BS EN 60645-6:2010

BSI Standards Publication

Electroacoustics — Audiometric equipment —

Part 6: Instruments for the measurement of otoacoustic emissions

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National foreword

This British Standard is the UK implementation of EN 60645-6:2010. It is identical to IEC 60645-6:2009.

The UK participation in its preparation was entrusted to Technical Committee EPL/29, Electroacoustics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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ISBN 978 0 580 60925 1

ICS 13.140; 17.140.50

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 28 February 2010

Amendments issued since publication

Amd. No.	Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60645-6

January 2010

ICS 17.140.50

English version

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

(IEC 60645-6:2009)

Electroacoustique -
Appareillage audiométrique -
Partie 6: Instruments pour la mesure
des émissions otoacoustiques
(CEI 60645-6:2009)

Akustik -
Audiometer -
Teil 6: Geräte zur Messung
von otoakustischen Emissionen
(IEC 60645-6:2009)

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Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Foreword

The text of document 29/673/FDIS, future edition 1 of IEC 60645-6, prepared by IEC TC 29, Electroacoustics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60645-6 on 2009-12-01.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2010-09-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-12-01

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60645-6:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

ISO 389-6	NOTE Harmonized as EN ISO 389-6 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
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	EN 60318-4	200X[1)]
IEC 60318-5	-	Electroacoustics - Simulators of human head and ear - Part 5: 2 cm³ coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts	EN 60318-5	-
IEC 60601-1	-	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	-
IEC 60601-1-2 (mod)	-	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	-
IEC 60601-1-4	-	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	EN 60601-1-4	-
IEC 60645-1	2001	Electroacoustics - Audiological equipment - Part 1: Pure-tone audiometers	EN 60645-1	2001
IEC 60645-3	2007	Electroacoustics - Audiometric equipment - Part 3: Test signals of short duration	EN 60645-3	2007
ISO/IEC Guide 98-3	-	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-

[1)] To be published.

CONTENTS

INTRODUCTION

Developments in the field of diagnostic hearing measurement have resulted in a number of instruments designed to evaluate the otoacoustic emissions of the human ear evoked by acoustic test signals having different spectral and temporal characteristics.

The practical use of such instruments concerns the measurement of sound energy emitted by the inner ear and its separation from sounds emerging from other physiological or artificial sources.

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 6: Instruments for the measurement of otoacoustic emissions

1 Scope

This part of IEC 60645 applies to instruments designed primarily for the measurement of otoacoustic emissions in the human external acoustic meatus evoked by acoustic probe pulses or tones. This standard defines the characteristics to be specified by the manufacturer, lays down performance specifications for two types of instruments[1] and specifies the functions to be provided on these types. This part of IEC 60645 describes methods of test to be used for approval testing and guidance on methods for undertaking routine calibration.

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

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60318-4, *Electroacoustics – Simulators of human head and ear – Part 4: Occluded-ear simulator for the measurement of earphones coupled to the ear by means of ear inserts*[2]

IEC 60318-5, *Electroacoustics – Simulators of human head and ear – Part 5: 2 cm^3 coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts*

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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

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

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1 Screening and full diagnostics.

2 To be published.

IEC 60645-3:2007, *Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration*

ISO/IEC Guide 98-3, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

3 Terms and definitions

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

3.1
otoacoustic emissions
OAE
general term covering all types of acoustic signals generated in the inner ear which can be recorded in the external acoustic meatus

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

3.2
transient-evoked otoacoustic emissions
TEOAE
acoustic signals emitted by the inner ear after stimulation with a stimulus of short duration

3.3
distortion product otoacoustic emissions
DPOAE
acoustic signals generated in the inner ear during stimulation with two pure tones (frequencies f_1 and f_2, f_1 being the lower frequency)

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

3.4
nominal test frequency
the frequency for which a DPOAE measurement is reported

3.5
primary tones
pure tone stimuli used to evoke DPOAEs

3.6
probe
part of the instrument, usually containing transducers, interfacing the instrument to the ear

3.7
ear tip
device used to provide a seal between the probe and the external acoustic meatus

3.8
probe signal
acoustic signal that is emitted into the external auditory meatus by means of a probe

3.9
peak-to-peak equivalent sound pressure level
peSPL
r.m.s. value of a long-duration sinusoidal sound signal which, when compared under the same test conditions with a short-duration output signal from the transducer under test, has the

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

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

4 Requirements for specific instruments

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

Instrument types

1 Diagnostic/clinical: Adjustable stimulus and recording parameters, result shown in a graphical format

2 Screening: Automatic testing, automatic evaluation, results as pass/refer

Table 1 – Mandatory functions for otoacoustic emission instruments

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

5 General specifications

5.1 Acoustic stimulus system

5.1.1 General requirements

Specifications for the acoustic stimulus system are as given in the relevant parts of Clauses 6, 8 and 10 of IEC 60645-1:2001 and Clause 5 of IEC 60645-3:2007 with the exceptions specified below.

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

5.1.2 Stimulus types

5.1.2.1 General

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

5.1.2.2 TEOAE

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

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

5.1.2.3 DPOAE

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

5.1.3 Stimulus frequency range

5.1.3.1 General

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

5.1.3.2 TEOAE

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

5.1.3.3 DPOAE

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

5.1.4 Stimulus level

5.1.4.1 General

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

5.1.4.2 TEOAE

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

5.1.4.3 DPOAE

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

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

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

5.1.5 Harmonic 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 %.

NOTE No requirements are specified for TEOAE.

5.2 Test quality assuring system

5.2.1 General

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.

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.

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.

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.

5.3.4 Frequency range

The frequency range shall be according to the applicable stimulus frequency range in 5.1.3.

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.

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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. During the measurement, a stimulus artefact rejection system shall be used, and its characteristics shall be specified by the manufacturer.

5.3.7 Quality estimates

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

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 display of the instrument and/or as paper printout. The explanation of the relevant information is shown in Table 2.

Table 2 – Documentation of test conditions, parameters and results

	Type	
	1 Diagnostic/clinical	2 Screening
Stimulus level	x	
Recorded OAEs	x	
Number of artefacts	x	
Artefact rejection limit	x	
Graphic display of full result [a]	x	
Display of PASS/REFER		x
Residual noise estimate	x	
OAE to noise ratio	x	
[a] Oscillogram (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).

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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 part of IEC 60645. Guidelines for routine calibration are described in Clause 9.

6.2 Probe signal

6.2.1 Probe signal spectrum

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

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 coupler according to IEC 60318-5, to which the probe is coupled with the ear tip placed according to instructions provided by the manufacturer.

6.3 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.

The expanded uncertainties of measurements given in Table 3 are the maximum permitted for demonstration of conformance to the requirements of this part of IEC 60645. If the actual expanded uncertainty of a measurement performed by the test laboratory exceeds the maximum permitted value in Table 3, the measurement shall not be used to demonstrate conformance to the requirements of this part of IEC 60645.

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Table 3 – Values of U_{max} for basic 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 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 in Clause 4, the model and its serial number as well as the identification of the transducer(s) employed.

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 part of IEC 60645.

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

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

7.4.2 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. The manufacturer shall state the settings of the instruments. 13.3 of IEC 60645-1:2001 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 part of IEC 60645 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. 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.

9 Routine calibration

For Type 1 instruments, the following parameters shall be verified at regular intervals:

- stimulus characteristics;
- microphone response to test stimuli delivered by probe receivers.

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

These parameters shall be verified 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 and reference values provided by the manufacturer.

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

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Bibliography

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

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