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STN	**Elektroakustika Audiometrické zariadenia Časť 7: Prístroje na meranie sluchovo evokovaných potenciálov**	**STN EN IEC 60645-7 36 8811**

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/25

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English Version

Electroacoustics - Audiometric equipment - Part 7: Instruments for the measurement of auditory evoked potentials (IEC 60645-7:2025)

Électroacoustique - Appareils audiométriques - Partie 7: Instruments pour le mesurage des potentiels évoqués auditifs (IEC 60645-7:2025)

Akustik - Audiometer - Teil 7: Geräte zur Messung von akustisch evozierten Potentialen (IEC 60645-7:2025)

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

The text of document 29/1189/CDV, future edition 2 of IEC 60645-7, prepared by TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60645-7:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2026-10-31
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2028-10-31

This document supersedes EN 60645-7:2010 and EN IEC 60645-3:2020 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60645-7:2025 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 61672-1	NOTE	Approved as EN 61672-1
ISO 8253-2	NOTE	Approved as EN ISO 8253-2
IEC 60645-6	NOTE	Approved as EN IEC 60645-6
IEC 60601-2-40	NOTE	Approved as EN IEC 60601-2-40

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60318-1	-	Electroacoustics - Simulators of human head and ear - Part 1: Ear simulator for the measurement of supra-aural and circumaural earphones	EN 60318-1	-
IEC 60318-3	-	Electroacoustics - Simulators of human head and ear - Part 3: Acoustic coupler for the calibration of supra-aural earphones used in audiometry	EN 60318-3	-
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	EN 60318-4	-
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	EN 60318-5	-
IEC 60318-6	-	Electroacoustics - Simulators of human head and ear - Part 6: Mechanical coupler for the measurement on bone vibrators	EN 60318-6	-
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	EN 60645-1	2017
IEC 61260-1	-	Electroacoustics - Octave-band and fractional-octave-band filters - Part 1: Specifications	EN 61260-1	-
ISO 389-6	-	Acoustics - Reference zero for the calibration of audiometric equipment – Part 6: Reference threshold of hearing for test signals of short duration	EN ISO 389-6	-
ISO/IEC Guide 98-3	-	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-

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INTERNATIONAL STANDARD

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

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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

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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IEC 60645-7 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 IEC 60645-3:2020. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition: the contents of IEC 60645-3:2020 have been incorporated into this document to bring it in line with other parts of the IEC 60645 series, 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
29/1189/CDV	29/1199/RVC

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.

A list of all parts in the IEC 60645 series, published under the general title *Electroacoustics – Audiometric equipment*, can be found on the IEC website.

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, or
– revised.

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.

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 either acoustic or vibratory stimuli of short duration. This document 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 document is to ensure that measurements made under comparable test conditions with different instruments complying with this document will be consistent. This document 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.

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 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 on bone vibrators*

IEC 60645-1:2017, *Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone and speech audiometry*

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

ISO/IEC Guide 98-3, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement* (GUM:1995)

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