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REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

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IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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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.

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 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

probe is removed from the ear and the stability of the measurement shall be derived from these checks. Optionally, intermediate checks can be performed.

5.2.2 Test quality assurance

The following functions shall be available: ambient noise detection, leak detection, blocked probe detection.

5.2.3 Individual stimulus recordings

~~An oscillogram and a frequency spectrum of the stimulus recorded in the ear canal shall be generated and stored for TEOAE results in Type 1 instruments.~~

~~NOTE Additional intermediate oscillograms and spectra should be provided during the recording process in instruments of Type 1.~~

For Type 1 TEOAE instruments, the waveform and/or frequency spectrum of the stimulus recorded in the external auditory meatus shall be stored. An option may be provided to display the stored results.

It is recommended that intermediate recordings of this stimulus are used to provide an indication of the probe stability during the measurement.

5.3 Measuring system

5.3.1 Units of measurement

SI units or derived SI units shall be used. The units of measurement shall be indicated.

5.3.2 Measurement range

~~The minimum measurement range for OAE shall be from –20 dB SPL to +30 dB SPL.~~

Instruments shall be able to measure TEOAE over a range of at least –20 dB SPL to +30 dB SPL and DPOAE over a range of at least –10 dB SPL to +30 dB SPL.

5.3.3 Accuracy of measurement

~~The difference between indicated and actual sound pressure levels shall not exceed ±3 dB for frequencies up to 4 kHz and ±5 dB for higher frequencies.~~

The probe microphone shall measure the actual sound pressure level over the OAE frequency range. The acceptance limit for this measurement is ±3 dB for frequencies up to 4 kHz and ±5 dB at higher frequencies. If measurement points other than the probe microphone position are used, then the actual measurement points shall be stated by the manufacturer.

NOTE This performance limit of the standard relates to the probe microphone and input channel calibration accuracy (see 6.2.3 for details).

5.3.4 Frequency range

The frequency range of the measuring system shall be according to the applicable stimulus frequency range in 5.1.3 with accuracy defined in 5.3.3.

5.3.5 Noise reduction

~~The ambient noise shall be reduced by at least 30 dB in the relevant frequency range when measured in an occluded-ear simulator according to IEC 60318-4 or in a reference coupler according to IEC 60318-5.~~

Instruments shall be able to reduce the influence of ambient noise by at least 30 dB in the relevant frequency range when measured in an occluded-ear simulator according to IEC 60318-4 or in a 2 cm^3 coupler according to IEC 60318-5.

NOTE Methods employed to reduce the influence of ambient noise include sound isolation provided by the probe tip and signal averaging and/or other signal processing techniques.

5.3.6 Response detection

~~If an algorithm is used for automatic detection, the statistical significance of the algorithm shall be validated by the manufacturer.~~ Instruments that provide an automated PASS/REFER decision algorithm shall document and make available the statistical sensitivity of the algorithm under realistic test conditions of no OAE present (see 6.3). During the measurement, a stimulus artefact rejection system shall be used, and its characteristics shall be specified by the manufacturer.

5.3.7 Response quality estimates

~~The method used for determination of the residual noise shall be described.~~

The instrument shall provide indication(s) as to the degree that the result is contaminated by the presence of noise (and/or other measurement quality metrics). The method used to determine the degree of contamination shall be described in the documentation.

5.3.8 Normative values

If normative values are used (e.g. for calibration, PASS/REFER criteria), the source of these values shall be stated in the instruction manual.

5.4 Presentation of results

~~5.4.1 General~~

All relevant information shall be stored and be available on demand. The information shall be presented on the display of the instrument, in electronic form and/or as a paper printout. The ~~explanation of the~~ relevant information required is given in Table 2.

