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Standards

Irish Standard
I.S. EN 60645-7:2010

Electroacoustics - Audiometric
equipment -- Part 7: Instruments for
the measurement of auditory
brainstem responses (IEC 60645-7:2009
(EQV))

I.S. EN 60645-7:2010

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EUROPEAN STANDARD

EN 60645-7

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EUROPÄISCHE NORM

January 2010

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English version

**Electroacoustics -
Audiometric equipment -
Part 7: Instruments for the measurement of auditory brainstem responses
(IEC 60645-7:2009)**

Electroacoustique -
Appareillage audiométrique -
Partie 7: Instruments pour la mesure
des réponses du tronc cérébral
à une stimulation auditive
(CEI 60645-7:2009)

Akustik -
Audiometer -
Teil 7: Geräte zur Messung
von akustisch evozierten Potentialen
(IEC 60645-7:2009)

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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

I.S. EN 60645-7:2010

EN 60645-7:2010

- 2 -

Foreword

The text of document 29/674/FDIS, future edition 1 of IEC 60645-7, prepared by IEC TC 29, Electroacoustics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60645-7 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 60645-7:2009 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:

IEC 60601-2-40 NOTE Harmonized as EN 60601-2-40 (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 60601-1	-	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	-
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 389	Series	Acoustics - Reference zero for the calibration - of audiometric equipment	-	-
ISO/IEC Guide 98-3	-	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-

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CONTENTS

FOREWORD.....	3
INTRODUCTION.....	5
1 Scope.....	6
2 Normative references	6
3 Terms and definitions	6
4 Requirements for specific instruments	7
5 General specifications	8
5.1 Measuring system	8
5.1.1 Units of measurement.....	8
5.1.2 Measurement range.....	8
5.1.3 Time resolution.....	8
5.2 Stimulus system	8
5.2.1 General requirements	8
5.2.2 Stimulus types	8
5.3 Test quality assuring system	8
5.3.1 Recording conditions	8
5.3.2 Response detection	9
5.3.3 Quality estimates	9
5.3.4 Reference values.....	9
5.4 Presentation of results	9
6 Demonstration of conformity with specifications.....	9
6.1 General.....	9
6.2 Signal-to-noise ratio improvement	9
6.3 Maximum permitted expanded uncertainty of measurements U_{\max}	9
7 General requirements	10
7.1 Marking	10
7.2 Instruction manual	10
7.3 Safety requirements	10
7.3.1 General	10
7.3.2 Immunity to power and radiofrequency fields	10
7.4 Warm-up time.....	10
7.5 Voltage supply variation and environmental conditions	11
7.5.1 Mains operation.....	11
7.5.2 Battery operation	11
7.5.3 Environmental conditions.....	11
8 Routine calibration	11
Bibliography.....	12
Table 1 – Instrumentation requirements	7
Table 2 – Documentation of test conditions, parameters and results	9
Table 3 – Values of U_{\max} for basic measurements	10

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ELECTROACOUSTICS –
AUDIOMETRIC EQUIPMENT –**
**Part 7: Instruments for the measurement
of auditory brainstem responses**

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 60645-7 has been prepared by IEC technical committee 29: Electroacoustics.

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

FDIS	Report on voting
29/674/FDIS	29/682/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.

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 auditory evoked potentials of the human hearing system which can be evoked by acoustic or vibratory signals having different spectral and temporal characteristics. The practical use of such instruments concerns the measurement of these electric potentials and their separation from electric signals emerging from other physiological or artificial sources.

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 7: Instruments for the measurement of auditory brainstem responses

1 Scope

This part of IEC 60645 applies to instruments designed for the measurement of auditory evoked potentials from the inner ear, the auditory nerve and the brainstem, evoked by acoustic and/or vibratory stimuli of short duration. This part of IEC 60645 defines the characteristics to be specified by the manufacturer, specifies performance requirements for two types of instrument, screening and diagnostic, and specifies the functions to be provided on these types.

The purpose of this part of IEC 60645 is to ensure that measurements made under comparable test conditions with different instruments complying with this standard will be consistent. This part of IEC 60645 is not intended to restrict development or incorporation of new features, nor to discourage innovative approaches.

The application of electric stimuli for special purposes is beyond the scope of this standard.

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 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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

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

ISO 389 (all parts), *Acoustics – Reference zero for the calibration of audiometric equipment*

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 auditory evoked potentials

AEP

electric potentials which can be evoked by acoustic or vibratory stimulation of the auditory system and recorded by means of electrodes

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