

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Electroacoustics – Audiometric equipment –
Part 6: Instruments for the measurement of otoacoustic emissions**
(standards.iteh.ai)

**Electroacoustique – Equipements audiométriques –
Partie 6: Instruments pour la mesure des émissions otoacoustiques**

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CONTENTS

| | |
|--|----|
| FOREWORD..... | 4 |
| INTRODUCTION..... | 6 |
| 1 Scope..... | 7 |
| 2 Normative references..... | 7 |
| 3 Terms and definitions..... | 8 |
| 4 Requirements for specific instruments..... | 9 |
| 5 General specifications..... | 9 |
| 5.1 Acoustic stimulus system..... | 9 |
| 5.1.1 General requirements..... | 9 |
| 5.1.2 Stimulus types..... | 9 |
| 5.1.3 Stimulus frequency range..... | 10 |
| 5.1.4 Stimulus level..... | 10 |
| 5.1.5 Harmonic distortion..... | 11 |
| 5.2 Test quality assuring system..... | 11 |
| 5.2.1 General..... | 11 |
| 5.2.2 Test quality assurance..... | 11 |
| 5.2.3 Individual stimulus recordings..... | 11 |
| 5.3 Measuring system..... | 11 |
| 5.3.1 Units of measurement..... | 11 |
| 5.3.2 Measurement range..... | 11 |
| 5.3.3 Accuracy of measurement..... | 11 |
| 5.3.4 Frequency range..... | 11 |
| 5.3.5 Noise reduction..... | 11 |
| 5.3.6 Response detection..... | 12 |
| 5.3.7 Quality estimates..... | 12 |
| 5.3.8 Normative values..... | 12 |
| 5.4 Presentation of results..... | 12 |
| 5.4.1 General..... | 12 |
| 5.4.2 Primary results..... | 12 |
| 5.4.3 Secondary results..... | 13 |
| 6 Demonstration of conformity with specifications..... | 13 |
| 6.1 General..... | 13 |
| 6.2 Probe signal..... | 13 |
| 6.2.1 Probe signal spectrum..... | 13 |
| 6.2.2 Probe signal level and harmonic distortion..... | 13 |
| 6.3 Maximum permitted expanded uncertainty of measurements U_{max} | 13 |
| 6.4 Function of the complete system..... | 14 |
| 7 General requirements..... | 14 |
| 7.1 Marking..... | 14 |
| 7.2 Instruction manual..... | 14 |
| 7.3 Safety requirements..... | 14 |
| 7.4 Immunity to power and radiofrequency fields..... | 14 |
| 7.5 Warm-up time..... | 15 |
| 7.6 Voltage supply variation and environmental conditions..... | 15 |
| 7.6.1 Mains operation..... | 15 |
| 7.6.2 Battery operation..... | 15 |

| | |
|--|----|
| 7.6.3 Environmental conditions..... | 15 |
| 8 Additional characteristics to be specified by the manufacturer | 15 |
| 9 Routine calibration | 15 |
| Bibliography..... | 16 |
| Table 1 – Mandatory functions for otoacoustic emission instruments | 9 |
| Table 2 – Documentation of test conditions, parameters and results | 12 |
| Table 3 – Values of U_{\max} for basic measurements | 14 |

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ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 6: Instruments for the measurement of otoacoustic emissions

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International Standard IEC 60645-6 has been prepared by IEC technical committee 29: Electroacoustics.

The text of this standard is based on the following documents:

| | |
|-------------|------------------|
| FDIS | Report on voting |
| 29/673/FDIS | 29/681/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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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 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 sources.

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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 meatus evoked by acoustic probe pulses or tones. This standard defines the characteristics to be specified by the manufacturer, lays down performance specifications for two types of instruments¹ 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.

The purpose of this part of IEC 60645 is to ensure that measurements made under comparable test conditions with different instruments complying with the standard will be consistent. Instruments which provide a measurement function not specifically within the scope of the standard shall still comply with any relevant requirements. This standard is not intended to restrict development or incorporation of new features, nor to discourage innovative approaches.

2 Normative references

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 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

IEC 60318-5, *Electroacoustics – Simulators of human head and ear – Part 5: 2 cm³ 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 compatibility – Requirements and tests*

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

IEC 60645-1:2001, *Electroacoustics – Audiological equipment – Part 1: Pure-tone audiometers*

¹ Screening and full diagnostics.

² To be published.

IEC 60645-3:2007, *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)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

otoacoustic emissions

OAE

general term covering all types of acoustic signals generated in the inner ear which can be recorded in the external acoustic meatus

NOTE The spontaneous otoacoustic emissions (SOAE) and stimulus frequency otoacoustic emissions (SFOAE) which are also a part of the otoacoustic emissions are not covered by this standard.

