

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

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

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

<https://standards.iteh.ai/catalog/standards/sist/15-1b499-ee42-460d-b9c1-370c651b2362/iec-60645-1-2012>



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Part 1: Equipment for pure-tone audiometry**

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ELECTROACOUSTICS –  
AUDIOMETRIC EQUIPMENT –**

**Part 1: Equipment for pure-tone audiometry**

**FOREWORD**

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

This third edition cancels and replaces the second edition, published in 2001, and IEC 60645-4 published in 1994. It constitutes an editorial revision.

The text of this standard is based on the following documents:

| FDIS        | Report on voting |
|-------------|------------------|
| 29/754/FDIS | 29/757/RVD       |

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

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

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

Future standard 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 publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

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

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

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

IEC 60645 series consists of the following parts:

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

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

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

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

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

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

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

# ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

## Part 1: Equipment for pure-tone audiometry

### 1 Scope

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

The object of this standard is to ensure:

- a) that tests of hearing in the frequency range 125 Hz to 16 000 Hz on a given human ear, performed with different audiometers which comply with this standard shall give substantially the same results;
- b) that the results obtained represent a valid comparison between the hearing of the ear tested and the reference threshold of hearing;
- c) that audiometers are classified according to the range of test signals they generate, according to the mode of operation or according to the complexity of the range of auditory functions they test.

### 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

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

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

IEC 60318-5, *Electroacoustics – Simulators of human head and ear – Part 5: 2 cm<sup>3</sup> coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts*

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

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

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

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

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

ISO 266, *Acoustics – Preferred frequencies*

ISO 389-1, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 1: Reference equivalent threshold sound pressure levels for pure tones and supra-aural earphones*

ISO 389-2, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 2: Reference equivalent threshold sound pressure levels for pure tones and insert earphones*

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

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

ISO 389-5, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 5: Reference equivalent threshold sound pressure levels for pure tones in the frequency range 8 kHz to 16 kHz*

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

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

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

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

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

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

### **3 Terms and definitions**

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

#### **3.1 equipment for pure-tone audiometry** **pure-tone audiometer**

instrument for the measurement of hearing for pure tones and in particular the threshold of hearing

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

**3.2**

**manual audiometer**

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

**3.3**

**automatic-recording audiometer**

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

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

**3.4**

**equipment for speech audiometry**

**speech audiometer**

instrument for the measurement of hearing for speech test material

**3.5**

**air conduction**

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

**3.6**

**bone conduction**

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

**3.7**

**extended high frequency**

**EHF**

audiometric test frequency in the range from 8 000 Hz to 16 000 Hz

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

**3.8**

**otologically normal person**

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

**3.9**

**equivalent threshold sound pressure level**

**monaural earphone listening**

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

**3.10**

**equivalent threshold force level**

**monaural listening**

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

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

### **3.11 reference equivalent threshold sound pressure level RETSPL**

at a specified frequency, the median, mean or modal value of the equivalent threshold sound pressure levels of a sufficiently large number of ears of otologically normal persons of both sexes aged between 18 years and 25 years inclusive, expressing the threshold of hearing in a specified ear simulator or acoustic coupler for a specified earphone

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

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

### **3.12 reference equivalent threshold force level RETFL**

at a specified frequency, the mean value of the equivalent threshold force levels of a sufficiently large number of ears of otologically normal persons of both sexes aged between 18 years and 25 years inclusive, expressing the threshold of hearing in a specified mechanical coupler for a specified configuration of bone vibrator

Note 1 to entry Mean values of reference equivalent threshold force levels are specified in ISO 389-3.

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

### **3.13 hearing level of a pure tone HL**

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

### **3.14 hearing threshold level for pure tones**

at a specified frequency, the threshold of hearing at that frequency expressed as hearing level

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

### **3.15 ear simulator**

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

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

### **3.16 acoustic coupler**

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

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

### **3.17 mechanical coupler**

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

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

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

**3.18  
masking**

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

**3.19  
effective masking level**

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

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

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

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

**4 Requirements for specific types of fixed frequency audiometer**

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

**Table 1 – Minimum facilities for fixed-frequency audiometers**

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

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

## 5 General requirements

### 5.1 General safety requirements

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

### 5.2 Acoustic safety requirements

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

### 5.3 Environmental conditions

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

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

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

### 5.4 Warm-up time

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

### 5.5 Power supply variation

#### 5.5.1 Interruption of power supply

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