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Electroacoustics - General specification for hearing aids

电声学　助听器通用规范

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Electroacoustics - General specification for hearing aids

1 Scope

This Standard specifies the technical requirements, measuring methods, inspection rules, marking, packaging, transportation and storage for hearing aids.

This Standard applies to air- and bone-conduct hearing aids.

2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For dated references, the subsequent amendments (excluding corrigendum) or revisions do not apply to this Standard, however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB/T 2421.1, *Environmental testing for electric and electronic products – General and guidance*

GB/T 2422, *Environmental testing for electric and electronic products – Terms and definitions*

GB/T 2423.1, *Environmental testing – Part 2: Test methods – Tests A: Cold* (GB/T 2423.1-2008, IEC 60068-2-1:2007, IDT)

GB/T 2424, *Environmental testing for electric and electronic products – Guidance for high temperature and low temperature tests*

GB/T 2828.1, *Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection* (GB/T 2828.1-2003, ISO 2859-1:1999, IDT)

GB/T 2829, *Sampling procedures and tables for periodic inspection by attributes (Apply to inspection of process stability)*

GB/T 6661, *Nipples for insert earphones*

3.4

box hearing aid

body-worn hearing aid

A hearing aid which is worn on the body of the hearer (not on the head).

3.5

behind-the-ear hearing aid; BTE

A hearing aid which is worn on the back of the auricle which is connected by an ear hook.

3.6

in-the-ear hearing aid; ITE

A hearing aid which is customized in accordance with the shape of the cavity of concha auriculae and worn in the concha auriculae of concha auriculae.

3.7

in-the-ear canal hearing aid

A hearing aid which is customized in accordance with the shape of the auditory meatus and worn in the auditory meatus.

3.8

glasses hearing aid

A hearing aid which is installed on the frame legs of glasses, similar to the ear back wearing method.

3.9

analog hearing aid

A hearing aid with which acoustic signals are converted into continuously variable electrical signals (analog signals) by microphone and transmitted to earphone for output after smoothing and amplification.

3.10

digital hearing aid

A hearing aid whose signal processing is carried out in the digital mode, i.e. acoustic

4.2.1 Sound pressure level when the input sound pressure level is 90 dB ($OSPL_{90}$)

4.2.1.1 Maximum $OSPL_{90}$

The nominal value is specified in the product standards or technical instructions of the manufacturer; the actually measured test value shall not be + 3 dB greater than the nominal value.

4.2.1.2 High-frequency average $OSPL_{90}$

The nominal value is specified in the product standards or technical instructions of the manufacturer; the allowable deviation of its actually measured test value is ± 4 dB.

4.2.2 Full-scale gain

The nominal value is specified in the product standards or technical instructions of the manufacturer; the allowable deviation of its actually measured high-frequency average is ± 5 dB.

4.2.3 Equivalent input noise level

The nominal value is specified in the product standard or technical instructions of the manufacturer; its maximum actually measured test value shall not exceed 32 dB and shall not be + 3 dB greater than the nominal value.

4.2.4 Total harmonic distortion

The nominal value is specified in the product standards or technical instructions of the manufacturer; the maximum actually measured test value shall not exceed 10% and shall not be greater than + 3%.

4.2.5 Frequency response range

The nominal range shall be as specified in the product standards or technical instructions of the manufacturer.

4.2.6 Rated supply current consumption

The nominal value is specified in the product standards or technical instructions of the manufacturer; the maximum actually measured test value shall not be greater than 120% of the rated value.

4.2.7 Sensitivity of inductive pickup coils

The rated value is specified in the product standards or technical instructions of the manufacturer; the allowable deviation of its actually measured test value is ± 6 dB.

4.4.5 Free fall test

Load test sample in a packaging box for transportation; carry out fall test on five surfaces in accordance with the masses and amplitudes specified in Table 1; after test, it shall be as specified in 4.1 and 4.3.

4.5 Electromagnetic compatibility

The test results shall be as specified in GB/T 25102.13-2010.

5 Measuring method

5.1 Measuring conditions

5.1.1 Air-conduct hearing aids shall be as specified in Clause 5 of GB/T 25102.100-2010; bone-conduct hearing aids shall be as specified in Clause 6 of SJ/Z 9143.2-1987.

5.1.2 Use a 2 cm^3 acoustic coupler complying with IEC 60318-5 or an occluded-ear simulator complying with IEC 60711 to carry out measurement. However, the manufacturer shall indicate which measuring coupler is to be used when it gives a specified value.