Table 2 – Documentation of test conditions, parameters and results

	Type	
	1 Diagnostic/clinical	2 Screening
Stimulus level	x	
~~Recorded OAEs~~ Number of epochs or time of recorded data	x	
Number of ~~artefacts~~ epochs or time of rejected data	x	
Artefact rejection limit	x	
Graphic display of ~~full~~ detailed result [a]	x	
Display of PASS/REFER		x
Residual noise estimate	x	
OAE to noise ratio	x	
[a] ~~Oscillogram~~ Waveform (TEOAE) and/or frequency spectrum (TEOAE and DPOAE), respectively.		

~~5.4.2 Primary results~~

~~5.4.2.1 Presentation~~

~~Averaged signal, estimated residual noise and total signal (OAE and noise) separately.~~

~~5.4.2.2 TEOAE~~

~~Time domain (oscillogram).~~

~~5.4.2.3 DPOAE~~

~~Frequency domain (spectrum).~~

~~5.4.3 Secondary results~~

~~5.4.3.1 TEOAE~~

~~Time slices and frequency ranges, estimated true level (noise correction), cross correlation (reproducibility).~~

~~5.4.3.2 DPOAE~~

~~Estimated true level (corrected for noise), signal-to-noise ratio.~~

6 Demonstration of conformity with specifications

6.1 General

The following procedures shall be used for ensuring that an instrument meets the specifications given in this document. Guidelines for ~~routine~~ periodic calibration are described in Clause 9.

6.2 Probe signal

6.2.1 Probe signal frequency spectrum

The probe signal frequency spectrum shall be measured by coupling the probe to an occluded-ear simulator or ~~reference~~ 2 cm^3 coupler according to IEC 60318-4 and IEC 60318-5, respectively, and according to the instructions provided by the manufacturer. The occluded-ear simulator or 2 cm^3 coupler to be used and the method of coupling shall be stated by the manufacturer.

Since both the occluded-ear simulator and 2 cm^3 couplers have ¼ wave resonances within the frequency range of typical OAE measurements, the manufacturer shall state clearly whether the probe signal spectrum is measured using the test-cavity measurement microphone or the probe microphone.

6.2.2 Probe signal level and harmonic distortion

The signal level and the harmonic distortion of the probe signal shall be measured by means of an occluded-ear simulator according to IEC 60318-4 or a ~~reference~~ 2 cm^3 coupler according to IEC 60318-5, to which the probe is coupled with the ear tip placed according to instructions provided by the manufacturer.

Since both the simulator and 2 cm^3 couplers have ¼ wave resonances within the frequency range of typical OAE measurements, the manufacturer shall state clearly whether the probe signal spectrum is measured using the cavity measurement microphone or the probe microphone.

6.2.3 Probe measurement accuracy

The probe microphone accuracy is determined by measuring the output of the probe microphone in the presence of a known sound field presented over the range of frequencies stipulated in 5.1.3.

Suggested verification methods are:

– free-field with a calibrated measurement microphone in the same sound field as the probe microphone;

– the use of a measurement microphone and a test cavity with dimensions such that the first ¼ wave resonance is above the highest OAE measurement frequency of the instrument.

If other measurement methods are used, these shall be specified by the manufacturer.

6.3 Complete system

The performance of the complete test system shall be tested by coupling the probe to an occluded-ear simulator according to IEC 60318-4 or a 2 cm^3 coupler according to IEC 60318-5, with the ear tip placed according to the instructions provided by the manufacturer. On completion of the test, no response shall be detected.

If the instrument provides automatic PASS/REFER decision algorithms, these tests shall be performed in the presence of acoustic noise with a typical frequency spectrum and at a level which triggers the noise rejection at least 10 % of the time. The procedures employed during this testing and the corresponding results shall be documented by the manufacturer.

Some test equipment specifically designed for neonatal hearing screening cannot perform these tests in the occluded-ear simulator or 2 cm^3 coupler specified above due to the cavity size. In this instance, the manufacturer shall provide the necessary information on how to perform the function test of the complete system using an alternative neonatal test cavity or ear simulator.

