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colour inside

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 6: Instruments for the measurement of otoacoustic emissions

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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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 60645-6:2009. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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.

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IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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 ~~other~~ physiological or ~~artificial~~ 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.

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 6: Instruments for the measurement of otoacoustic emissions

1 Scope

This part of IEC 60645 applies to instruments designed primarily for the measurement of otoacoustic emissions in the human external ~~acoustic~~ auditory meatus evoked by acoustic probe ~~pulses or tones~~ stimuli. This document defines the characteristics to be specified by the manufacturer, ~~lays down performance specifications for two types of instruments[1] and specifies the functions to be provided on these types. This part of IEC 60645 describes methods of test to be used for approval testing and guidance on methods for undertaking routine calibration~~ 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 ~~which~~ can provide a measurement function not specifically within the scope of this document ~~shall~~ and still comply with ~~any~~ 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*[2]

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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 ~~compatibility~~ disturbances – Requirements and tests*

~~IEC 60601-1-4, *Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems*~~

~~[1] Screening and full diagnostics.~~

~~[2] To be published.~~

IEC 60645-1:~~2001~~2017, *Electroacoustics – ~~Audiological~~ Audiometric equipment – Part 1: ~~Pure-tone audiometers~~ Equipment for pure-tone and speech audiometry*

IEC 60645-3:~~2007~~2020, *Electroacoustics – Audiometric equipment – Part 3: 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)*

IEC 60645-6

Edition 2.0 2022-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Électroacoustique – Appareils audiométriques – Partie 6: Instruments pour la mesure des émissions otoacoustiques

IEC 60645-6:2022-03(en-fr)

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Part 6: Instruments for the measurement of otoacoustic emissions

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IEC 60645-3:2020, *Electroacoustics – Audiometric equipment – Part 3: 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)*

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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ÉLECTROACOUSTIQUE – APPAREILS AUDIOMÉTRIQUES –

Partie 6: Instruments pour la mesure des émissions otoacoustiques

AVANT-PROPOS

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L'IEC 60645-6 a été établie par le comité d'études 29 de l'IEC: Électroacoustique. Il s'agit d'une Norme internationale.

Cette deuxième édition annule et remplace la première édition parue en 2009. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) la fréquence d'essai nominale utilisée dans les émissions otoacoustiques de produit de distorsion (DPOAE – *Distortion Product Otoacoustic Emissions*) est désormais définie comme la plus élevée des deux fréquences, f_2;

b) l'écart permis du signal de stimulus pour les émissions otoacoustiques évoquées transitoires (TEOAE – *Transient-Evoked Otoacoustic Emissions*) a été spécifié;

c) la plage de fréquences pour les signaux de stimulus des DPOAE a été redéfinie;

d) les exigences relatives au niveau de stimulus pour les TEOAE ont été redéfinies;

e) les exigences relatives au niveau de stimulus pour les DPOAE ont été redéfinies;

f) les exigences relatives à la distorsion harmonique pour les DPOAE ont été redéfinies;

g) une étendue de mesure minimale pour les DPOAE a été ajoutée.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
29/1109/FDIS	29/1114/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous http://www.iec.ch/standardsdev/publications.

Une liste de toutes les parties de la série IEC 60645, publiées sous le titre général *Électroacoustique – Appareils audiométriques*, peut être consultée sur le site web de l'IEC.

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- amendé.

INTRODUCTION

Les développements dans le domaine du mesurage de l'audition à des fins de diagnostic ont permis la conception de différents instruments permettant d'évaluer les émissions otoacoustiques de l'oreille humaine. Ces émissions peuvent être évoquées par des signaux acoustiques d'essai ayant différentes caractéristiques spectrales et temporelles.

L'utilisation pratique de ces instruments concerne le mesurage de l'énergie acoustique émise par l'oreille interne et sa séparation des sons provenant de sources physiologiques ou autres.

Les émissions otoacoustiques spontanées (SOAE – *Spontaneous Otoacoustic Emissions*) et les émissions otoacoustiques à fréquence de stimuli (SFOAE – *Stimulus Frequency Otoacoustic Emissions*), qui comprennent une partie des émissions otoacoustiques, ne sont pas couvertes par le présent document.

La conformité aux spécifications de performances du présent document est démontrée lorsque l'écart mesuré par rapport à un objectif de conception est inférieur ou égal à la ou aux limites d'acceptation correspondantes et que le laboratoire a démontré que l'incertitude de mesure associée est inférieure ou égale à l'incertitude maximale admise spécifiée dans le présent document.

ÉLECTROACOUSTIQUE – APPAREILS AUDIOMÉTRIQUES –

Partie 6: Instruments pour la mesure des émissions otoacoustiques

1 Domaine d'application

La présente partie de l'IEC 60645 s'applique aux instruments conçus principalement pour le mesurage des émissions otoacoustiques dans le conduit auditif externe humain qui sont évoquées par des stimuli provenant d'une sonde acoustique. Le présent document définit les caractéristiques à spécifier par le fabricant, spécifie les fonctions obligatoires minimales pour deux types d'instruments et fournit des spécifications de performance applicables à ces deux types d'instruments. Le présent document décrit les méthodes à utiliser pour démontrer la conformité aux spécifications du présent document et des recommandations relatives aux méthodes d'étalonnage périodique.

Le présent document a pour objet d'assurer que des mesurages réalisés dans des conditions d'essai comparables avec différents instruments conformes au présent document sont cohérents. Il est possible que les instruments assurent une fonction de mesure qui ne relève pas spécifiquement du domaine d'application du présent document et soient cependant conformes aux exigences pertinentes du présent document concernant les fonctions qui relèvent du présent domaine d'application. Le présent document n'est pas destiné à limiter l'élaboration ou l'ajout de nouvelles caractéristiques ni à décourager les approches innovantes.

2 Références normatives

Les documents suivants sont cités dans le texte de sorte qu'ils constituent, pour tout ou partie de leur contenu, des exigences du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

IEC 60318-4, *Électroacoustique – Simulateurs de tête et d'oreille humaines – Partie 4: Simulateur d'oreille occluse pour la mesure des écouteurs couplés à l'oreille par des embouts*

IEC 60318-5, *Électroacoustique – Simulateurs de tête et d'oreille humaines – Partie 5: Coupleur de 2 cm^3 pour la mesure des appareils de correction auditive et des écouteurs couplés à l'oreille par des embouts*

IEC 60601-1, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*

IEC 60601-1-2, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

IEC 60645-1:2017, *Électroacoustique – Appareils audiométriques – Partie 1: Appareils pour l'audiométrie tonale et vocale*

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