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INTERNATIONAL STANDARD

colour inside

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

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ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 6: Instruments for the measurement of otoacoustic emissions

FOREWORD

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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.

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.

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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. 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]

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~~ disturbances – Requirements and tests*

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

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[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)*

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

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 ~~distortions $3f_1$, $2f_1-f_2$, $2f_2-f_1$, $3f_2$~~ 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 provide a seal between the probe and the external acoustic meatus~~
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:~~2007~~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.

~~**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~~	
~~*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~~	

	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:~~2001~~2017 and Clause 5 of IEC 60645-3:~~2007~~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:~~2001~~2017 ~~should apply~~ 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:~~2007~~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_1~~ f_2. If ~~f_2~~ 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 ~~0,5~~ 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 actual frequencies shall not differ from their nominal values by more than ±1 %.~~

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

~~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.~~

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.

To combat possible probe placement movement during the test, it is recommended that the stimulus level be confirmed regularly during data acquisition for both Type 1 and Type 2 instruments.

The acceptance limit of the stimulus signal given above is ±1,5 dB.

NOTE Type 2 instruments are expected to provide a stimulus level between 80 dB peSPL and 86 dB peSPL to maintain compatibility with established neonatal hearing screening programs.

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.~~

~~NOTE The levels should be optionally tested at regular intervals during data acquisition in instruments of Type 1.~~

For Type 1 instruments, the stimulus levels of the primary tones shall be adjustable with a step size no greater than 5 dB and include a range from 30 dB SPL to 70 dB SPL. For Type 2 instruments, a single fixed level for each of the two stimuli is acceptable but shall be stated clearly in the documentation since it impacts on the specificity of screening for a certain level of hearing loss. This measurement shall be performed in an occluded-ear simulator according to IEC 60318-4 or in a 2 cm^3 coupler according to IEC 60318-5 using the occluded-ear simulator or 2 cm^3 coupler microphone. The level L_1 of the primary tone with the lower frequency shall be equal to or higher than L_2 but shall not exceed 90 dB SPL.

To combat possible probe placement movement during the test, it is recommended that the stimuli level be confirmed regularly during data acquisition for both Type 1 and Type 2 instruments.

The acceptance limit of the primary tones given above under test conditions is 1,5 dB.

NOTE Type 2 instruments are expected to provide stimuli levels that fall between 55 dB SPL and 70 dB SPL at all signal frequencies to maintain compatibility with established neonatal hearing screening programs.

5.1.5 ~~Harmonic~~ Intermodulation distortion

~~For DPOAE stimuli, the total harmonic distortion of the acoustic test signal shall be less than 0,1 %. The total cubic distortion due to non-linear interactions between the two primary tones shall be less than 0,01 %.~~

The intermodulation distortion due to non-linear interactions between the two primary tones shall be less than 0,01 % at the clinically important distortion product frequency of $2f_1 - f_2$. This measurement shall be performed in an occluded-ear simulator according to IEC 60318-4 or in a 2 cm^3 coupler according to IEC 60318-5 using the microphone and measurement system of the OAE instrument. The maximum distortion limit of 0,01 % shall be achieved over the entire frequency range and stimuli levels offered by the instrument.

NOTE No requirements are specified for TEOAE.

5.2 Test quality assuring system

5.2.1 ~~General~~ Stability of acoustic response in the external auditory meatus

~~The acoustic conditions in the ear canal shall be checked by the ear probe and optionally adapted automatically to a predefined waveform and level before starting data acquisition and after its completion. From the comparison of the initial and the final state, stability shall be derived.~~

The acoustic conditions in the external auditory meatus shall be checked by measuring the acoustic response and optionally adapting this to a pre-defined level and waveform. The acoustic conditions shall be checked again after the data acquisition is completed before the