SLOVENSKI STANDARD
oSIST prEN IEC 60645-7:2025

01-februar-2025

Elektroakustika - Avdiometrična oprema - 7. del: Instrumenti za merjenje slušnih potencialov

Electroacoustics - Audiometric equipment - Part 7: Instruments for the measurement of auditory evoked potentials

Akustik - Audiometer - Teil 7: Geräte zur Messung von akustisch evozierten Potentialen

Electroacoustique - Equipements audiométriques - Partie 7: Instruments pour la mesure des réponses du tronc cérébral à une stimulation auditive

Ta slovenski standard je istoveten z: **prEN IEC 60645-7:2024**

ICS:

17.140.50	Elektroakustika	Electroacoustics

oSIST prEN IEC 60645-7:2025 **en**

IEC

29/1189/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60645-7 ED2**	
DATE OF CIRCULATION: **2024-12-06**	CLOSING DATE FOR VOTING: **2025-02-28**
SUPERSEDES DOCUMENTS: **29/1160/CD, 29/1165A/CC**	

IEC TC 29 : ELECTROACOUSTICS	
SECRETARIAT: Denmark	SECRETARY: Ms Lise Aagesen
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED:	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING **Attention IEC-CENELEC parallel voting** The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

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Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

Electroacoustics - Audiometric equipment - Part 7: Instruments for the measurement of auditory evoked potentials

PROPOSED STABILITY DATE: 2025

NOTE FROM TC/SC OFFICERS:

At its meeting April 2024 in Warsaw, IEC/TC 29 took the following decision, doc. 29/1174/DL, refers:

DECISION 5

TC 29 decides to proceed with 1CD 60645-7 "Electroacoustics – Audiometric equipment – Part 7: Instruments for the measurement of auditory evoked potentials" as a CDV with David Canning, UK, as new project leader with the following target dates:

CDV: 2025-02-28

FDIS: 2026-06-30

Publication: 2026-09-30

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT

Part 7: Instruments for the measurement of auditory evoked potentials

FOREWORD

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IEC 61252 has been prepared by IEC technical committee 29: Electroacoustics. It is an International Standard.

This second edition cancels and replaces the first edition published in 2009 and the third edition of IEC 60645-3, published in 2020. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) The contents of IEC 60645-3:2020, *Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration* have been incorporated into this standard to bring it in line with other parts of IEC 60645, where the specification of the instrument and the associated test stimuli are included together in the same standard.

The text of this International Standard is based on the following documents:

Draft	Report on voting
XX/XX/FDIS	XX/XX/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document 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.

Conformance to the performance specification in this document is demonstrated when a measured deviation from a design goal equals or does not exceed the corresponding acceptance limit(s), and the laboratory has demonstrated that the associated uncertainty of measurement equals or does not exceed the maximum permitted uncertainty specified in this document.

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT

Part 7: Instruments for the measurement of auditory evoked potentials

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 instruments (screening and diagnostic/clinical), and specifies the functions to be provided on these types. It also specifies a means of describing the physical characteristics, in terms of electrical waveforms, of audiometric reference and test signals of short duration used with auditory evoked potential equipment and other equipment (e.g. otoacoustic emission instruments), and methods for their measurement.

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.

Evoked response measurement using the application of electric stimuli to a subject is beyond the scope of this document standard.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60645-1:2017, *Electroacoustics – Audiometric equipment – Part 1: Equipment for pure-tone and speech audiometry*

IEC 60318-1, *Electroacoustics – Simulators of human head and ear – Part 1: Ear simulator for the measurement of supra-aural and circumaural earphones*

IEC 60318-3, *Electroacoustics – Simulators of human head and ear – Part 3: Acoustic coupler for the calibration of supra-aural earphones used in audiometry*

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*

IEC 60318-5, *Electroacoustics – Simulators of human head and ear – Part 5: 2 cm^3 coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts*

IEC 60318-6, *Electroacoustics – Simulators of human head and ear – Part 6: Mechanical coupler for the measurement of bone vibrators*

IEC 61260-1, *Electroacoustics – Octave-band and fractional-octave-band filters – Part 1: Specifications*

ISO 389-6, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 6: Reference threshold of hearing for 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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

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
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 1 to entry: A method for recording the ABRs is also known as BERA (brainstem electric response audiometry).

3.3
automated auditory brainstem response
AABR
automatic detection of auditory brainstem responses

3.4
Normal Hearing Level
NHL
hearing level of ontologically normal adults as determined through the use of short-duration signals calibrated using the peak-to-peak method

3.5
short-duration signal
signal having a duration of less than 200 ms

3.6
click
transient acoustic or vibratory signal whose frequency spectrum covers a broad frequency range, produced by applying a single rectangular electrical pulse to the terminals of the transducer

Note 1 to entry: See Figure 1 and Figure 2.