NOTE One example of an alternative neonatal test cavity is given in IEC 60318-8.

6.4 Maximum permitted expanded uncertainty of measurements U_{max}

~~Table 3 specifies the maximum permitted expanded uncertainty U_{max} calculated with a coverage factor of k = 2 to give a level of confidence of approximately 95 %, associated with the measurements undertaken in this part of IEC 60645, according to ISO/IEC Guide 98-3. One set of values for U_{max} is given for basic type approval measurements.~~

Table 3 specifies the maximum permitted expanded uncertainty for a coverage factor of k = 2 according to ISO/IEC Guide 98-3, associated with the measurements undertaken in this document. One set of values for U_{max} is given for conformance testing and periodic calibration.

The expanded uncertainties of measurement given in Table 3 are the maximum permitted for demonstration of conformance to the requirements of this document. If the actual expanded uncertainty of a measurement performed by the test laboratory or maintenance service exceeds the maximum permitted value in Table 3, the measurement shall not be used to demonstrate conformance to the requirements of this document.

Table 3 – Values of U_{max} for ~~basic~~ conformance and periodic calibration measurements

Measured quantity	Relevant subclause number	Basic $U_{max}(k = 2)$
Stimulus levels	5.1.4.2, 5.1.4.3	1,0 dB
Stimulus level deviation	5.1.4.3	0,4 dB
Frequency	5.1.3.2, 5.1.3.3	0,5 %
~~Total harmonic distortion~~	~~5.1.5~~	~~0,05 %~~
~~Cubic~~ Intermodulation distortion	5.1.5	0,005 %
Measurement range	5.3.2	1,0 dB
Accuracy of measurement up to 4 kHz	5.3.3	0,7 dB
Accuracy of measurement higher than 4 kHz	5.3.3	1,2 dB
~~Noise reduction~~	~~5.3.5~~	~~1,0 dB~~
Temperature	7.6.3	0,5 °C
Relative humidity	7.6.3	5 %
Ambient pressure	7.6.3	0,1 kPa

~~**6.4 Function of the complete system**~~

~~The function of the complete test system shall be proven by coupling the probe to an occluded-ear simulator according to IEC 60318-4 or a reference coupler according to IEC 60318-5, with the ear tip placed according to the instructions provided by the manufacturer and performing the test. No response shall be detected.~~

~~NOTE If the test cannot be performed with the occluded-ear simulator or reference coupler specified above, the manufacturer should provide the necessary information on how to perform the function test of the complete system.~~

7 General requirements

7.1 Marking

The instrument shall be marked with the name of the manufacturer, the type as defined in Clause 4, the model and its serial number ~~as well as the identification of the transducer(s) employed~~.

If a transducer can be detached by the user, the transducer and/or the instrument shall be marked or identified, for example with a serial number, to prevent unintended interchange of transducers.

7.2 Instruction manual

An instruction manual shall be supplied with each instrument. In this manual, the manufacturer shall specify all characteristics as required by this document.

7.3 Safety requirements

Limitations of the applications shall be specified. Instruments shall conform to IEC safety requirements specified in IEC 60601-1 ~~and IEC 60601-1-4~~.

7.4 Immunity to power and radiofrequency fields

Instruments shall meet the requirements of IEC 60601-1-2 for electromagnetic compatibility (EMC).

During, and as a result of any EMC immunity testing, under the EMC test conditions, the unwanted sound from any air conduction transducer shall not exceed a hearing level corresponding to 80 dB peSPL when the transducer is coupled to an occluded-ear simulator according to IEC 60318-4 or a 2 cm^3 coupler according to IEC 60318-5. The manufacturer shall state the settings of the instruments. IEC 60645-1:~~2001~~2017, 13.3, gives methods for showing conformity.

7.5 Warm-up time

The maximum warm-up time shall be specified by the manufacturer and shall not exceed 10 min when the unit has been stored at room temperature. The performance requirements of this document shall be met after the stated warm-up time has elapsed and after any setting-up adjustments have been carried out in the manner prescribed by the manufacturer.

