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विधुतध्वानिकी ऑडियोमेट्रिक उपकरण  
भाग 6 ओटोअकॉस्टिक उत्सर्जन मापन के लिए  
उपकरण

**Electroacoustics — Audiometric  
Equipment**  
**Part 6 Instruments for the Measurement  
of Otoacoustic Emissions**

ICS 17.140.50

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## NATIONAL FOREWORD

This Indian Standard (Part 6) which is Identical with IEC 60645-6 : 2022 'Electroacoustics audiometric equipment — Part 6: Instruments for the measurement of Otoacoustic Emissions' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendations of the Audio, Video and Multimedia Systems and Equipment Sectional Committee and approval of the Electronics and Information Technology Division Council.

The other parts in this series are:

- Part 1 Equipment for pure — Tone and speech audiometry
- Part 3 Test signals of short duration
- Part 5 Instruments for the measurement of aural acoustic impedance admittance
- Part 7 instruments for the measurement of auditory brainstem responses

The text of IEC standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appears referring to this standard, they should be read as 'Indian Standard'; and
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current Practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for editions indicated. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
IEC 60318-5 Electroacoustics — Simulators of human head and ear Part 5: 2 cm <sup>3</sup> coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts	IS/IEC 60318-5 : 2006 Electroacoustics — Simulators of human head and ear: Part 5 2 cm <sup>3</sup> Coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts	Identical
IEC 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2018/IEC 60601-1 : 2012 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance ( <i>second revision</i> )	Identical
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	IS 13450 (Part 1/Sec 2) : 2018/IEC 60601-1-2 : 2014 Medical electrical equipment: Part 1 General requirements for the basic safety and essential performance, Section 2 Collateral standard: electromagnetic disturbances — Requirements and tests ( <i>first revision</i> )	Identical

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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 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.



*Indian Standard*

# 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<sup>3</sup> 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  $\pm 5$  dB as measured in an occluded-ear simulator according to IEC 60318-4 or a 2 cm<sup>3</sup> coupler according to IEC 60318-5, using the ear simulator or 2 cm<sup>3</sup> 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  $\pm 1$  %.

## 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<sup>3</sup> coupler according to IEC 60318-5, using the occluded-ear simulator or 2 cm<sup>3</sup> 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  $\pm 1,5$  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<sup>3</sup> coupler according to IEC 60318-5 using the occluded-ear simulator or 2 cm<sup>3</sup> 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<sup>3</sup> 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  $\pm 3$  dB for frequencies up to 4 kHz and  $\pm 5$  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  $2\text{ cm}^3$  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 <sup>a</sup>	x	
Display of PASS/REFER		x
Residual noise estimate	x	
OAE to noise ratio	x	

<sup>a</sup> 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<sup>3</sup> 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<sup>3</sup> coupler to be used and the method of coupling shall be stated by the manufacturer.

Since both the occluded-ear simulator and 2 cm<sup>3</sup> 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<sup>3</sup> 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<sup>3</sup> 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  $\frac{1}{4}$  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<sup>3</sup> 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<sup>3</sup> 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<sup>3</sup> 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  $\pm 10\%$  and mains frequency  $\pm 5\%$ . 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<sup>3</sup> 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*

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<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
IEC 60645-1 : 2017 Electroacoustics — Audiometric equipment — Part 1: Equipment for puretone and speech audiometry	IS/IEC 60645-1 : 2017 Electroacoustics — Audiometric equipment: Part 1 equipment for pure — Tone and speech audiometry	Identical
IEC 60645-3 : 2020 Electroacoustics — Audiometric equipment – Part 3: Test signals of short duration	IS/IEC 60645-3 : 2020 Electroacoustics — Audiometric equipment: Part 3 Test signals of short duration	Identical

The Committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

<i>International Standard</i>	<i>Title</i>
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
ISO/IEC Guide 98-3	Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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This Indian Standard has been developed from Doc No.: LITD 07 (20180).

### Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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