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 (frequencies f_1 and f_2 , f_1 being the lower frequency)

NOTE The frequencies of the DPOAE are given by the formulas for distortions $3f_1$, $2f_1-f_2$, $2f_2-f_1$, $3f_2$, etc.

3.4

nominal test frequency

the frequency for which a DPOAE measurement is reported

3.5

primary tones

pure tone stimuli used to evoke DPOAEs

3.6

probe

part of the instrument, usually containing transducers, interfacing the instrument to the ear

3.7

ear tip

device used to provide a seal between the probe and the external acoustic meatus

3.8

probe signal

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

3.9

peak-to-peak equivalent sound pressure level

peSPL

r.m.s. value of a long-duration sinusoidal sound signal which, when compared under the same test conditions with a short-duration output signal from the transducer under test, has the

same peak-to-peak value (i.e., difference between the extreme positive and the extreme negative values) as the short-duration signal

NOTE See IEC 60645-3:2007, Figure 2.

4 Requirements for specific instruments

Two different types of otoacoustic emission instrument are specified by the requirements for minimum mandatory functions (see Table 1). Additional functions are not precluded. The two types relate to their presumed primary application (screening and diagnostic/clinical).

Instrument types

- 1 Diagnostic/clinical: Adjustable stimulus and recording parameters, result shown in a graphical format
- 2 Screening: Automatic testing, automatic evaluation, results as pass/refer

Table 1 – Mandatory functions for otoacoustic emission instruments

| | Type | |
|---------------------------------------|--------------------------|----------------|
| | 1 Diagnostic/clinical | 2 Screening |
| Automatic test | x | x |
| Manual test | x | |
| <i>Presentation of results</i> | | |
| Display of full result | x | |
| Display of PASS/REFER | | x |
| Display of a quality measure estimate | x | |
| Display of response significance | x | |
| Digital storage of full result | x | |
| Printout | x | |

5 General specifications

5.1 Acoustic stimulus system

5.1.1 General requirements

Specifications for the acoustic 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.

NOTE If the instrument is designed to allow also the measurement of hearing thresholds, the full text of IEC 60645-1:2001 should apply.

5.1.2 Stimulus types

5.1.2.1 General

The general properties and temporal characteristics of the acoustic stimulus signals are specified within the following sections depending on the type of OAEs.

5.1.2.2 TEOAE

The full characteristics of the short-duration signal used for the measurements of TEOAEs shall be specified by the manufacturer (i.e., as specified in IEC 60645-3:2007).

NOTE Series of clicks with different polarity and levels are often used, usually referred to as non-linear click series. The specifications found in IEC 60645-3 are applicable to each single click in the series.

5.1.2.3 DPOAE

The stimulus signal used for the measurement of DPOAEs shall be composed of two primary tones, f_1 and f_2 . The nominal test frequency normally refers to f_1 . If f_2 is used as the nominal test frequency, this shall be stated by the manufacturer. If additional test signals are used, their full characteristics shall be specified by the manufacturer.

5.1.3 Stimulus frequency range

5.1.3.1 General

The frequency of the stimulus signals shall meet at least the requirements specified in the following subclauses depending on the type of OAEs.

5.1.3.2 TEOAE

The stimulus shall cover the range from 0,5 kHz to 4 kHz for Type 1 instruments and the range from 1,5 kHz to 3 kHz for Type 2 instruments.

5.1.3.3 DPOAE

For the measurement of DPOAEs, stimulus frequencies between 0,5 kHz and 8 kHz in at least three steps per octave shall be provided in instruments of Type 1 and at least two frequencies between 1 kHz and 4 kHz for Type 2. The frequency ratio of the two primary tones shall be from 1:1,15 to 1:1,25. The actual frequencies shall not differ from their nominal values by more than ± 1 %.

5.1.4 Stimulus level

5.1.4.1 General

The sound pressure level of the stimulus signals shall be variable within the ranges specified in the following clauses depending on the type of OAEs. Its actual value within the residual ear-canal volume shall be measured prior to each recording with the probe microphone.

5.1.4.2 TEOAE

The stimulus level shall provide the range from 30 dB peSPL to 90 dB peSPL for instruments of Type 1 and from 60 dB peSPL to 80 dB peSPL for instruments of Type 2 as measured according to IEC 60318-4 or IEC 60318-5.

5.1.4.3 DPOAE

The levels of the primary tones under test conditions shall not deviate from the nominal levels by more than 1,5 dB.

The stimulus levels of the primary tones shall, as a minimum, be adjustable over the range from 0 dB SPL to 70 dB SPL for instruments of Type 1 and from 50 dB SPL to 65 dB SPL for instruments of Type 2 at all signal frequencies as measured in an occluded-ear simulator according to IEC 60318-4 or in a reference coupler according to IEC 60318-5. The level L_1 of the primary tone with the lower frequency must be equal to or higher than L_2 but shall not exceed 90 dB SPL.