7.6 Voltage supply variation and environmental conditions

7.6.1 Mains operation

The specifications shall be met ~~when any long-term deviation in any supply voltage or mains frequency in combination is least favourable within the limits of ±10 % supply voltage or ±5 % mains frequency~~ over the full combined ranges of any long-term deviation in supply voltage of ±10 % and mains frequency ±5 %. When any short-term line variation has occurred that affects the performance of the instrument, the instrument shall revert to a mode that will not endanger the subject under test, nor yield invalid results.

7.6.2 Battery operation

The manufacturer shall state the limits of battery voltages within which the specification shall be met, and a suitable indicator shall be provided to inform the operator whether the battery voltage is within the limits for correct performance.

7.6.3 Environmental conditions

The specifications shall be met for all combinations of temperature within the range +15 °C to +35 °C, relative humidity within the range 30 % to 90 %, and static pressure within the range 98 kPa to 104 kPa.

8 Additional characteristics to be specified by the manufacturer

Procedures to measure the test quality according to 5.2 shall be specified by the manufacturer.

9 ~~Routine~~ Periodic calibration

For both Type 1 and Type 2 instruments, the following parameters shall be ~~verified at regular intervals~~ calibrated regularly:

– stimulus characteristics according to manufacturer's guidelines;

– microphone signal level response to test stimuli delivered by probe ~~receivers~~ transducers.

NOTE A typical ~~regular~~ time interval for ~~routine~~ periodic calibration is 12 months.

These parameters shall be ~~verified~~ measured by coupling the probe to an occluded-ear simulator, according to IEC 60318-4 or a ~~reference~~ 2 cm^3 coupler according to IEC 60318-5, with the ear tip placed according to the instructions ~~and reference values~~ provided by the manufacturer and using reference levels provided by the manufacturer.

~~For Type 2 instruments the parameters listed above should be verified as described for Type 1 instruments.~~

A system test, as detailed in 6.3, shall also be performed to verify the complete system performance.

Bibliography

IEC 60318-8, *Electroacoustics – Simulators of human head and ear – Part 8: Acoustic coupler for high-frequency measurements of hearing aids and earphones coupled to the ear by means of ear inserts*

ISO 389-6, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 6: Reference threshold of hearing for test signals of short duration*

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)

CONTENTS

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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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.

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

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 Intermodulation distortion

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 Stability of acoustic response in the external auditory meatus

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 probe is removed from the ear and the stability of the measurement shall be derived from these checks. Optionally, intermediate checks can be performed.

5.2.2 Test quality assurance

The following functions shall be available: ambient noise detection, leak detection, blocked probe detection.

5.2.3 Individual stimulus recordings

For Type 1 TEOAE instruments, the waveform and/or frequency spectrum of the stimulus recorded in the external auditory meatus shall be stored. An option may be provided to display the stored results.

It is recommended that intermediate recordings of this stimulus are used to provide an indication of the probe stability during the measurement.

5.3 Measuring system

5.3.1 Units of measurement

SI units or derived SI units shall be used. The units of measurement shall be indicated.

5.3.2 Measurement range

Instruments shall be able to measure TEOAE over a range of at least –20 dB SPL to +30 dB SPL and DPOAE over a range of at least –10 dB SPL to +30 dB SPL.

5.3.3 Accuracy of measurement

The probe microphone shall measure the actual sound pressure level over the OAE frequency range. The acceptance limit for this measurement is ±3 dB for frequencies up to 4 kHz and ±5 dB at higher frequencies. If measurement points other than the probe microphone position are used, then the actual measurement points shall be stated by the manufacturer.

NOTE This performance limit of the standard relates to the probe microphone and input channel calibration accuracy (see 6.2.3 for details).

5.3.4 Frequency range

The frequency range of the measuring system shall be according to the applicable stimulus frequency range in 5.1.3 with accuracy defined in 5.3.3.

