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Elektroakustik – Audiometrar – Del 1: Tonaudiometrar

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

Som svensk standard gäller europastandarden EN 60645-1:2015. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60645-1:2015.

Nationellt förord

Europastandarden EN 60645-1:2015

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60645-1, Third edition, 2012 - Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone audiometry**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 60645-1, utgåva 2, 2001 och SS-EN 60645-4, utgåva 1, 1996 gäller ej fr o m 2017-11-05.

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English Version

**Electroacoustics - Audiometric equipment -
Part 1: Equipment for pure-tone audiometry
(IEC 60645-1:2012)**

Électroacoustique - Appareils audiométriques -
Partie 1: Appareils pour l'audiométrie tonale
(IEC 60645-1:2012)

Akustik - Audiometer -
Teil 1: Reinton-Audiometer
(IEC 60645-1:2012)

This European Standard was approved by CENELEC on 2014-11-05. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 29/754/FDIS, future edition 3 of IEC 60645-1, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60645-1:2015.

The following dates are fixed:

- latest date by which the document has to be (dop) 2015-08-05
implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2017-11-05
standards conflicting with the
document have to be withdrawn

This document supersedes EN 60645-1:2001 and EN 60645-4:1995.

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

This standard covers the Principle Elements of the Safety Objectives for Electrical Equipment Designed for Use within Certain Voltage Limits (LVD - 2006/95/EC).

Endorsement notice

The text of the International Standard IEC 60645-1:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 61260	NOTE	Harmonized as EN 61260.
ISO 389-9	NOTE	Harmonized as EN ISO 389-9.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 When 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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60268-3	-	Sound system equipment - Part 3: Amplifiers	EN 60268-3	-
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 cm ³ 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	-
IEC 60645-2	-	Audiometers - Part 2: Equipment for speech audiometry	EN 60645-2	-
IEC 61672-1	-	Electroacoustics - Sound level meters - Part 1: Specifications	EN 61672-1	-

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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 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 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 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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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 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*

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*