

**Elektroakustika. Audiomeetriaseadmed. Osa 6:  
Otoakustilise emissiooni mõõteriistad**

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60645-6:2010 sisaldab Euroopa standardi EN 60645-6:2010 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 28.02.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 08.01.2010.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN 60645-6:2010 consists of the English text of the European standard EN 60645-6:2010.

This standard is ratified with the order of Estonian Centre for Standardisation dated 28.02.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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The standard is available from Estonian standardisation organisation.

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

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European Committee for Electrotechnical Standardization  
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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with the EN have to be withdrawn (dow) 2012-12-01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.

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## 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).

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## 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 <sup>1)</sup>
IEC 60318-5	-	Electroacoustics - Simulators of human head and ear - Part 5: 2 cm <sup>3</sup> 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)		-

<sup>1)</sup> 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.

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## **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 instruments<sup>1</sup> 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*<sup>2</sup>

IEC 60318-5, *Electroacoustics – Simulators of human head and ear – Part 5: 2 cm<sup>3</sup> 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*

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<sup>1</sup> Screening and full diagnostics.

<sup>2</sup> 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)*

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

#### 3.1 otoacoustic emissions

##### OAE

general term covering all types of acoustic signals generated in the inner ear which can be recorded in the external acoustic meatus

NOTE The spontaneous otoacoustic emissions (SOAE) and stimulus frequency otoacoustic emissions (SFOAE) which are also a part of the otoacoustic emissions are not covered by this standard.

#### 3.2 transient-evoked otoacoustic emissions

##### TEOAE

acoustic signals emitted by the inner ear after stimulation with a stimulus of short duration

#### 3.3 distortion product otoacoustic emissions

##### DPOAE

acoustic signals generated in the inner ear during stimulation with two pure tones (frequencies  $f_1$  and  $f_2$ ,  $f_1$  being the lower frequency)

NOTE The frequencies of the DPOAE are given by the formulas for distortions  $3f_1$ ,  $2f_1-f_2$ ,  $2f_2-f_1$ ,  $3f_2$ , etc.

#### 3.4 nominal test frequency

the frequency for which a DPOAE measurement is reported

#### 3.5 primary tones

pure tone stimuli used to evoke DPOAEs

#### 3.6 probe

part of the instrument, usually containing transducers, interfacing the instrument to the ear

#### 3.7 ear tip

device used to provide a seal between the probe and the external acoustic meatus

#### 3.8 probe signal

acoustic signal that is emitted into the external auditory meatus by means of a probe

#### 3.9 peak-to-peak equivalent sound pressure level

##### peSPL

r.m.s. value of a long-duration sinusoidal sound signal which, when compared under the same test conditions with a short-duration output signal from the transducer under test, has the