SLOVENSKI STANDARD
SIST EN 60645-1:2002

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Nadomešča:
SIST EN 60645-1:1999

Elektroakustika - Avdiološka oprema - 1. del: Avdiometri čistega tona (IEC 60645-1:2001)

Electroacoustics - Audiological equipment - Part 1: Pure-tone audiometers (IEC 60645-1:2001)

Akustik - Audiometer - Teil 1: Reinton-Audiometer (IEC 60645-1:2001)

Electroacoustique - Appareils d'audiologie - Partie 1: Audiomètres tonaux (CEI 60645-1:2001)

Ta slovenski standard je istoveten z: **EN 60645-1:2001**

ICS:

13.140	Vpliv hrupa na ljudi	Noise with respect to human beings
17.140.50	Elektroakustika	Electroacoustics

SIST EN 60645-1:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60645-1

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English version

Electroacoustics - Audiological equipment
Part 1: Pure-tone audiometers
(IEC 60645-1:2001)

Electroacoustique - Appareils d'audiologie
Partie 1: Audiomètres tonaux
(CEI 60645-1:2001)

Akustik - Audiometer
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(IEC 60645-1:2001)

This European Standard was approved by CENELEC on 2001-09-25. 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, 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

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Foreword

The text of document 29/489/FDIS, future edition 2 of IEC 60645-1, prepared by IEC TC 29, Electroacoustics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60645-1 on 2001-09-25.

This European Standard supersedes EN 60645-1:1994.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2002-07-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2004-10-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60645-1:2001 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 61260	NOTE	Harmonized as EN 61260:1995 (not modified).

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

Due to the development of the later parts of IEC 60645, part 1 now confines its scope solely to the requirements of pure tone audiometers. One consequence of this is that no reference is now made 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.

This second edition now specifies performance requirements separate from the test requirements to show conformity. Conformance to the specifications in this International 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 International Standard extended by the values for U_{max} given in table 7. By this, 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 use of the audiometer are increased by U_{max} compared with those of the previous edition.

ELECTROACOUSTICS – AUDIOLOGICAL EQUIPMENT –

Part 1: Pure-tone audiometers

1 Scope and object

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, in comparison with standard reference threshold levels by means of psychoacoustic test methods.

The object of this International Standard is to ensure:

a) that tests of hearing, particularly threshold, in the frequency range 125 Hz to 8 000 Hz on a given human ear performed with different audiometers which comply with this International Standard using methods described in ISO 8253-1 and ISO 6189 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 normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 60645. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of IEC 60645 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

IEC 60126, *IEC reference coupler for the measurement of hearing aids using earphones coupled to the ear by means of ear inserts*

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 calibration of supra-aural earphones*

IEC 60318-2, *Electroacoustics – Simulators of human head and ear – Part 2: An interim acoustic coupler for the calibration of audiometric earphones in the extended high frequency range*

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 60373, *Mechanical coupler for measurements on bone vibrators*

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

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

IEC 60601-1-4, *Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems*

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

IEC 60711, *Occluded-ear simulator for the measurement of earphones coupled to the ear by ear inserts*

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

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

ISO 6189, *Acoustics – Pure tone air conduction threshold audiometry for hearing conservation purposes*

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

[1] To be published.

3 Terms and definitions

For the purposes of this part of IEC 60645, the following terms and definitions apply.

3.1
pure tone audiometer
instrument for the measurement of hearing for pure tones and in particular the threshold of hearing

NOTE The 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 Direction of hearing level changes is under subject's control and is recorded automatically.

3.4
computer-controlled audiometer
audiometer in which the test procedure is controlled by computer or microprocessor and not by a manual operator

3.5
speech audiometer
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
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 (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

3.10
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 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 mean/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 earphone

NOTE Values of RETSPL are specified in ISO 389-1 and ISO 389-2.

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

NOTE Mean values of reference equivalent threshold force levels are specified in ISO 389-3.

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 or mechanical coupler minus the appropriate RETSPL or RETFL

3.14
hearing threshold level for pure tones
at a specified frequency, the threshold of hearing of a given ear at that frequency expressed as hearing level

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

3.15
ear simulator
general term used to describe devices such as artificial ears (3.16) and acoustic couplers (3.17) which are used to measure the output sound pressure from earphones

3.16
artificial ear
device for the calibration of an earphone which presents to the earphone an acoustic impedance equivalent to the impedance presented by the average adult human ear

NOTE 1 It is equipped with a microphone for the measurement of the sound pressure developed by the earphone.

NOTE 2 An artificial ear is specified in IEC 60318-1 for supra-aural earphones. IEC 60711 specifies an artificial ear for insert earphones.