utilisant différents types de transducteurs, des conditions de mesure équivalentes au champ acoustique doivent être utilisées pour spécifier et soumettre à l'essai les caractéristiques de l'audiomètre vocal.

Pour les audiomètres des classes A et B pour lesquels il n'existe pas d'exigence visant à assurer une telle comparabilité, les conditions de mesure d'écouteurs non corrigés doivent être utilisées pour spécifier et soumettre à l'essai les caractéristiques de l'audiomètre vocal.

Pour les limites d'acceptation relatives à l'utilisation des conditions de mesure d'écouteurs non corrigés, voir 6.3.2.

6.1.2 Niveau de sortie d'écouteur équivalent en champ libre

Pour les audiomètres des classes A-E et B-E, le niveau de pression acoustique de sortie et la réponse en fréquence globale de l'audiomètre vocal, y compris l'écouteur, doivent être spécifiés en termes de niveau de pression acoustique équivalent en champ libre. La méthode de mesure fondamentale du niveau de pression acoustique équivalent en champ libre d'écouteurs est décrite dans l'IEC 60268-7.

NOTE Les étalonnages périodiques peuvent être effectués à l'aide d'un simulateur d'oreille ou d'un coupleur acoustique et en appliquant des valeurs de correction pour la différence entre le niveau de sensibilité en champ libre et le niveau de sensibilité paraphonique pour le type d'écouteur en cours d'essai.

6.1.3 Niveau de sortie d'écouteur non corrigé

Pour les audiomètres des classes A et B, le niveau de pression acoustique de sortie et la réponse en fréquence globale de l'audiomètre vocal, y compris l'écouteur, doivent être spécifiés en termes de niveau de pression acoustique non corrigé, mesuré dans un simulateur d'oreille conformément à l'IEC 60318-1 ou à l'IEC 60318-4 ou dans un coupleur acoustique conformément à l'IEC 60318-3 ou à l'IEC 60318-5. Le fabricant doit spécifier la méthode de mesure, ainsi que le simulateur d'oreille ou le coupleur acoustique employé.

6.1.4 Niveau de sortie de haut-parleur

Le niveau de pression acoustique de sortie et la réponse en fréquence globale de l'audiomètre vocal, y compris le haut-parleur, doivent être spécifiés selon une mesure effectuée dans le champ acoustique à une distance minimale de 1 m sur l'axe de référence du haut-parleur.

NOTE Les performances mesurées dans les conditions de référence peuvent ne pas s'appliquer dans des conditions autres que celles d'un champ acoustique et d'une distance de 1 m.

6.1.5 Niveau de sortie d'ossivibrateur

Pour les audiomètres des classes A-E et B-E, le niveau de force vibratoire en sortie et la réponse en fréquence globale de l'audiomètre vocal, y compris l'ossivibrateur, doivent être spécifiés en termes de niveau de pression acoustique équivalent en champ libre. S'il n'existe pas de données correspondant au type d'ossivibrateur utilisé, les caractéristiques doivent être spécifiées en termes de niveau de force vibratoire non corrigé, mesuré sur un coupleur mécanique conforme à l'IEC 60318-6.

6.1.6 Réponse en fréquence d'un signal vocal

Pour les conditions de référence données en 6.1.4 et les signaux spécifiés en 13.6, le niveau de pression acoustique de sortie produit par le haut-parleur doit être compris à l'intérieur des limites d'acceptation suivantes:

Si des filtres de bande de tiers d'octave sont utilisés, le niveau de pression acoustique produit par le haut-parleur avec un signal d'essai quelconque centré sur la fréquence médiane du