5.3.5 Noise reduction

Instruments shall be able to reduce the influence of ambient noise by at least 30 dB in the relevant frequency range when measured in an occluded-ear simulator according to IEC 60318-4 or in a 2 cm^3 coupler according to IEC 60318-5.

NOTE Methods employed to reduce the influence of ambient noise include sound isolation provided by the probe tip and signal averaging and/or other signal processing techniques.

5.3.6 Response detection

Instruments that provide an automated PASS/REFER decision algorithm shall document and make available the statistical sensitivity of the algorithm under realistic test conditions of no OAE present (see 6.3). During the measurement, a stimulus artefact rejection system shall be used, and its characteristics shall be specified by the manufacturer.

5.3.7 Response quality estimates

The instrument shall provide indication(s) as to the degree that the result is contaminated by the presence of noise (and/or other measurement quality metrics). The method used to determine the degree of contamination shall be described in the documentation.

5.3.8 Normative values

If normative values are used (e.g. for calibration, PASS/REFER criteria), the source of these values shall be stated in the instruction manual.

5.4 Presentation of results

All relevant information shall be stored and be available on demand. The information shall be presented on the display of the instrument, in electronic form and/or as a paper printout. The relevant information required is given in Table 2.

Table 2 – Documentation of test conditions, parameters and results

	Type	
	1 Diagnostic/clinical	2 Screening
Stimulus level	x	
Number of epochs or time of recorded data	x	
Number of epochs or time of rejected data	x	
Artefact rejection limit	x	
Graphic display of detailed result [a]	x	
Display of PASS/REFER		x
Residual noise estimate	x	
OAE to noise ratio	x	
[a] Waveform (TEOAE) and/or frequency spectrum (TEOAE and DPOAE), respectively.		

6 Demonstration of conformity with specifications

6.1 General

The following procedures shall be used for ensuring that an instrument meets the specifications given in this document. Guidelines for periodic calibration are described in Clause 9.

6.2 Probe signal

6.2.1 Probe signal frequency spectrum

The probe signal frequency spectrum shall be measured by coupling the probe to an occluded-ear simulator or 2 cm^3 coupler according to IEC 60318-4 and IEC 60318-5, respectively, and according to the instructions provided by the manufacturer. The occluded-ear simulator or 2 cm^3 coupler to be used and the method of coupling shall be stated by the manufacturer.

Since both the occluded-ear simulator and 2 cm^3 couplers have ¼ wave resonances within the frequency range of typical OAE measurements, the manufacturer shall state clearly whether the probe signal spectrum is measured using the test-cavity measurement microphone or the probe microphone.

6.2.2 Probe signal level and harmonic distortion

The signal level and the harmonic distortion of the probe signal shall be measured by means of an occluded-ear simulator according to IEC 60318-4 or a 2 cm^3 coupler according to IEC 60318-5, to which the probe is coupled with the ear tip placed according to instructions provided by the manufacturer.

Since both the simulator and 2 cm^3 couplers have ¼ wave resonances within the frequency range of typical OAE measurements, the manufacturer shall state clearly whether the probe signal spectrum is measured using the cavity measurement microphone or the probe microphone.

6.2.3 Probe measurement accuracy

The probe microphone accuracy is determined by measuring the output of the probe microphone in the presence of a known sound field presented over the range of frequencies stipulated in 5.1.3.

Suggested verification methods are:

– free-field with a calibrated measurement microphone in the same sound field as the probe microphone;

– the use of a measurement microphone and a test cavity with dimensions such that the first ¼ wave resonance is above the highest OAE measurement frequency of the instrument.

If other measurement methods are used, these shall be specified by the manufacturer.

6.3 Complete system

The performance of the complete test system shall be tested by coupling the probe to an occluded-ear simulator according to IEC 60318-4 or a 2 cm^3 coupler according to IEC 60318-5, with the ear tip placed according to the instructions provided by the manufacturer. On completion of the test, no response shall be detected.

