BS EN 60645-7:2010

BSI Standards Publication

Electroacoustics — Audiometric equipment —

Part 7: Instruments for the measurement of auditory brainstem responses

National foreword

This British Standard is the UK implementation of EN 60645-7:2010. It is identical to IEC 60645-7:2009.

The UK participation in its preparation was entrusted to Technical Committee EPL/29, Electroacoustics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

ISBN 978 0 580 60926 8

ICS 13.140; 17.140.50

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 28 February 2010

Amendments issued since publication

Amd. No.	Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60645-7

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)

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

Ref. No. EN 60645-7:2010 E

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.

Publication	Year	Title	EN/HD	Year
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)	-	-

CONTENTS

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

3.2
electric response audiometry
ERA
method for recording the AEPs

3.3
auditory brainstem response
ABR
transient AEPs generated in the inner ear, the auditory nerve and the brainstem after stimulation of the ear with an acoustic or vibratory force stimulus of short duration

NOTE A method for recording the ABRs is also known as BERA (brainstem electric response audiometry).

3.4
automated auditory brainstem response
AABR
automatic detection of auditory brainstem responses

4 Requirements for specific instruments

Two different types of ERA instrument are specified by the requirements for minimum mandatory functions (see Table 1). Other functions are not precluded. The two types relate to their presumed primary application (diagnostic/clinical and screening).

Table 1 – Instrumentation requirements

	Type	
Feature	**1 Diagnostic/clinical**	**2 Screening**
Stimulus		
Stimulus according to IEC 60645-3	x	x [1]
Adjustable stimulus level, level control	x	
Contra-lateral masking facility	x [2]	
Signal processing		
Artefact rejection	x	x
User adjustable averaging	x	
Automatic response detection		x
Presentation of results		
Display of result	x	
Display of PASS/REFER		x
Display of a quality measure	x	
Documentation		
Display, internal/external storage, and export of test results/parameters	x	

[1] If a different test signal is used, it shall be described by the manufacturer.

[2] Usually a white noise signal is used for contra-lateral masking.

5 General specifications

5.1 Measuring system

5.1.1 Units of measurement

SI units or derived SI units shall be used. The units of measurement shall be indicated.

5.1.2 Measurement range

The minimum measurement ranges for AEP shall be from 10 nV to 2 μV for instruments of Type 1.

5.1.3 Time resolution

The time resolution shall be 0,1 ms or better for instruments of Type 1.

NOTE The minimum time resolution is determined by the sampling rate of the device. The amplitude accuracy limit is given by the internal noise.

5.2 Stimulus system

5.2.1 General requirements

Specifications for the stimulus system are as given in the relevant parts of Clauses 6, 8 and 10 of IEC 60645-1:2001, and Clause 5 of IEC 60645-3:2007 with the exceptions specified below.

5.2.2 Stimulus types

5.2.2.1 General

The general properties and temporal characteristics of the stimulus signal are specified in IEC 60645-3. Other stimulus types shall be specified by the manufacturer, if applicable.

5.2.2.2 Masking signal

The manufacturer shall provide the frequency characteristics and levels of the masking signal.

5.2.2.3 Stimulus levels

For instruments of Type 1, stimulus levels shall cover a hearing level range of at least 30 dB to 80 dB. For instruments of Type 2, the stimulus level range shall be specified by the manufacturer.

5.3 Test quality assuring system

5.3.1 Recording conditions

A facility for checking the test conditions shall be provided, for example, by checking the electrical impedance between the electrodes.

The system shall be able to improve the initial signal-to-noise ratio by at least 30 dB in the relevant frequency range, for example, by an averaging procedure.

An artefact rejection system shall be provided.

5.3.2 Response detection

If an algorithm is used for automatic detection (mandatory for Type 2 instruments), its statistical significance shall be validated by the manufacturer.

5.3.3 Quality estimates

The efficiency of the method used for estimation of residual noise shall be documented by the manufacturer.

5.3.4 Reference values

Reference hearing threshold values are given in the ISO 389 series. If other reference values are used, these data shall be validated and documented by the manufacturer.

5.4 Presentation of results

All relevant information concerning stimulus, recording conditions and results according to Table 2 shall be stored and be available on demand. The information shall be presented on display of the instrument and/or as paper printout.

Table 2 – Documentation of test conditions, parameters and results

	Type	
	1 Diagnostic/clinical	2 Screening
Stimulus level	x	x
Contra-lateral masking	x	
Test conditions[1]	x	
Number of rejected and accepted records	x	
Artefact rejection limit	x	
Graphic display of full result	x	
Display of PASS/REFER		x
Test quality	x	
[1] For example, artefacts during test, EEG level, electrode impedance, etc.		

6 Demonstration of conformity with specifications

6.1 General

The following procedures shall be used for ensuring that an instrument meets the specifications given in this part of IEC 60645.

6.2 Signal-to-noise ratio improvement

The improvement of the signal-to-noise ratio by at least 30 dB in the relevant frequency range shall be verified by a suitable procedure as specified by the manufacturer.

