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Hearing aids

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Descriptors : hearing aids, artificial mastoids, hearing defects, hearing (auditory perception)

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C 5512 : 2000

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of International Trade and Industry and the Minister of Health and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Acoustical Society of Japan (ASJ), with a draft of Industrial Standard based on the provision of Clause 1, Article 12 of the Industrial Standardization Law.

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Hearing aids

Introduction This Japanese Industrial Standard specifies the performances and measurement methods and the construction of hearing aids which are used being attached to the human body of an individual and which carry out electrical amplification utilizing the built-in battery as the power supply. Some parts of the provisions referring to the performances of hearing aids covered by this Standard are identical with the corresponding provisions of **IEC 60118-5**, *Hearing aids—Part 5 : Nipples for insert earphones* published in 1983 as the first edition, **IEC 60118-11**, *Hearing aids—Part 11 : Symbols and other markings on hearing aids and related equipment* published in 1983 as the first edition and **IEC 60118-12**, *Hearing aids—Part 12 : Dimensions of electrical connector systems* published in 1996 as the first edition excluding the details, however, the performances not stated in the International Standards are included in this Standard. The provisions referring to the measurements of performances included in this Standard are identical with the corresponding provisions of **IEC 60118-0**, *Hearing aids—Part 0 : Measurement of electroacoustical characteristics* published in 1983 as the second edition (including the amendment published in 1994), **IEC 60118-1**, *Hearing aids—Part 1 : Hearing aids with induction pick-up coil input* published in 1995 as the third edition (including the amendment published in 1998) and **IEC 60118-7**, *Hearing aids—Part 7 : Measurement of performance characteristics of hearing aids for quality inspection for delivery purposes* published in 1983 as the first edition (including the amendment published in 1994). Concerning occluded-ear simulator for measurement and 2 cm³ coupler, the provisions for the measurement by means of such equipment and their construction are identical with the provisions stated in **IEC 60711**, *Occluded-ear simulator for the measurement of earphones coupled to the ear by ear inserts* published in 1981 as the first edition and **IEC 60126** (**IEC Recommendation**), *IEC reference coupler for the measurement of hearing aids using earphones coupled to the ear by means of ear inserts* published in 1973 as the second edition.

The contents of this Standard mainly consist of the provisions selected from the provisions stated in **IEC 60118** *Hearing aids* series to meet the real situation in Japan.

1 Scope This Japanese Industrial Standard specifies hearing aids which are used being attached to the human body of an individual and which carry out electrical amplification utilizing the built-in battery as the power supply.

- Remarks 1 The equipment utilizing a bone-conduction vibrator is excluded.
- 2 For the equipment utilizing radio transmitter and receiver, this Standard is applicable to the portions other than the said radio equipment.

2 Normative references The following standards contain provisions which, through reference in this Standard, constitute provisions of this Standard. The most recent editions of the standards indicated below shall be applied.

JIS C 1102-2 *Direct acting indicating analogue electrical measuring instruments and their accessories Part 2 : Special requirements for ammeters and voltmeters*

JIS C 5515 *Standard condenser microphones*

JIS Z 8703 *Standard atmospheric conditions for testing*

3 Definitions For the purpose of this Standard, the following principal definitions apply:

- a) **sound pressure level** The difference in amplitude of sound pressure defined as $20 \log_{10} \left(\frac{p}{p_0} \right)$. The sound pressure is expressed in the r.m.s. value and the reference sound pressure p_0 is 20 μ Pa.
- b) **input sound pressure level** The sound pressure which is inputted in a hearing aid in a free sound field.
- c) **output sound pressure level** The sound pressure which appears in an occluded-ear simulator when the earphone of a hearing aid is coupled with the occluded-ear simulator.
- d) **acoustic gain** The difference between output sound level and input sound level.
- e) **principal gain control** The gain control which is used in the state of being borne by the user.
- f) **reference tone** The representative tone of the hearing aid assigned by the manufacturer.
- g) **output limiter** The circuit and device which limit the amplitude of output.
- h) **induction pick-up coil** The coil which generate an electromotive force by receiving the induction from the magnetic field due to the speech current which flows through the loop wired for the purpose of utilizing it for the hearing aid.
- i) **reference test frequency** The frequency used as the reference for the test. Normally it is 1 600 Hz. However, it is 2 500 Hz for some hearing aids.

4 Performances

4.1 Operation Hearing aids shall not show any abnormality in their allover operation and function under the service conditions.

