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**Audiometric equipment — Part 1:
Equipment for pure-tone and speech
audiometry**

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Foreword

This Japanese Industrial Standard has been revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Acoustical Society of Japan (ASJ)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied mutatis mutandis pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS T 1201-1** : 2011), which has been technically revised.

However, **JIS T 1201-1** : 2011 remains valid for three years from the date of public notice of the revision of this Standard. **JIS T 1201-2** : 2000, which has been integrated into this Standard, will not be withdrawn at the same time as the revision of this Standard, but will be withdrawn after three years have elapsed from the date of public notice of the revision of this Standard, due to the relationship with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

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Audiometric equipment — Part 1 : Equipment for pure-tone and speech audiometry

Introduction

This Japanese Industrial Standard has been prepared based on **IEC 60645-1** : 2017, Edition 4, with some modifications of the technical contents in order to deal with the medical examination system, etc. in Japan.

Parts where dotted underlines are drawn and Annex JA are unique to **JIS** and not given in the corresponding International Standard. A list of modifications with the explanations is given in Annex JB.

1 Scope

This Standard specifies general requirements for equipment designed for use in determining hearing threshold levels, relative to standard reference threshold levels established by means of psychoacoustic test methods, and that designed to perform psychoacoustic tests using speech material (hereafter referred to as audiometers).

The object of this standard is to ensure :

- a) that tests of hearing in the frequency range 125 Hz to 16 kHz on a given human ear, performed with different pure-tone audiometers which comply with this Standard, give substantially the same results;
- b) that the results obtained represent a valid comparison between the hearing of the ear tested and the reference threshold of hearing;
- c) that a means of presenting speech material to a subject in a standardized manner is provided. This will ensure that tests of hearing using a specific speech signal and a specific manner of signal presentation, when performed with different audiometers which comply with this Standard, give substantially the same results;
- d) that audiometers are classified according to the range of test signals they present, according to the mode of operation or according to their presumed primary application.

NOTE The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

IEC 60645-1 : 2017 *Electroacoustics — Audiometric equipment — Part 1 : Equipment for pure-tone and speech audiometry* (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the indication of the year, only editions of the year indicated shall be applied, and the revisions (including amendments) made thereafter shall not be applied. For those without the indication of the year, the most recent editions (including amendments) shall be applied.

JIS C 1509-1 *Electroacoustics — Sound level meters — Part 1 : Specifications*

NOTE Corresponding International Standard: IEC 61672-1 *Electroacoustics — Sound level meters — Part 1 : Specifications*

JIS C 1514 *Electroacoustics — Octave-band and fractional-octave-band filters*

NOTE Corresponding International Standard : IEC 61260-1 *Electroacoustics — Octave-band and fractional-octave-band filters — Part 1 : Specifications*

JIS T 0601-1 *Medical electrical equipment — Part 1 : General requirements for basic safety and essential performance*

NOTE Corresponding International Standard : IEC 60601-1 *Medical electrical equipment — Part 1 : General requirements for basic safety and essential performance*

JIS T 0601-1-2 *Medical electrical equipment — Part 1-2 : General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

NOTE Corresponding International Standard : 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 60268-3 *Sound system equipment — Part 3 : Amplifiers*

IEC 60268-7 *Sound system equipment — Part 7 : Headphones and earphones*

IEC 60268-17 *Sound system equipment. Part 17: Standard volume indicators*

IEC 60318-1 *Electroacoustics — Simulators of human head and ear — Part 1 : Ear simulator for the measurement of supra-aural and circumaural earphones*

IEC 60318-3 *Electroacoustics — Simulators of human head and ear — Part 3 : Acoustic coupler for the calibration of supra-aural earphones used in audiometry*

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 cm³ coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts*