6.3 Maximum permitted expanded uncertainty of measurements U_{max}

Table 3 specifies the maximum permitted expanded uncertainty U_{max} calculated with a coverage factor of k = 2 to give a level of confidence of approximately 95 %, associated with the measurements undertaken in this part of IEC 60645, according to ISO/IEC Guide 98-3. One set of values for U_{max} is given for basic type approval measurements.

The expanded uncertainties of measurements given in Table 3 are the maximum permitted for demonstration of conformance to the requirements of this standard. If the actual expanded uncertainty of a measurement performed by the test laboratory exceeds the maximum permitted value in Table 3, the measurement shall not be used to demonstrate conformance to the requirements of this part of IEC 60645.

Table 3 – Values of U_{max} for basic measurements

Measured quantity	Relevant subclause number	Basic $U_{max}(k = 2)$
Measurement range	5.1.2	3 nV
Time resolution	5.1.3	0,03 ms
Stimulus levels	5.2.2.3	1,0 dB
Signal-to-noise ratio	5.3.1	1,0 dB
Temperature	7.5.3	0,5 °C
Relative humidity	7.5.3	5 %
Ambient pressure	7.5.3	0,1 kPa

7 General requirements

7.1 Marking

The instrument shall be marked according to the requirements of 15.1 of IEC 60645-1:2001.

7.2 Instruction manual

An instruction manual shall be supplied with each instrument. In this manual the manufacturer shall specify all characteristics as required by this standard and by the relevant statements of 15.2 of IEC 60645-1:2001, as well as the efficiency and supporting evidence for the validation of the screening algorithm, e.g. the PASS/REFER criteria.

7.3 Safety requirements

7.3.1 General

Instruments shall conform to IEC safety requirements specified in IEC 60601-1.

7.3.2 Immunity to power and radiofrequency fields

During, and as a result of, any EMC immunity testing under the EMC test conditions, the unwanted sound from any transducer shall not exceed a hearing level of 80 dB. Subclause 13.3 of IEC 60645-1 gives methods for showing conformity.

7.4 Warm-up time

The maximum warm-up time shall be specified by the manufacturer and shall not exceed 10 min when the unit has been stored at room temperature. The performance requirements of this standard shall be met after the started warm-up time has elapsed and after any setting-up adjustments have been carried out in the manner prescribed by the manufacturer.

7.5 Voltage supply variation and environmental conditions

7.5.1 Mains operation

The specifications shall be met when any long-term deviation in any supply voltage or mains frequency in combination is least favourable within the limits of ± 10 % supply voltage or ± 5 % mains frequency. When any short-term line variation has occurred that affects the performance of the instrument, the instrument shall revert to a mode that will not endanger the subject under test, nor yield invalid results.

7.5.2 Battery operation

The manufacturer shall state the limits of battery voltages within which the specification shall be met, and a suitable indicator shall be provided to inform the operator that the battery voltage is within the limits for correct performance.

7.5.3 Environmental conditions

The specifications shall be met for all combinations of temperature within the range +15 °C to +35 °C, relative humidity within the range 30 % to 90 % and static pressure within the range 98 kPa to 104 kPa.

8 Routine calibration

The following parameters shall be verified at regular intervals:

- stimulus characteristics;
- recording system characteristics.

NOTE A typical regular time interval for routine calibration is 12 months.

Bibliography

[1] IEC 60601-2-40, *Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment*

This page deliberately left blank

British Standards Institution (BSI)

BSI is the independent national body responsible for preparing British Standards and other standards-related publications, information and services.
It presents the UK view on standards in Europe and at the international level.

It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover.

Tel: +44 (0)20 8996 9001 Fax: +44 (0)20 8996 7001

BSI offers Members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Tel: +44 (0)20 8996 7669 Fax: +44 (0)20 8996 7001
Email: plus@bsigroup.com

Buying standards

You may buy PDF and hard copy versions of standards directly using a credit card from the BSI Shop on the website **www.bsigroup.com/shop.** In addition all orders for BSI, international and foreign standards publications can be addressed to BSI Customer Services.

Tel: +44 (0)20 8996 9001 Fax: +44 (0)20 8996 7001
Email: orders@bsigroup.com

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Knowledge Centre.

Tel: +44 (0)20 8996 7004 Fax: +44 (0)20 8996 7005
Email: knowledgecentre@bsigroup.com

Various BSI electronic information services are also available which give details on all its products and services.

Tel: +44 (0)20 8996 7111 Fax: +44 (0)20 8996 7048
Email: info@bsigroup.com

BSI Subscribing Members are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration.

Tel: +44 (0)20 8996 7002 Fax: +44 (0)20 8996 7001
Email: membership@bsigroup.com

Information regarding online access to British Standards via British Standards Online can be found at **www.bsigroup.com/BSOL**

Further information about BSI is available on the BSI website at **www.bsigroup.com/standards**

Copyright

Tel: +44 (0)20 8996 7070
Email: copyright@bsigroup.com

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Tel +44 (0)20 8996 9001
Fax +44 (0)20 8996 7001
www.bsigroup.com/standards

raising standards worldwide™