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# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

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

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

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# ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

## Part 6: Instruments for the measurement of otoacoustic emissions

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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.

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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 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.

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 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 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*

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1 Screening and full diagnostics.

2 To be published.

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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 be 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

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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<br>Diagnostic/clinical | 2<br>Screening |
| Automatic test | x | x |
| Manual test | x | |
| *Presentation of results* | | |
| 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.

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