



**SLOVENSKI STANDARD**  
**SIST EN 60645-1:1999**

**01-julij-1999**

---

**Audiometers -- Part 1: Pure-tone audiometers (IEC 60645-1:1992+corrigendum Feb.1993)**

Audiometers -- Part 1: Pure-tone audiometers

Audiometer -- Teil 1: Reinton-Audiometer

Audiomètres -- Partie 1: Audiomètres tonaux

**STANDARD PREVIEW**  
**(standards.iteh.ai)**

**Ta slovenski standard je istoveten z: EN 60645-1:1994**

SIST EN 60645-1:1999  
<https://standards.iteh.ai/catalog/standards/sist/9103b8b-58a6-4f9d-a6fb-0f92addcde0c/sist-en-60645-1-1999>

**ICS:**

17.140.50      Elektroakustika                      Electroacoustics

**SIST EN 60645-1:1999**                      **en**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN 60645-1:1999](https://standards.iteh.ai/catalog/standards/sist/910f3b8b-58a6-4f9d-a6fb-0f92addcde0c/sist-en-60645-1-1999)

<https://standards.iteh.ai/catalog/standards/sist/910f3b8b-58a6-4f9d-a6fb-0f92addcde0c/sist-en-60645-1-1999>

EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

EN 60645-1

August 1994

ICS 11.140.50

Descriptors: Electromedical device, pure-tone audiometer, definitions, specifications for safety and metrology, calibration, testing

English version

Audiometers  
Part 1: Pure-tone audiometers

(IEC 645-1 : 1992 + corrigendum 1993)

Audiomètres  
Partie 1: Audiomètres tonaux  
(CEI 645-1 : 1992 + corrigendum 1993)

Audiometer  
Teil 1: Reinton-Audiometer  
(IEC 645-1 : 1992 + Corrigendum 1993)

This European Standard was approved by CENELEC on 1994-07-05. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

## CENELEC

European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

## Foreword

The CENELEC questionnaire procedure, performed for finding out whether or not the International Standard IEC 645-1 : 1992 and its corrigendum February 1993 could be accepted without textual changes, has shown that no common modifications were necessary for the acceptance as a European Standard.

The reference document was submitted to the CENELEC members for formal vote and was approved by CENELEC as EN 60645-1 on 5 July 1994.

The following dates were fixed:

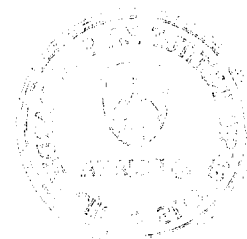
- latest date of publication  
of an identical national  
standard (dop) 1995-03-15
- latest date of withdrawal  
of conflicting national  
standards (dow) 1995-03-15

Annexes designated 'normative' are part of the body of the standard. In this standard, annex ZA is normative.

**STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN 60645-1:1999

<https://standards.iteh.ai/catalog/standards/sist/9103b8b-58a6-4f9d-a6fb-0f92addcde0c/sist-en-60645-1-1999>



2004 08 10

## CONTENTS

	Page
INTRODUCTION .....	4
<b>Clause</b>	
1 Scope and object .....	5
2 Normative references .....	6
3 Definitions .....	7
4 Requirements for specific types of fixed frequency audiometer .....	9
5 General requirements .....	10
5.1 Safety requirements .....	10
5.2 Subject's response system .....	10
5.3 Warm-up time .....	11
5.4 Supply variation and environmental conditions .....	11
5.5 Unwanted sound .....	13
5.6 Testing of automatic recording and computer-controlled audiometers .....	14
6 Test signal sources .....	14
6.1 Pure tones .....	14
6.2 External signal source .....	17
6.3 Masking sounds .....	17
7 Signal level control .....	19
7.1 Marking .....	19
7.2 Signal indicator .....	19
7.3 Accuracy of sound pressure level and vibratory force level .....	19
7.4 Hearing level control .....	20
7.5 Masking sound .....	21
7.6 Tone switching .....	21
8 Reference tone .....	23
8.1 Frequencies .....	23
8.2 Reference tone level control .....	23
9 Transducers .....	24
9.1 Air conduction .....	24
9.2 Bone conduction .....	25
10 Marking and instruction manual .....	26
10.1 Marking .....	26
10.2 Instruction manual .....	26
Annex ZA (normative) Other international publications quoted in this standard with the references of the relevant European publications .....	28

## INTRODUCTION

Developments in the field of hearing measurements for diagnostic hearing conservation and rehabilitation purposes have resulted in a large increase in the range of audiometers available. However, in spite of the wide range available, it is possible to consider the audiometer in terms of functional units which can be specified independently. By specifying these functional units it is then possible to specify properties of other audiometric equipment which use such units.

