



Edition 4.0 2017-03 REDLINE VERSION

# INTERNATIONAL STANDARD



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

### **Document Preview**

IEC 60645-1:2017

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





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### **Document Preview**

IEC 60645-1:201

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#### INTERNATIONAL ELECTROTECHNICAL COMMISSION

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#### **ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –**

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

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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,
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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.<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 2017 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.

<sup>1</sup> These requirements are specified in ISO 8253-1.

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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

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#### ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

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

#### 1 Scope

This part of IEC 60645 specifies general requirements for audiometers<u>and particular</u> 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 <u>generate</u> present, according to the mode of operation or according to the <u>complexity of the range of</u> auditory functions they test their presumed primary application.

#### 2 Normative references

EC 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 cm<sup>3</sup> coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts

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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

Itps://standards.iteh.ar/catalog/standards/iec/12181577-7b94-4741-80bb-d8c222b54cb7/iec-60645-1-2017 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 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.

#### 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

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#### 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