

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Electroacoustics – Audiometric equipment –
Part 7: Instruments for the measurement of auditory brainstem responses**
(standards.iteh.ai)

**Electroacoustique – Equipements audiométriques –
Partie 7: Instruments pour la mesure des réponses du tronc cérébral à une
stimulation auditive**
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IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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Email: csc@iec.ch

Tél.: +41 22 919 02 11

Fax: +41 22 919 03 00



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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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

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- withdrawn;
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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.

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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

[IEC 60645-7:2009](#)

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
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Feature	Type	
	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 μ V 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.

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5.2.2 Stimulus types

5.2.2.1 General

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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.