

SLOVENSKI STANDARD SIST EN 60645-7:2010

01-marec-2010

Elektroakustika - Avdiometrična oprema - 7. del: Instrumenti za merjenje slušnih potencialov (IEC 60645-7:2009)

Electroacoustics - Audiometric equipment - Part 7: Instruments for the measurement of auditory evoked potentials (IEC 60645-7:2009)

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

Electroacoustique - Appareillage audiométrique - Partie 7: Instruments pour la mesure des potentiels évoqués auditifs (CEI 60645-7:2009)10

https://standards.iteh.ai/catalog/standards/sist/c00ae6fe-d930-472f-9ad9-

Ta slovenski standard je istoveten z: EN 60645-7-2010

ICS:

17.140.50 Elektroakustika Electroacoustics

SIST EN 60645-7:2010 en,fr SIST EN 60645-7:2010

iTeh STANDARD PREVIEW (standards.iteh.ai)

EUROPEAN STANDARD

EN 60645-7

NORME EUROPÉENNE EUROPÄISCHE NORM

January 2010

ICS 17.140.50

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)

iTeh STANDARD PREVIEW (standards.iteh.ai)

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. Sixt/c00ae6fe-d930-472f-9ad9-

97c3f368211e/sist-en-60645-7-2010

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

- 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).

(standards.iteh.ai)

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>	EN/HD	<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	·iTo	Uncertainty of measurement PRF Part 3: Guide to the expression of uncertainty in measurement (GUM:1995) hai	W	-

SIST EN 60645-7:2010

iTeh STANDARD PREVIEW (standards.iteh.ai)



IEC 60645-7

Edition 1.0 2009-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Electroacoustics + Audiometric equipment - PREVIEW
Part 7: Instruments for the measurement of auditory brainstem responses

Electroacoustique – Equipements audiométriques –
Partie 7: Instruments pour la mesure des réponses du tronc cérébral à une stimulation auditive 97c3f368211e/sist-en-60645-7-2010

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX

M

ICS 17.140.50 ISBN 2-8318-1038-4

CONTENTS

FO	REWC	PRD	3			
INT	RODU	JCTION	5			
1	Scop	e	6			
2	Norm	ative references	6			
3	Terms and definitions					
4		irements for specific instruments				
5		ral specifications				
•	5.1	Measuring system				
	J. I	5.1.1 Units of measurement				
		5.1.2 Measurement range				
		5.1.3 Time resolution				
	5.2	Stimulus system				
	0.2	5.2.1 General requirements				
		5.2.2 Stimulus types				
	5.3	Test quality assuring system				
		5.3.1 Recording conditions				
		5.3.2 Response detection				
		5.3.3 Quality estimates A.N.D.A.R.DP.R.E.V.I.E.W				
	5.4	5.3.4 Reference values. Presentation of results Standards.iteh.ai)	9			
6	Demonstration of conformity with specifications					
	6.1	General : https://standards.iteh.ai/catalog/standards/sist/c00ae6fe-d930-472f-9ad9	9			
	6.2	Signal-to-noise ratio improvement/sist-en-60645-7-2010	9			
	6.3	Maximum permitted expanded uncertainty of measurements $U_{\sf max}$				
7	Gene	ral 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				
	7.5	Voltage supply variation and environmental conditions	11			
		7.5.1 Mains operation	11			
		7.5.2 Battery operation				
		7.5.3 Environmental conditions				
8		ne calibration				
Bibl	liogra	Dhy	12			
Tab	ole 1 –	Instrumentation requirements	7			
Tab	le 2 –	Documentation of test conditions, parameters and results	9			
		Values of $U_{\sf max}$ for basic measurements				

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees. The property of the property o
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity TEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.