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Part 6: Instruments for the measurement of otoacoustic emissions

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IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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Electroacoustics - Audiometric equipment - Part 6: Instruments for the measurement of otoacoustic emissions

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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60645-6 edition 2.1 contains the second edition (2022-03) [documents 29/1109/FDIS and 29/1114/RVD] and its amendment 1 (2026-08) [documents 29/1240/FDIS and 29/1242/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

IEC 60645-6 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. This edition constitutes a technical revision.

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

a) the nominal test frequency used in DPOAE is now defined as the higher of the two frequencies, f_2;

b) the permitted deviation of the stimulus signal for TEOAE has been specified;

c) the frequency range for DPOAE stimulus signals has been redefined,

d) the stimulus level requirements for TEOAE have been redefined;

e) the stimulus level requirements for DPOAE have been redefined;

f) the harmonic distortion requirements for DPOAE have been redefined;

g) a minimum measurement range for DPOAE has been added.

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

Draft	Report on voting
29/1109/FDIS	29/1114/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 http://www.iec.ch/standardsdev/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 and its amendment 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 otoacoustic emissions of the human ear. Such emissions may be evoked by acoustic test signals having different spectral and temporal characteristics.

The practical use of such instruments concerns the measurement of sound energy emitted by the inner ear and its separation from sounds emerging from physiological or other sources.

The spontaneous otoacoustic emissions (SOAE) and stimulus frequency otoacoustic emissions (SFOAE), which comprise part of the otoacoustic emissions, are not covered by this document.

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.

INTRODUCTION to Amendment 1

The second edition of IEC 60645-6 was published in 2022 and included normative references to test signals of short duration specified in IEC 60645-3:2020. In 2025, IEC 60645-3:2020 was withdrawn, and its normative content was incorporated into IEC 60645-7:2025.

Consequently, IEC/TC 29 approved a project to develop Amendment 1 to IEC 60645-6:2022. This amendment includes

– replacing the references to the withdrawn IEC 60645-3:2020 with the relevant parts of IEC 60645-7:2025 concerning the requirements for short-duration signals, and

– editorial clarification of the two-sided (±) acceptance limits for the stimulus levels of DPOAE primary tones.

This amendment does not introduce any technical changes to the document.

1 Scope

This part of IEC 60645 applies to instruments designed primarily for the measurement of otoacoustic emissions in the human external auditory meatus evoked by acoustic probe stimuli. This document defines the characteristics to be specified by the manufacturer, specifies minimum mandatory functions for two types of instruments and provides performance specifications applicable to both instrument types. This document describes methods to be used to demonstrate conformance with the specifications in this document and guidance on methods for periodic calibration.

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. Instruments can provide a measurement function not specifically within the scope of this document and still comply with the relevant requirements of this document for the functions that are within the scope. This document is not intended to restrict development or incorporation of new features, nor to discourage innovative approaches.

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 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 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

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

~~IEC 60645-3:2020, *Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration*~~

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

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 terminological databases for use in standardization at the following addresses:

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

3.1
otoacoustic emissions
OAE
acoustic signals generated in the inner ear which can be recorded in the external auditory meatus

3.2
transient-evoked otoacoustic emissions
TEOAE
acoustic signals emitted by the inner ear after stimulation with a stimulus of short duration

3.3
distortion product otoacoustic emissions
DPOAE
acoustic signals generated in the inner ear during stimulation with two pure tones

Note 1 to entry: The pure tones are frequencies f_1 and f_2, f_1 being the lower frequency.

Note 2 to entry: The frequencies of the DPOAE are given by the formulas for intermodulation distortions (IMD), i.e. $2f_1 - f_2$, $2f_2 - f_1$, etc.

3.4
nominal test frequency
frequency for which a DPOAE measurement is reported

3.5
primary tones
pure-tone stimuli used to evoke DPOAE

3.6
probe
part of the instrument, usually containing acoustic transducers, interfacing the instrument to the ear

3.7
ear tip
device used to assist acoustic coupling, to reduce acoustic leakage, to reduce the influence of environmental noise on measurements and to aid retention of the probe in the external auditory meatus

3.8
probe signal
acoustic stimulus signal that is emitted into the external auditory meatus by means of a probe