

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 1201-1 : 2020

(ASJ/JSA)

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

ICS 11.040.55 ; 17.140.50

Reference number : JIS T 1201-1 : 2020 (E)

PROTECTED BY COPYRIGHT

26 S

T 1201-1 : 2020

Date of Establishment: 2000-08-01

Date of Revision: 2020-06-01

Date of Public Notice in Official Gazette: 2020-06-01

Investigated by: Japanese Industrial Standards Committee
Standards Board for ISO area
Technical Committee on Medical Equipment

JIS T 1201-1 : 2020, First English edition published in 2021-09

Translated and published by: Japanese Standards Association
Mita MT Building, 3-13-12, Mita, Minato-ku, Tokyo, 108-0073 JAPAN

In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

© JSA 2021

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Printed in Japan

AH/HN

PROTECTED BY COPYRIGHT

Contents

| | Page |
|--|------|
| Introduction | 1 |
| 1 Scope | 1 |
| 2 Normative references | 2 |
| 3 Terms and definitions | 3 |
| 4 Requirements by type and class of audiometer | 9 |
| 5 General requirements | 11 |
| 5.1 General safety requirements | 11 |
| 5.2 Acoustic safety requirements | 11 |
| 5.3 Environmental conditions | 11 |
| 5.4 Warm-up time | 11 |
| 5.5 Power supply variation | 11 |
| 5.6 Electromagnetic compatibility | 12 |
| 5.7 Unwanted sound | 12 |
| 5.8 Testing of automatic-recording audiometers | 13 |
| 5.9 Interface connections | 14 |
| 6 Test signals | 14 |
| 6.1 Speech signals | 14 |
| 6.2 Pure tones | 17 |
| 6.3 External signal sources | 19 |
| 6.4 Operator and test subject speech communication | 20 |
| 6.5 Masking sound | 22 |
| 7 Transducers | 24 |
| 7.1 Types of transducers | 24 |
| 7.2 Headband | 24 |
| 7.3 Loudspeaker | 24 |
| 8 Signal level control | 25 |
| 8.1 Marking of pure-tone and speech signal level controls | 25 |
| 8.2 Signal level indicator | 25 |
| 8.3 Sound pressure level and vibratory force level acceptance limits | 26 |
| 8.4 Signal level control | 26 |
| 8.5 Masking sound level control | 27 |
| 8.6 Signal switching | 28 |
| 9 Reference tone | 30 |
| 9.1 General | 30 |
| 9.2 Frequencies | 30 |

| | | |
|------------------------|---|----|
| 9.3 | Reference tone level control | 30 |
| 10 | Calibration | 31 |
| 11 | Electrical output of test signals | 32 |
| 12 | Audiogram format | 32 |
| 13 | Test requirements to demonstrate conformity | 33 |
| 13.1 | General | 33 |
| 13.2 | Environmental conditions and power supply variation | 33 |
| 13.3 | Electromagnetic compatibility | 33 |
| 13.4 | Unwanted sound | 34 |
| 13.5 | Total harmonic distortion of test signals | 35 |
| 13.6 | Microphone for live voice speech testing | 36 |
| 13.7 | Signal accuracy | 36 |
| 13.8 | Masking sound | 36 |
| 13.9 | Headbands | 37 |
| 14 | Maximum permitted expanded uncertainty of measurements U_{\max} | 37 |
| 15 | Marking and instruction manual | 38 |
| 15.1 | Marking | 38 |
| 15.2 | Instruction manual | 38 |
| Annex A (informative) | Relationship between tolerance interval, corresponding acceptance interval and the maximum permitted uncertainty of measurement | 41 |
| Annex JA (normative) | Specifications for Type 5 pure-tone audiometers | 43 |
| Annex JB (informative) | Comparison table between JIS and corresponding International Standard | 44 |

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.

This **JIS** document is protected by the Copyright Act.

Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, published patent application or utility model rights. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, published patent application or utility model rights.

Blank

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**.