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I.S. EN 60645-6:2010

Electroacoustics - Audiometric equipment -- Part 6: Instruments for the measurement of otoacoustic emissions (IEC 60645-6:2009 (EQV))

I.S. EN 60645-6:2010

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EUROPEAN STANDARD

EN 60645-6

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January 2010

ICS 17.140.50

English version

**Electroacoustics -
Audiometric equipment -
Part 6: Instruments for the measurement of otoacoustic emissions
(IEC 60645-6:2009)**

Electroacoustique -
Appareillage audiométrique -
Partie 6: Instruments pour la mesure
des émissions otoacoustiques
(CEI 60645-6:2009)

Akustik -
Audiometer -
Teil 6: Geräte zur Messung
von otoakustischen Emissionen
(IEC 60645-6:2009)

This European Standard was approved by CENELEC on 2009-12-01. 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.

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CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

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Foreword

The text of document 29/673/FDIS, future edition 1 of IEC 60645-6, prepared by IEC TC 29, Electroacoustics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60645-6 on 2009-12-01.

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) 2010-09-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2012-12-01

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60645-6:2009 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 389-6 NOTE Harmonized as EN ISO 389-6 (not modified).

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	200X ¹⁾
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 60601-1	-	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	-
IEC 60601-1-2 (mod)	-	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	-
IEC 60601-1-4	-	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	EN 60601-1-4	-
IEC 60645-1	2001	Electroacoustics - Audiological equipment - Part 1: Pure-tone audiometers	EN 60645-1	2001
IEC 60645-3	2007	Electroacoustics - Audiometric equipment - Part 3: Test signals of short duration	EN 60645-3	2007
ISO/IEC Guide 98-3	-	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-

¹⁾ To be published.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ELECTROACOUSTICS –
AUDIOMETRIC EQUIPMENT –****Part 6: Instruments for the measurement
of otoacoustic emissions**

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 60645-6 has been prepared by IEC technical committee 29: Electroacoustics.

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

FDIS	Report on voting
29/673/FDIS	29/681/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.

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

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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 diagnostic hearing measurement have resulted in a number of instruments designed to evaluate the otoacoustic emissions of the human ear evoked by acoustic test signals having different spectral and temporal characteristics.

The practical use of such instruments concerns the measurement of sound energy emitted by the inner ear and its separation from sounds emerging from other physiological or artificial sources.

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 6: Instruments for the measurement of otoacoustic emissions

1 Scope

This part of IEC 60645 applies to instruments designed primarily for the measurement of otoacoustic emissions in the human external acoustic meatus evoked by acoustic probe pulses or tones. This standard defines the characteristics to be specified by the manufacturer, lays down performance specifications for two types of instruments¹ and specifies the functions to be provided on these types. This part of IEC 60645 describes methods of test to be used for approval testing and guidance on methods for undertaking routine calibration.

The purpose of this part of IEC 60645 is to ensure that measurements made under comparable test conditions with different instruments complying with the standard will be consistent. Instruments which provide a measurement function not specifically within the scope of the standard shall still comply with any relevant requirements. This standard is not intended to restrict development or incorporation of new features, nor to discourage innovative approaches.

2 Normative references

The following referenced documents are indispensable for the application 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 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*²

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

IEC 60645-1:2001, *Electroacoustics – Audiological equipment – Part 1: Pure-tone audiometers*

¹ Screening and full diagnostics.

² To be published.

This is a free preview. Purchase the entire publication at the link below:

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