If the instrument provides automatic PASS/REFER decision algorithms, these tests shall be performed in the presence of acoustic noise with a typical frequency spectrum and at a level which triggers the noise rejection at least 10 % of the time. The procedures employed during this testing and the corresponding results shall be documented by the manufacturer.

Some test equipment specifically designed for neonatal hearing screening cannot perform these tests in the occluded-ear simulator or 2 cm^3 coupler specified above due to the cavity size. In this instance, the manufacturer shall provide the necessary information on how to perform the function test of the complete system using an alternative neonatal test cavity or ear simulator.

NOTE One example of an alternative neonatal test cavity is given in IEC 60318-8.

6.4 Maximum permitted expanded uncertainty of measurements U_{max}

Table 3 specifies the maximum permitted expanded uncertainty for a coverage factor of k = 2 according to ISO/IEC Guide 98-3, associated with the measurements undertaken in this document. One set of values for U_{max} is given for conformance testing and periodic calibration.

The expanded uncertainties of measurement given in Table 3 are the maximum permitted for demonstration of conformance to the requirements of this document. If the actual expanded uncertainty of a measurement performed by the test laboratory or maintenance service exceeds the maximum permitted value in Table 3, the measurement shall not be used to demonstrate conformance to the requirements of this document.

Table 3 – Values of U_{max} for conformance and periodic calibration measurements

Measured quantity	Relevant subclause number	Basic $U_{max}(k = 2)$
Stimulus levels	5.1.4.2, 5.1.4.3	1,0 dB
Stimulus level deviation	5.1.4.3	0,4 dB
Frequency	5.1.3.2, 5.1.3.3	0,5 %
Intermodulation distortion	5.1.5	0,005 %
Measurement range	5.3.2	1,0 dB
Accuracy of measurement up to 4 kHz	5.3.3	0,7 dB
Accuracy of measurement higher than 4 kHz	5.3.3	1,2 dB
Temperature	7.6.3	0,5 °C
Relative humidity	7.6.3	5 %
Ambient pressure	7.6.3	0,1 kPa

7 General requirements

7.1 Marking

The instrument shall be marked with the name of the manufacturer, the type as defined in Clause 4, the model and its serial number.

If a transducer can be detached by the user, the transducer and/or the instrument shall be marked or identified, for example with a serial number, to prevent unintended interchange of transducers.

7.2 Instruction manual

An instruction manual shall be supplied with each instrument. In this manual, the manufacturer shall specify all characteristics as required by this document.

7.3 Safety requirements

Limitations of the applications shall be specified. Instruments shall conform to IEC safety requirements specified in IEC 60601-1.

7.4 Immunity to power and radiofrequency fields

Instruments shall meet the requirements of IEC 60601-1-2 for electromagnetic compatibility (EMC).

During, and as a result of any EMC immunity testing, under the EMC test conditions, the unwanted sound from any air conduction transducer shall not exceed a hearing level corresponding to 80 dB peSPL when the transducer is coupled to an occluded-ear simulator according to IEC 60318-4 or a 2 cm^3 coupler according to IEC 60318-5. The manufacturer shall state the settings of the instruments. IEC 60645-1:2017, 13.3, gives methods for showing conformity.

7.5 Warm-up time

The maximum warm-up time shall be specified by the manufacturer and shall not exceed 10 min when the unit has been stored at room temperature. The performance requirements of this document shall be met after the stated warm-up time has elapsed and after any setting-up adjustments have been carried out in the manner prescribed by the manufacturer.

7.6 Voltage supply variation and environmental conditions

7.6.1 Mains operation

The specifications shall be met over the full combined ranges of any long-term deviation in supply voltage of ±10 % and mains frequency ±5 %. When any short-term line variation has occurred that affects the performance of the instrument, the instrument shall revert to a mode that will not endanger the subject under test, nor yield invalid results.

