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# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

Part 1: Equipment for pure-tone and speech audiometry (Standards.iten.al)

Électroacoustique – Appareils audiométriques – Partie 1: Appareils pour l'audiométrie tonale et vocale 4741-80bb-

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Tel.: +41 22 919 02 11 **IEC Central Office** 3, rue de Varembé Fax: +41 22 919 03 00

CH-1211 Geneva 20 info@iec.ch Switzerland www.iec.ch

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Edition 4.0 2017-03

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

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

Électroacoustique – Appareils audiométriques –
Partie 1: Appareils pour l'audiométrie tonale et vocale 4741-80bb-

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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### INTERNATIONAL ELECTROTECHNICAL COMMISSION

### **ELECTROACOUSTICS - AUDIOMETRIC EQUIPMENT -**

### Part 1: Equipment for pure-tone and speech audiometry

### **FOREWORD**

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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 ANDARD PREVIEW
- amended. (standards.iteh.ai)

IEC 60645-1:2017 https://standards.iteh.ai/catalog/standards/sist/f218f577-7b94-4741-80bb-d8c222b54cb7/iec-60645-1-2017

### 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.<sup>1</sup>

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.

IEC 60645-12017

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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.

<sup>1</sup> 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 https://standards.iteh.ai/catalog/standards/sist/f218f577-7b94-4741-80bb-d8c222b54cb7/jec-60645-1-2017

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 **iTeh STANDARD PREVIEW** 

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 4 tones with the frequency range 8 kHz to 16 kHz d8c222b54cb7/iec-60645-1-2017

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 puretone 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.

### 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.

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### 3.5

### air conduction

transmission of sound through the external and middle ear to the inner ear

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### 3.6

### bone conduction

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

### 3.7

### extended high-frequency

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.

### 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

### 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 11 en STANDARD PREVIEW

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

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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

### $\mathsf{HL}$

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

## (standards.iteh.ai)

### speech signal

test signal generated by a natural human or synthetic voice

https://standards.iteh.ai/catalog/standards/sist/f218f577-7b94-4741-80bb-d8c222b54cb7/iec-60645-1-2017

### 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

(Standards.iten.al)

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 nearing 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.