4.2 Electroacoustic performances

4.2.1 Method for expression of frequency response When the relation between output sound pressure level and frequency such as the frequency response is indicated by a curve, a graph paper shall be used that sound level is plotted in decibel on the ordinate of linear scale and the frequency is plotted on the abscissa of logarithmic scale and the length of ordinate corresponding to 50 dB is equal to the length corresponding to 10 times the frequency.

4.2.2 Reference conditions The reference conditions of a hearing aid shall be as stated below.

- a) The tone control is set to the position of reference tone.
- b) The output limiter is set to the position where its action is minimum (or "off" state if it becomes off). If its action is fixed, such state is employed.

4.2.3 Frequency range for specifying performances The frequency range under which the performances of hearing aids are specified is 200 Hz to 8 000 Hz. This is referred to as the test frequency range hereafter.

4.2.4 Performances with microphone input The performances with microphone input shall be as stated below when the input selector is set for microphone input.

a) **Maximum output sound pressure level (SPL) for an input SPL of 90 dB** The maximum output SPL for an input SPL of 90 dB is expressed by the output SPL for a pure sound input of 90 dB in SPL under the reference conditions where all the gain controls are set to their full-on positions. This is also written as $OSPL_{90}$.

- 1) Maximum output SPL frequency response for an input SPL of 90 dB (hereafter referred to as " $OSPL_{90}$ frequency response") shows the maximum output SPL for an input SPL of 90 dB at each frequency covering the test frequency range.
- 2) The representative values of $OSPL_{90}$ are those at 500 Hz and the reference test frequency, and the output SPL at the reference test frequency shall fall within ± 5 dB from the indicated value. If the reference test frequency is 2 500 Hz the value at 500 Hz is not necessary.
- 3) The peak value of $OSPL_{90}$ means the highest value of $OSPL_{90}$ frequency response, and this level shall not exceed the indicated value.

b) **Full-on acoustic gain** The full-on acoustic gain means the acoustic gain for a pure sound input of 60 dB SPL when all the gain controls are set to their full-on positions and sufficient linearity holds between the input and the output under the reference conditions. However, in such cases that no linearity holds between the input and the output when the input SPL is 60 dB or disconnection of the output limiter is impossible, the value when the input SPL is 50 dB shall be employed, and this shall be clearly stated in the instruction manual.

Remarks : The linearity between the input and the output shall be such a state that the change in output SPL falls within 10 ± 1 dB when the input SPL is changed by 10 dB.

- 1) The full-on acoustic gain frequency response shows the full-on acoustic gain at each frequency covering the test frequency range.
- 2) The representative value of full-on acoustic gain is the value of full-on acoustic gain at the reference frequency, and the tolerances of the indicated value are ± 5 dB.

c) **Reference test gain control position and reference test gain** The reference test gain control position means the setting of the gain control which provides an output sound pressure level of 15 ± 1 dB less than $OSPL_{90}$ for an input sound pressure level of 60 dB at the reference test frequency under the reference conditions. The acoustic gain at this setting is called the reference test gain. If the output sound pressure level does not reach $OSPL_{90} - (15 \pm 1)$ dB when the gain control is set to a position 7 dB below the full-on acoustic gain position, the said position is employed as the reference test gain control position and this shall be stated in the instruction manual.

- d) **Basic frequency response** This shows the output sound pressure level for a pure sound input of 60 dB SPL at each frequency covering the test frequency range while the gain control is set to the reference position under the reference conditions.

The tolerances of the indicated curve are ± 6 dB from 500 Hz to a frequency of either $0.8 f$ or 6 400 Hz whichever is lower. However, at application of this tolerances, the boundaries showing this tolerances (Fig. 1) may be shifted along the frequency axis by ± 10 % in the range of 500 Hz to 2 000 Hz and by ± 20 % in the range of over 2 000 Hz up to either $0.8 f$ or 6 400 Hz whichever is lower.

Further, the f means the upper limit value on the basic frequency response curve which causes a sound pressure level 15 dB below the output sound pressure level at the reference test frequency.

