IEC 60645-6

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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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ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 6: Instruments for the measurement of otoacoustic emissions

FOREWORD

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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 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,
- replaced by a revised edition, or
- amended.

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.

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 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*

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

3.9
peak-to-peak equivalent sound pressure level
peSPL
root mean squared (RMS) 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 1 to entry: See IEC 60645-3:2020, Figure 2.

4 Requirements for specific instruments

Two different types of otoacoustic emission instruments 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 (diagnostic/clinical or screening); however, a device of one type is not required to comply with the additional specifications of the other type.

Table 1 – Mandatory functions for otoacoustic emission instruments

	Type	
	1 Diagnostic/clinical	2 Screening
Automatic test	x	x
Manual test	x	
Display of PASS/REFER		x
Display of detailed result in graphical and/or tabular format	x	
Display of stability of acoustic response in the external auditory meatus (see 5.2.1)	x	
Display of response quality estimate (see 5.3.7)	x	
Digital storage of detailed result	x	
Export of full test report	x	
Type 1. This type of devices shall include the ability to manually start the test and to adjust the parameters of the test. Type 2. This type of device shall include the ability to automatically start the test.		

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 Clause 6, Clause 8 and Clause 10 of IEC 60645-1:2017 and Clause 5 of IEC 60645-3:2020 with the exceptions specified below.

NOTE If the instrument is designed to also allow the measurement of hearing thresholds, the full text of the relevant clauses of IEC 60645-1:2017 applies.

5.1.2 Stimulus types

5.1.2.1 General

The general properties and temporal characteristics of the acoustic stimulus signals are specified within 5.1.2.2 and 5.1.2.3 depending on the type of OAE being measured.

5.1.2.2 TEOAE

The full characteristics of the short-duration signal used for the measurements of TEOAE shall be specified by the manufacturer (i.e., as specified in IEC 60645-3:2020).

NOTE A series of clicks with different polarity and levels is often used and this is usually referred to as a "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 DPOAE shall be composed of two primary tones with frequencies f_1 and f_2. Although the DPOAE of principal interest is at a frequency of $2f_1 - f_2$, the nominal test frequency of the measurement normally refers to f_2. If f_1 is used as the nominal test frequency, this shall be stated by the manufacturer. If additional test signals are used (such as those used for masking), their full characteristics shall be specified by the manufacturer.

5.1.3 Stimulus frequency range

5.1.3.1 General

The frequency content of the stimulus signal shall, as a minimum, meet the requirements specified in 5.1.3.2 and 5.1.3.3 depending on the type of OAEs being measured.

5.1.3.2 TEOAE

The frequency spectrum of the transient stimulus signal shall at least 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. The stimulus level frequency spectrum shall be flat within a limit of ±5 dB as measured in an occluded-ear simulator according to IEC 60318-4 or a 2 cm^3 coupler according to IEC 60318-5, using the ear simulator or 2 cm^3 coupler microphone, over the frequency range.

5.1.3.3 DPOAE

For the measurement of DPOAE, nominal stimulus frequencies between 0,75 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 stated by the manufacturer and shall normally be from 1:1,15 to 1:1,25.

The acceptance limit of the actual frequencies is ±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 5.1.4.2 and 5.1.4.3 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

For Type 1 instruments, the stimulus level shall be adjustable with a step size no greater than 5 dB and include a range of at least 60 dB peSPL to 85 dB peSPL. For Type 2 instruments, a single fixed level of stimulus is acceptable, and this level shall be stated clearly in the documentation since it impacts on the specificity of screening for a certain level of hearing loss. The stimulus levels stated shall be measured in an occluded-ear simulator according to IEC 60318-4 or a 2 cm^3 coupler according to IEC 60318-5, using the occluded-ear simulator or 2 cm^3 coupler microphone.