IEC 645: Audiometers, will consist of a number of parts. This part is the first of the series and covers the requirements for pure-tone audiometers.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN 60645-1:1999

<https://standards.iteh.ai/catalog/standards/sist/9103b8b-58a6-4f9d-a6fb-0f92addcde0c/sist-en-60645-1-1999>

## AUDIOMETERS

### Part 1: Pure-tone audiometers

#### 1 Scope and object

This part of International Standard IEC 645 specifies general requirements for audiometers and particular requirements for pure-tone audiometers designed for use in determining hearing threshold levels in comparison with the standard reference threshold level by means of psycho-acoustic test methods.

The purpose of this part is to ensure:

- a) that tests of hearing, particularly threshold, on a given human ear performed with different audiometers which comply with this part using methods described in ISO 8253-1 and ISO 6189 (see clause 2) 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.

Audiometers can be classified in the following ways: according to the type of test signal they generate, according to the mode of operation or according to the complexity of the range of auditory functions they test (i.e. diagnostic, screening, etc.). However, in order to rationalize the classification of audiometers, five types are defined. Audiometers with which it is possible to make a diagnostic assessment (i.e. having as a minimum both air and bone conduction facilities) are classified as types 1, 2 and 3. Instruments with air conduction facilities only are classified as types 4 and 5.

This part covers the general requirements for audiometers as a whole as well as their functional units: signal sources, signal level controls and transducers.

In addition, since the units specified cover the majority of audiometric applications, instruments which may not necessarily be conventional pure-tone audiometers and not specified in this part (such as an auditory stimulator for evoked potential recording), but which contain circuitry used for measurement of auditory sensitivity or presentation of supraliminal signals should, where possible, conform to the appropriate clauses of this part. By using table 1, the reader can find the appropriate clauses (5 to 9) of this part which describe the performance requirements for a given instrument.

Table 1 – Guide to the requirements for various parts of an audiometer

General requirements	Requirements for signal sources	Requirements for signal level control	Requirements for transducers
5.1 Safety requirements	6.1 Pure tones	7.1 Marking	9.1 Air conduction
5.2 Subject's response system	6.2 External signal source	7.2 Signal indicator	9.2 Bone conduction
5.3 Warm-up time	6.3 Masking sounds	7.3 Accuracy of sound pressure level and vibratory force level	
5.4 Supply variation and environmental conditions	8 Reference tone	7.4 Hearing level control	
5.5 Unwanted sound		7.5 Masking sound	
10 Marking and instruction manual		7.6 Tone switching	

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

SIST EN 60645-1:1999

**2 Normative references** <https://standards.iteh.ai/catalog/standards/sist/9103b8b-58a6-4f9d-a6fb-0f92addcde0c/sist-en-60645-1-1999>

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 645. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of IEC 645 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 225: 1966, *Octave, half-octave and third-octave band filters intended for the analysis of sounds and vibrations.*

IEC 268-3: 1988, *Sound system equipment - Part 3: Amplifiers.*

IEC 303: 1970, *IEC provisional reference coupler for the calibration of earphones used in audiometry.*

IEC 318: 1970, *An IEC artificial ear, of the wide band type, for the calibration of earphones used in audiometry.*

IEC 373: 1990, *Mechanical coupler for measurements on bone vibrators.*

IEC 601-1: 1988, *Medical electrical equipment - Part 1: General requirements for safety.*



IEC 651: 1979, *Sound level meters.*

ISO 389: 1991, *Acoustics - Standard reference zero for the calibration of pure-tone air conduction audiometers.*

ISO 4869-1: 1990, *Acoustics - Hearing protectors - Part 1: Subjective method for the measurement of sound attenuation.*

ISO 6189: 1983, *Acoustics - Pure-tone air conduction threshold audiometry for hearing conservation purposes.*

ISO 7566: 1987, *Acoustics - Standard reference zero for the calibration of pure-tone bone conduction audiometers.*

ISO 8253-1: 1989, *Acoustics - Audiometric test methods - Part 1: Basic pure-tone air and bone conduction threshold audiometry.*

ISO 8798: 1987, *Acoustics - Reference levels for narrow-band masking noise.*

**iTeh STANDARD PREVIEW**  
(standards.iteh.ai)

### 3 Definitions

SIST EN 60645-1:1999

For the purpose of this part of IEC 645, the following definitions apply:

**3.1 pure-tone audiometer:** An instrument for the measurement of hearing for pure tones and in particular the threshold of hearing. The audiometer may be either a fixed or continuous sweep frequency type.

**3.2 manual audiometer:** An audiometer in which signal presentations and recording of results are performed manually.

**3.3 automatic recording audiometer:** An audiometer in which signal presentations, hearing level variation, frequency selection or frequency variation, and recording of subject's responses are implemented automatically. Direction of hearing level changes is under subject's control and is recorded automatically.

**3.4 computer-controlled audiometer:** An audiometer in which the test procedure is controlled by computer or microprocessor.