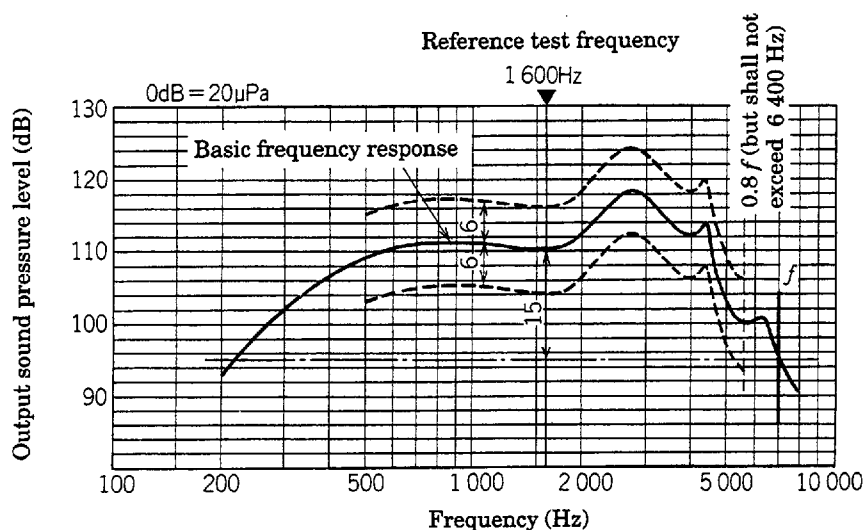


Fig. 1 Example of boundaries denoting allowable range of basic frequency response

- e) **Gain control** The acoustic gain at the reference test frequency when all of the gain controls are set to their minimum gain positions under the reference condition shall be 15 dB or less or shall show a value 30 dB or more below the representative value of full-on acoustic gain. Principal gain controls shall show the relations of the setting position and the gain in graphs.
- f) **Effect of tone control** The frequency response of the output sound pressure level for a pure sound input of 60 dB SPL, when the tone control is set from its reference state to various tone positions while the gain control is set to its reference position, shall be shown together with the basic frequency response.
- g) **Equivalent input noise level** When the output sound pressure level for a pure sound input of 60 dB SPL (this is denoted by L_1) while the gain control is set to its reference position under the reference conditions is denoted by L_s , and the output sound pressure level due to the internal noise when the sound supply is cut off is denoted by L_2 , the equivalent input noise level L_N shall be obtained from the following equation:

$$L_N = L_2 - (L_s - L_1)$$

This value shall not exceed the indicated value. If the output limiter can not be cut off, the L_1 shall take small value so that linearity is held between the input and the output, and the value shall be clearly stated.

- h) **Battery current** This means the current flowing through the battery when the gain control is set to its reference position and a pure sound of 60 dB SPL is employed as the input under the reference conditions, and the value shall not exceed the indicated value.
- i) **Total harmonic distortion** The total harmonic distortion of the output sound shall be obtained from the equation given below for the test sounds at 500 Hz, 800 Hz and 1 600 Hz of 70 dB in input sound pressure level produced under the reference conditions while the gain control is set to its reference position, and the values so obtained shall not exceed the respective indicated values.

In such a case that there is a difference of 12 dB or more in the output sound pressure level between the distortion measuring frequency and a frequency corresponding to its second harmonic, the measurement at the said frequency may be omitted.

$$\text{THD} = 100 \times \sqrt{\frac{p_2^2 + p_3^2 + \dots}{p^2}}$$

where, THD : total harmonic distortion (%)

p : output sound pressure (Pa)

p_i : output sound pressure of i th harmonic (Pa)

4.2.5 Performances of hearing aid with induction pick-up coil input The performances with induction pick-up coil input shall be as stated below when the input selector is set for induction pick-up coil.

- a) **Frequency response with induction pick-up coil input** The gain control is set to its reference position under the reference conditions, the hearing aid is so placed in an a.c. magnetic field with a strength of (31.6 ± 1.58) mA/m that the output sound level becomes the maximum. This response under such states means the output sound pressure level at each frequency covering the test frequency range.

Remarks : In such a case that the linearity between the input and the output does not hold at the reference position of the gain control, it is necessary to weaken the magnetic field strength or to lower the gain of the gain control. In this case the conditions shall be clearly stated.

- b) **Maximum sensitivity with induction pick-up coil input** All the gain controls are set to their full-on gain positions from the conditions stated in a), the measurement is made at the highest possible input where the linearity holds sufficiently between the input and the output at the reference test frequency, then the maximum induction pick-up coil input sensitivity is expressed as the output SPL at a magnetic field strength of 1 mA/m, and the value shall fall within ± 6 dB from the indicated value.