- IEC 60318-6 *Electroacoustics — Simulators of human head and ear — Part 6 : Mechanical coupler for the measurement on bone vibrators*
- ISO 266 *Acoustics — Preferred frequencies*
- ISO 389-1 *Acoustics — Reference zero for the calibration of audiometric equipment — Part 1 : Reference equivalent threshold sound pressure levels for pure tones and supra-aural earphones*
- ISO 389-2 *Acoustics — Reference zero for the calibration of audiometric equipment — Part 2 : Reference equivalent threshold sound pressure levels for pure tones and insert earphones*
- ISO 389-3 *Acoustics — Reference zero for the calibration of audiometric equipment — Part 3 : Reference equivalent threshold vibratory force levels for pure tones and bone vibrators*
- ISO 389-4 : 1994 *Acoustics — Reference zero for the calibration of audiometric equipment — Part 4 : Reference levels for narrow-band masking noise*
- ISO 389-5 *Acoustics — Reference zero for the calibration of audiometric equipment — Part 5 : Reference equivalent threshold sound pressure levels for pure tones in the frequency range 8 kHz to 16 kHz*
- ISO 389-7 *Acoustics — Reference zero for the calibration of audiometric equipment — Part 7 : Reference threshold of hearing under free-field and diffuse-field listening conditions*
- ISO 389-8 *Acoustics — Reference zero for the calibration of audiometric equipment — Part 8 : Reference equivalent threshold sound pressure levels for pure tones and circumaural earphones*
- ISO 4869-1 *Acoustics — Hearing protectors — Part 1 : Subjective method for the measurement of sound attenuation*
- ISO 8253-1 : 2010 *Acoustics — Audiometric test methods — Part 1 : Pure-tone air and bone conduction audiometry*
- ISO 8253-2 *Acoustics — Audiometric test methods — Part 2 : Sound field audiometry with pure-tone and narrow-band test signals*
- ISO 8253-3 *Acoustics — Audiometric test methods — Part 3 : Speech audiometry*

3 Terms and definitions

For the purpose of this Standard, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses :

- IEC Electropedia : <http://www.electropedia.org>
- ISO Online Browsing Platform : <https://www.iso.org/obp>

3.1

equipment for pure-tone audiometry

pure-tone audiometer

instrument for the measurement of hearing for pure tones and in particular of the threshold of hearing

NOTE 1 The term audiometer sometimes indicates pure-tone audiometer.

NOTE 2 The pure-tone audiometer may be either of a fixed or continuous sweep frequency type.

3.2

manual audiometer

audiometer in which signal presentation and recording of results are performed manually

3.3

automatic-recording audiometer

audiometer in which signal presentation, hearing level variation, frequency selection or frequency variation and recording of the subject's responses are implemented automatically

NOTE 1 Hearing level change is under the subject's control and is recorded automatically.

3.4

equipment for speech audiometry

speech audiometer

instrument for the measurement of hearing using speech material (aural signal)

3.5

air conduction

transmission of sound through the external and middle ear to the inner ear

3.6

bone conduction

stimulation of the inner ear mediated primarily by mechanical vibration of the cranial bones

3.7

extended high-frequency, EHF

audiometric test frequency in the range from 8 kHz to 16 kHz

NOTE The frequency 8 kHz is considered both as the highest frequency in the conventional range and as the lowest frequency of the extended

high-frequency range.

3.8

otologically normal person

person in a normal state of health who is free from all signs and symptoms of ear disease and from obstructing wax in the ear canal and has no history of undue exposure to noise, to potentially ototoxic drugs, or of familial hearing loss

3.9

equivalent threshold sound pressure level (monaural earphone listening)

for a given ear, at a specified frequency, for a specified type of earphone and for a stated force of application of the earphone to a human ear, the sound pressure level set up by the earphone in a specified ear simulator or acoustic coupler when the earphone is activated by that electrical input which, with the earphone applied to the ear, would correspond to the threshold of hearing

3.10

equivalent threshold vibratory force level (monaural listening)

for a given ear, at a specified frequency, for a specified configuration and model of bone vibrator on a specified mechanical coupler, the force level set up by the bone vibrator in a specified mechanical coupler when the bone vibrator is activated by that voltage which, with the bone vibrator applied to the mastoid prominence or to the forehead, would correspond to the threshold of hearing

NOTE This definition requires the non-test ear to be masked in accordance with **ISO 389-4**.

