BS EN 60645-1:2017

BSI Standards Publication

Electroacoustics - Audiometric equipment

Part 1: Equipment for pure-tone and speech audiometry (IEC 60645-1:2017)

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Full document details: BS EN 60645-1:2017

National foreword

This British Standard is the UK implementation of EN 60645-1:2017. It is identical to IEC 60645-1:2017. It supersedes BS EN 60645-1:2015 and BS EN 60645-2:1997, which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EPL/29, Electroacoustics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Published by BSI Standards Limited 2017

ISBN 978 0 580 90338 0

ICS 13.140; 17.140.50

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2017.

Amendments/corrigenda issued since publication

Date	Text affected

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60645-1

October 2017

ICS 17.140.50

Supersedes EN 60645-1:2015

English Version

Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone and speech audiometry (IEC 60645-1:2017)

Electroacoustique - Appareils audiométriques - Partie 1: Appareils pour l'audiométrie tonale et vocale (IEC 60645-1:2017)

Akustik - Audiometer - Teil 1: Reinton-Audiometer (IEC 60645-1:2017)

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

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European foreword

The text of document 29/927/FDIS, future edition 4 of IEC 60645-1, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60645-1:2017.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2018-04-06
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2020-10-06

This document supersedes EN 60645-1:2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60645-1:2017 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:

ISO 389-9	NOTE	Harmonized as EN ISO 389-9.

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60268-3	-	Sound system equipment - Part 3: Amplifiers	EN 60268-3	-
IEC 60268-7	-	Sound system equipment - Part 7: Headphones and earphones	EN 60268-7	-
IEC 60268-17	-	Sound system equipment - Part 17: Standard volume indicators	HD 483.17 S1	-
IEC 60318-1	-	Electroacoustics - Simulators of human head and ear - Part 1: Ear simulator for the measurement of supra-aural and circumaural earphones	EN 60318-1	-
IEC 60318-3	-	Electroacoustics - Simulators of human head and ear - Part 3: Acoustic coupler for the calibration of supra-aural earphones used in audiometry	EN 60318-3	-
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	EN 60318-4	-
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	EN 60318-5	-
IEC 60318-6	-	Electroacoustics - Simulators of human head and ear - Part 6: Mechanical coupler for the measurements on bone vibrators	EN 60318-6	-
IEC 60601-1	-	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	-
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	EN 60601-1-2	-

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Publication	Year	Title	EN/HD	Year
IEC 61260-1	-	Electroacoustics - Octave-band and fractional-octave-band filters - Part 1: Specifications	EN 61260-1	-
IEC 61672-1	-	Electroacoustics - Sound level meters - Part 1: Specifications	EN 61672-1	-
ISO 266	-	Acoustics - Preferred frequencies	EN ISO 266	-
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	EN ISO 389-1	-
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	EN ISO 389-2	-
ISO 389-3	-	Acoustics - Reference zero for the calibration of audiometric equipment - Part 3: Reference equivalent threshold vibratory force levels for pure tones and bone vibrators	EN ISO 389-3	-
ISO 389-4	1994	Acoustics - Reference zero for the calibration of audiometric equipment - Part 4: Reference levels for narrow-band masking noise	EN ISO 389-4	1998
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	EN ISO 389-5	-
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	EN ISO 389-7	-
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	EN ISO 389-8	-
ISO 4869-1	-	Acoustics - Hearing protectors - Part 1: Subjective method for the measurement of sound attenuation	EN 24869-1	-
ISO 8253-1	2010	Acoustics - Audiometric test methods - Part 1: Pure-tone air and bone conduction audiometry	EN ISO 8253-1	2010
ISO 8253-2	-	Acoustics - Audiometric test methods - Part 2: Sound field audiometry with pure-tone and narrow-band test signals	EN ISO 8253-2	-
ISO 8253-3	-	Acoustics - Audiometric test methods - Part 3: Speech audiometry	EN ISO 8253-3	-

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 1: Equipment for pure-tone and speech audiometry

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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.

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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
- amended.

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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 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.[1]

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.

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.

[1] These requirements are specified in ISO 8253-1.

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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 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

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*

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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*

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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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- 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 using speech 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 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

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, would correspond to the threshold of hearing

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