4.3 Mechanical performances

4.3.1 Resistance to shock The resistance to shock of a hearing aid shall be such that the hearing aid satisfies the requirements of 4.1 when it is subjected to three free-falls from a height of 0.7 m onto the center of an oak plate about 10 mm in thickness or a wooden plate equivalent or superior thereto in hardness.

4.3.2 Earphone cord A weight of 100 g is suspended from one end of the cord plug while the opposite side plug is held, and gradually tilted symmetrically through angles of 90° so that the lead out of cord from the plug serves as the fulcrum. This series of operations is counted as one cycle, and the specimen shall be subjected to the bends of 1 000 cycles or more. Further, the same test shall be carried out on the opposite side plug, and neither breaking, short circuit of cord nor any abnormality on the appearance shall appear in both cases.

4.3.3 Retention of plug The force necessary for drawing out the plug of earphone side of an earphone cord in the direction of most easily coming out from the jack shall be within 7 N to 30 N after plugging-in and drawing-out of 20 times or more. The force necessary for drawing out of the plug on amplifier side of an earphone cord in the direction of most easily coming out from the jack shall be within 4 N to 12 N after plugging-in and drawing-out of 20 times or more.

4.4 Weather resistance The hearing aid shall satisfy the requirements of 4.1 after such series of conditioning that it is left in a chamber at a temperature of -10 °C to -5 °C for 1 h at first and in a chamber at a temperature of 40 °C to 43 °C and a relative humidity of 90 % to 95 % for 1 h, then taken out of the chamber and left in the room temperature for 30 min.

5 Construction and dimensions

5.1 Construction in general Hearing aids shall generally be structured as stated below.

- a) A hearing aid shall consist of a microphone, amplifier, earphone, power supply battery, etc. and shall be so structured that it can be used being mounted on a human body.

Remarks: The principal parts of a hearing aid including amplifier, battery, etc. is called hearing aid main body (abbreviated as "main body"). The enclosure of main body is called main body case (abbreviated as "case").

- b) The switches, controls, etc. shall surely operate.
- c) The materials for hearing aid case, earphone, earphone cord, acoustic guide tube, ear insert, etc. shall be not easily damaged by sweat and the like and shall not affect healthy skin.
- d) The symbols and letters to be marked on such components intended to be operated by the user as the gain control, power supply switch, input change-over gear, battery holder shall have a size identifiable by a human having normal eyesight. For a hearing aid on which enough space to mark the symbols and letters is not available due to its small size, substitutional means shall be provided, and the operating method of gain control and the like, including the description of substitutional indicating means, shall be clearly stated in the instruction manual.

- e) The symbols and letters to be marked on the controls intended to be operated by those who tune up the hearing aid shall express the details as far as possible. For a hearing aid on which enough space to mark the symbols and letters is not available due to its small size, means to explain the operating method shall be provided separately.
- f) For a hearing aid in which the control function is intended to be operated by those who tune up the hearing aid using an external device, means to explain the operating method shall be provided separately.

5.2 Power supply switch The symbol given below, which shows the operating state, shall be marked on a hearing aid.

Position of disconnecting power supply	Off or ○
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5.3 Input selector If an input selector is provided in a hearing device equipped with an induction pick-up coil or the like, the symbols given below, which show the types of input, shall be marked on its knob or the circumferential part of the case.

Position showing microphone input	M or graphical symbol
Position showing induction pick-up coil input	T or graphical symbol
Position showing both of microphone input and induction pick-up coil input	MT ⁽¹⁾

Note (1) When the position of MT is between M position and T position and it is difficult to place a symbol of MT between M and T, the position may be shown by “.”.

5.4 Gain control The gain control which adjusts the acoustic gain shall be as follows:

- a) The direction along which the acoustic gain increases and the degree of the increase shall be indicated on the knob of the gain control or the circumferential part of the case by means of symbols, numerals, scales, etc. Provided that, the numerals are so arranged that the numerical value increases in the direction of increasing acoustic gain, and the mark “○” shall not be used for the principal gain controls except such a case that the control also serves as the power supply switch.
- b) When two or more gain controls are provided, each of the controls shall be indicated as stated in a).
- c) The acoustic gain control shall be capable of being set to an arbitrary value without causing discontinuity exceeding 2 dB covering the maximum value obtainable when all the gain controls are set to their full-on gain positions and the minimum value obtainable when all the gain controls are set to their minimum gain position.
- d) All the gain controls shall be continuously variable or variable at steps not exceeding 2 dB.