3.11

reference equivalent threshold sound pressure level, RETSPL

at a specified frequency, the median, mean or modal value of the equivalent threshold sound pressure levels of a sufficiently large number of ears of otologically normal persons of both sexes aged between 18 years and 25 years inclusive, expressing the threshold of hearing in a specified ear simulator or acoustic coupler for a specified earphone type

NOTE 1 Values of RETSPL are specified in **ISO 389-1**, **ISO 389-2**, **ISO 389-5** and **ISO 389-8**.

NOTE 2 Some parts of the **ISO 389** series specify reference equivalent threshold levels for the age group 18 years to 30 years inclusive.

3.12

reference equivalent threshold vibratory force level, RETVFL

at a specified frequency, the mean of the equivalent threshold vibratory force levels of a sufficiently large number of ears of otologically normal persons of both sexes aged between 18 years and 25 years inclusive, expressing the threshold of hearing on a

specified mechanical coupler for a specified model of bone vibrator

NOTE 1 The mean of RETVFL are specified in **ISO 389-3**.

NOTE 2 Some parts of the **ISO 389** series specify reference equivalent threshold levels for the age group 18 years to 30 years inclusive.

3.13

close-coupled sensitivity

at a given frequency, the quotient of the sound pressure level generated by the earphone in an ear simulator or acoustic coupler and the voltage applied to the terminals of the earphone

NOTE This term is also used in the case where an ear simulator is used for the measurement of the sound pressure level generated by the earphone.

3.14

close-coupled sensitivity level

ten times the logarithm to the base ten of the quotient of the squared close-coupled sensitivity by the squared reference sensitivity, expressed as 1 Pa/V

3.15

free-field sensitivity

at a given frequency and for at least 10 otologically normal subjects, the quotient of the sound pressure level of a frontally incident plane progressive sound wave (0° sound incident) and of that voltage of equal frequency which is applied to the terminals of the earphone in order that the subjects, on average, judge the sound wave and the sound produced by the earphone as equally loud, with both sounds being received in the same ear

NOTE Test methods are described in **IEC 60268-7**. Though the loudness comparison may be performed binaurally, the resulting sensitivity is that of a single earphone.

3.16

free-field sensitivity level

ten times the logarithm to the base ten of the quotient of the squared free-field sensitivity to the squared reference sensitivity, expressed as 1 Pa/V

NOTE Free-field sensitivity and free-field sensitivity level of a bone vibrator are defined in a corresponding way.

3.17

free-field equivalent earphone output level

for a speech audiometer, the sound pressure level generated by an earphone corrected by the difference between the close-coupled and the free-field sensitivity levels of the earphone

3.18

hearing level of a pure tone, HL

In the case of air conduction (sound pressure level), at a specified frequency, for a specific type of earphone and for a specified manner of application, the sound pressure level of a pure tone generated by the earphone in an ear simulator or acoustic coupler minus the appropriate RETSPL

In the case of bone conduction (vibratory force level), at a specified frequency, for a specific type of bone vibrator and for a specified manner of application, the vibratory force level of a pure tone generated by the bone vibrator in a specified mechanical coupler minus the appropriate RETVFL

3.19**hearing threshold level for pure tones**

at a specified frequency, the threshold of hearing at that frequency expressed as hearing level

NOTE Methods for determining thresholds of hearing are specified in **ISO 8253-1**.

3.20**hearing level for speech**

for a specified speech signal and a specified manner of signal presentation, the speech level minus the appropriate reference speech recognition threshold level

3.21**speech signal**

test signal generated by a natural human or synthetic voice

3.22**speech level**

sound pressure level or vibratory force level of the speech signal as measured in an appropriate ear simulator, acoustic coupler or mechanical coupler or in a sound field with specified frequency weighting and specified time weighting

3.23**speech recognition threshold level, SRT level**

for a given test subject, a specified speech signal and a specified manner of signal presentation, the lowest speech level at which the speech recognition score is equal to 50 %

3.24**reference SRT level**

for a specified speech signal and a specified manner of signal presentation, the median value of the speech recognition threshold levels of a sufficiently large number of otologically normal test subjects, of both sexes, aged between 18 years and 25 years inclu-

sive and for whom the test material is appropriate

3.25

ear simulator

device for measuring the acoustic output of sound sources where the sound pressure is measured by a calibrated microphone coupled to the source so that the overall acoustical impedance of the device approximates that of the normal human ear at a given location and in a given frequency band

NOTE Two types of ear simulator are specified in **IEC 60318-1** and **IEC 60318-4**.