7.6.2 Battery operation

The manufacturer shall state the limits of battery voltages within which the specification shall be met, and a suitable indicator shall be provided to inform the operator whether the battery voltage is within the limits for correct performance.

7.6.3 Environmental conditions

The specifications shall be met for all combinations of temperature within the range +15 °C to +35 °C, relative humidity within the range 30 % to 90 %, and static pressure within the range 98 kPa to 104 kPa.

8 Additional characteristics to be specified by the manufacturer

Procedures to measure the test quality according to 5.2 shall be specified by the manufacturer.

9 Periodic calibration

For both Type 1 and Type 2 instruments, the following parameters shall be calibrated regularly:

– stimulus characteristics according to manufacturer's guidelines;
– microphone signal level response to test stimuli delivered by probe transducers.

NOTE A typical time interval for periodic calibration is 12 months.

These parameters shall be measured by coupling the probe to an occluded-ear simulator, according to IEC 60318-4 or a 2 cm^3 coupler according to IEC 60318-5, with the ear tip placed according to the instructions provided by the manufacturer and using reference levels provided by the manufacturer.

A system test, as detailed in 6.3, shall also be performed to verify the complete system performance.

Bibliography

IEC 60318-8, *Electroacoustics – Simulators of human head and ear – Part 8: Acoustic coupler for high-frequency measurements of hearing aids and earphones coupled to the ear by means of ear inserts*

ISO 389-6, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 6: Reference threshold of hearing for test signals of short duration*

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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ÉLECTROACOUSTIQUE – APPAREILS AUDIOMÉTRIQUES –

Partie 6: Instruments pour la mesure des émissions otoacoustiques

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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.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous webstore.iec.ch dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- 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 cm³ 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*

IEC 60645-3:2020, *Électroacoustique – Appareils audiométriques – Partie 3: Signaux d'essai de courte durée*

Guide ISO/IEC 98-3, *Incertitude de mesure – Partie 3: Guide pour l'expression de l'incertitude de mesure (GUM:1995)*

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions suivants s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

3.1
émissions otoacoustiques
OAE
terme général qui couvre tous les types de signaux acoustiques générés dans l'oreille interne qui peuvent être enregistrés dans le conduit auditif externe

Note 1 à l'article: L'abréviation "OAE" est dérivée du terme anglais développé correspondant "otoacoustic emissions".

3.2
émissions otoacoustiques évoquées transitoires
TEOAE
signaux acoustiques émis par l'oreille interne après stimulation par un stimulus de courte durée

Note 1 à l'article: L'abréviation "TEOAE" est dérivée du terme anglais développé correspondant "transient-evoked otoacoustic emissions".

3.3
émissions otoacoustiques de produit de distorsion
DPOAE
signaux acoustiques générés dans l'oreille interne au cours de la stimulation avec deux sons purs

Note 1 à l'article: Les sons purs sont les fréquences f_1 et f_2, f_1 correspondant à la fréquence la plus basse.

Note 2 à l'article: Les fréquences des DPOAE sont données par les formules des distorsions d'intermodulation (IMD – intermodulation distortion), c'est-à-dire $2f_1 - f_2$, $2f_2 - f_1$, etc.

Note 3 à l'article: L'abréviation "DPOAE" est dérivée du terme anglais développé correspondant "distortion product otoacoustic emissions".

3.4
fréquence d'essai nominale
fréquence pour laquelle un mesurage de DPOAE est consigné

3.5
sons primaires
stimuli de son pur utilisés pour évoquer les DPOAE

3.6
sonde
partie de l'instrument, contenant généralement des transducteurs acoustiques, qui assure l'interface entre l'instrument et l'oreille

3.7
embout
dispositif utilisé pour faciliter le couplage acoustique, pour réduire les fuites acoustiques, pour réduire l'influence du bruit environnemental sur les mesurages et pour aider au maintien de la sonde dans le conduit auditif externe