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Elektroakustik – Audiometrar – Del 6: Utrustning för mätning av otoakustiska emissioner

*Electroacoustics –
Audiometric equipment –
Part 6: Instruments for the measurement of otoacoustic emissions*

Som svensk standard gäller europastandarden EN 60645-6:2010. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60645-6:2010.

Nationellt förord

Europastandarden EN 60645-6:2010

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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.

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, 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

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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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.

IEC 60645-3:2007, *Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration*

ISO/IEC Guide 98-3, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

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