3.26

acoustic coupler

device for measuring the acoustic output of sound sources where the sound pressure level is measured by a calibrated microphone coupled to the source by a cavity of pre-determined shape and volume which does not necessarily approximate the acoustical impedance of the normal human ear

NOTE Two types of acoustic coupler are specified in **IEC 60318-3** and **IEC 60318-5**.

3.27

mechanical coupler

device designed to present a specified mechanical impedance to a vibrator applied with a specified static force and equipped with a mechano-electric transducer to enable the alternating force level at the surface of contact between the vibrator and the mechanical coupler to be determined

NOTE A mechanical coupler is specified in **IEC 60318-6**.

3.28

masking

process by which the threshold of hearing of a sound is raised by the presence of another (masking) sound

3.29

effective masking level

level of a specified masking sound which is numerically equal to that hearing level to which the pure-tone threshold of the notional normal person would be raised by the presence of that masking sound

NOTE 1 The notional normal person is one whose hearing conforms to the standards for threshold and effective masking (**ISO 389-1**, **ISO 389-2**, **ISO 389-4** and **ISO 389-8**).

NOTE 2 Effective masking is thus analogous to hearing level (see **3.18**), i.e. it is a measure of sound on a physical scale, independent of the particular

ear under test.

NOTE 3 Reference values for effective masking are given in **ISO 389-4**.

3.30

speech weighted noise

weighted random noise for the masking of speech

3.31

effective masking level for speech

level of a specified masking sound which is numerically equal to that hearing level for speech to which the speech recognition threshold level for a specified speech signal for a notional normal hearing person would be raised by the presence of that masking sound

NOTE The notional normal person is one whose hearing conforms to the standards for threshold and effective masking (**ISO 389-1**, **ISO 389-2**, **ISO 389-4** and **ISO 389-8**).

4 Requirements by type and class of audiometer

Pure-tone audiometers are specified as five different types by the requirements for minimum mandatory facilities in Table 1 and Annex JA. Other facilities are not precluded. The five types relate to their presumed primary application.

Speech audiometers are specified as two classes, and the requirements for minimum facilities are given in Table 1.

Table 1 Minimum facilities for audiometers

Facility	Pure-tone types					Speech class	
	Type 1 Advanced clinical/ research	Type 2 Clinical	Type 3 Basic diagnos- tic	Type 4 Screen- ing/ moni- toring	EHF ^{g)} Extended high- frequen- cy	Class A	Class B
Transducers							
– two earphones	X	X	X	X	X	X ^{d)}	X ^{d)}
– two insert earphones	X						
– two loud speakers or elec- trical outputs ^{e)}	X	X				X	
– bone conduction	X	X	X			X	
Hearing levels and Test fre- quencies (see Table 2)	X	X	X	X	X	X	X
Output level control	X	X	X	X	X	X	X
Masking level control	X	X	X		X	X	X
Test signal switching							
– presentation/interruption	X	X	X	X ^{b)}	X	X	X
– pulsed tone	X	X			X		
– frequency modulation (FM)	X	X					
Reference tone ^{c)}							
– alternate presentation	X	X					
– simultaneous presentation	X						
Speech input							
– signal level indicator	X	X				X	X
– acoustical or visual moni- tor for speech test material						X	X
– integrated playback device or input for external signal	X ^{f)}	X ^{f)}				X ^{f)}	X ^{f)}
– microphone for live voice testing						X	
– operator and subject speech communication						X	
Masking							
– narrow-band noise	X	X	X		X		
– speech weighted noise						X	X
Routing of masking							
– contralateral earphone	X	X	X		X	X	X
– ipsilateral earphone	X					X	
– loudspeaker or electrical output ^{e)}	X	X				X	
– bone vibrator	X					X	
Subject's response system	X	X	X	X ^{a)}	X		
Signal indicator	X	X			X	X	X
Monitoring of test signal	X					X	X
Operator to test subject speech communication (talk-forward)	X	X				X	
Test subject to operator speech communication (talk-back)	X					X	