**3.5 speech audiometer:** An instrument for the measurement of hearing for speech test material.

**3.6 air conduction:** Transmission of sound through the external and middle ear to the inner ear.

**3.7 bone conduction:** Transmission of sound to the inner ear mediated primarily by mechanical vibration of the cranial bones.

**3.8 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 acoustic coupler or artificial ear when the earphone is activated by that voltage which, with the earphone applied to the ear concerned, would correspond to the threshold of hearing.

**3.9 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 - This definition requires the non-test ear to be masked in accordance with ISO 7566.

**3.10 reference equivalent threshold sound pressure level (RETSPL):** At a specified frequency, the 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 and 30 years inclusive, expressing the threshold of hearing in a specified acoustic coupler or artificial ear for a specified type of earphone.

NOTE - Values of reference equivalent threshold sound pressure levels are specified in ISO 389.

<https://standards.iteh.ai/catalog/standards/sist/9103b8b-58a6-4f9d-a6fb-0f92addcde0c/sist-en-60645-1-1999>

**3.11 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 and 30 years inclusive, expressing the threshold of hearing in a specified mechanical coupler for a specified configuration of bone vibrator.

NOTE - Values of reference equivalent threshold force levels are specified in ISO 7566.

**3.12 hearing level of a pure tone:** 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 of this signal set up by the transducer in a specified acoustic or mechanical coupler or an artificial ear minus the appropriate reference equivalent threshold level for air or bone conduction as applicable.

**3.13 hearing threshold level for pure tones:** The hearing threshold level of a given ear at a specified frequency is the threshold of hearing at that frequency expressed as hearing level.

NOTE - Methods of determining thresholds of hearing are specified in ISO 6189 and ISO 8253-1.

**3.14 artificial ear; (ear simulator):** Device for the calibration of an earphone which presents to the earphone an acoustic impedance equivalent to the impedance presented by the average human ear. It is equipped with a calibrated microphone for the measurement of the sound pressure developed by the earphone.

NOTE - An artificial ear is specified in IEC 318.

**3.15 acoustic coupler:** Cavity of predetermined shape and volume which is used for the calibration of an earphone in conjunction with a calibrated microphone to measure the sound pressure developed within the cavity.

NOTE - An acoustic coupler is specified in IEC 303.

**3.16 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 vibrator and mechanical coupler to be determined.

NOTE - A mechanical coupler is specified in IEC 373.

**3.17 masking:**

- 1)** Process by which the threshold of hearing of a sound is raised by the presence of another (masking) sound.
- 2)** The amount by which the hearing threshold level is so raised, expressed in decibels.

**3.18 effective masking level:** The 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. The notional normal person is one whose hearing conforms to the standards for threshold and for masking efficiency (ISO 389 and ISO 8798).

#### NOTES

- 1 Effective masking level is thus analogous to hearing level (see 3.12), that is, it is measure of sound on a physical scale, independent of a particular ear under test.
- 2 Reference values for effective masking are given in ISO 8798.

**3.19 otologically normal subject:** An otologically normal subject is a person in a normal state of health who is free from all signs or symptoms of ear disease and from obstructing wax in the ear canal and has no history of undue exposure to noise.

## 4 Requirements for specific types of fixed frequency audiometer

Five different types of audiometers are specified by the requirements for minimum mandatory facilities given in table 2. Other facilities are not precluded.

Table 2 – Minimum facilities for various types of fixed frequency audiometers

Facility	Type 1	Type 2	Type 3	Type 4	Type 5
Air conduction	x	x	x	x	x
– two earphones	x	x	x	x	
– insert earphone	x				
Bone conduction	x	x	x		
Masking					
– narrow-band noise	x	x			
– narrow-band or other noise			x		
– broad-band noise	x	x			
Routing of masking					
– contralateral earphone	x	x	x		
– ipsilateral earphone	x				
– bone vibrator	x				
Tone switching					
– tone presentation/interruption	x	x <sup>1)</sup>	x	x <sup>1)</sup>	x
– pulsed tone	x	x <sup>1)</sup>			
Reference tone					
– alternate presentation	x	x <sup>2)</sup>			
– simultaneous presentation					
Subject's response system	x	x	x	x <sup>1)</sup>	
Auxiliary electrical signal output	x				
Input for external signals	x	x			
Hearing levels and test frequencies (see table 4)					
Signal indicator	x	x			
Audible monitoring of test signal	x				
Operator to subject speech communication	x				
<sup>1)</sup> Not mandatory for manual audiometers. <sup>2)</sup> Not mandatory for automatic recording audiometers.					

## 5 General requirements

Computer-controlled audiometers shall meet the requirements for manual or automatic recording audiometers.

### 5.1 Safety requirements

Instruments shall conform to minimum IEC safety requirements (see IEC 601-1).

### 5.2 Subject's response system

The subject's response system is a means by which the tester may be made aware that the subject has perceived the test signal.