5.1.3 Digital hearing aids shall be measured in the working state as specified by the manufacturer.

5.2 Appearance, structural requirements, etc.

Use the visual inspection and hand feeling methods for inspection.

5.3 Electroacoustic performance measuring method

5.3.1 When the input sound pressure level is 90 dB, the output sound pressure level ($OSPL_{90}$) is measured as specified in 7.2 of GB/T 25102.100-2010.

5.3.2 The full-scale gain is measured as specified in 7.3 of GB/T 25102.100-2010.

5.3.3 The equivalent input noise level is measured as specified in 7.14 of GB/T 25102.100-2010.

5.3.4 The total harmonic distortion is measured as specified in 7.12.1 of GB/T 25102.100: the recommended frequencies for test are 500 Hz, 800 Hz and 1,600 Hz; the input sound pressure level at 500 Hz and 800 Hz is 70 dB; the input sound pressure level at 1,600 Hz is 65 dB.

5.3.5 Frequency response range:

temperature is 23°C ± 5°C, the relative humidity is 40% ~ 80% and the barometric pressure is 101.3^{+5}_{-20} kPa.

5.4.2.2 Preconditioning method

Place unpackages sample into the test chamber complying with the preconditioning conditions specified in 5.4.2.1; store for more than 1 h.

5.4.3 Inspection before environmental testing

Sample's inspection before environmental testing includes appearance and structural requirements and electroacoustic performance inspection. The inspection for appearance, structural requirements, etc. shall be as specified in 5.2; the inspection for electroacoustic performance is as specified in 5.3 and 5.4.

5.4.4 Environmental testing equipment requirements

The environmental testing equipment shall meet all relevant test equipment requirements in GB/T 2423 and GB/T 2424.

5.4.5 Low-temperature load and storage test

5.4.5.1 Place test sample at room temperature into the test chamber, which is not packaged, not powered on and is in the normal working position. Then the temperature of the test chamber is room temperature.

NOTE: The "normal working position" refers to that, except that the power is not connected, all parts of sample are connected in the use state and the volume control is adjusted to the reference test gain position. The meanings of the "normal working position" in 5.4.6.1, 5.4.7.1 and 5.4.8.1 of this Clause are the same as in this note.

Low-temperature load-storage test and high-temperature load-storage test are carried out as specified in Part 2 of GB/T 2423.1 and Part 2 of GB/T 2423.2.

5.4.5.2 When the temperature of the test box (chamber) reduces to - 10°C ± 3°C at the average rate of 1°C/min, switch on the power of the hearing aid; cut off the power supply after working continuously for 1 h; continue to reduce the temperature of the test chamber to - 40°C ± 3°C; remain for 4 h after sample achieves temperature stabilization.

NOTE: Average rate refers to the average value within each 5 min. The meanings of "average rate" in 5.4.5.3, 5.4.6.2, 5.4.6.3 and 5.4.7.2 of this Clause are the same as in this note.

5.4.5.3 The temperature of the test chamber increases to the test conditions specified in 5.4.2.1 at the average rate of 1°C/min.

5.4.5.4 In order to prevent condensation occurring on the surface of sample, it is

6.1.6 Classification of nonconformity-product

a) nonconformity-products of category A: unit products where there are one or more nonconformities of category A and possibly nonconformities of category B and/or category C;

b) nonconformity-products of category B: unit products where there are one or more nonconformities of category B and possibly nonconformities of category C, but there are no nonconformities of category A;

c) nonconformity-products of category C: unit products where there are one or more nonconformities of category C, but there are no nonconformities of categories A and B.

6.1.7 Evaluation of acceptance and unacceptance of inspection lots

In accordance with the results of sample inspection, if the number of nonconformity-products found in sample is less than or equal to the number of acceptance, then the lot is determined to be acceptable; if the number of nonconformity-products found in sample is greater or equal to the number of rejection, then the inspection lot is determined to be unacceptable.

6.1.8 Handlings of inspection results

a) the inspection lot shall be accepted if it passes the inspection;

b) the inspection lot shall be rejected if it fails to pass the inspection. The manufacturer shall rework such products; after all products pass their self-inspection, they shall be submitted once again for sampling inspection; if they are still rejected, then they shall be reworked until they pass the sampling inspection.

6.1.9 Handlings of samples

For samples passing the acceptance inspection: all qualified-samples shall be delivered for use as qualified-products after repackaging; all unqualified-samples can be repaired by the manufacturer and then packaged and delivered for use after they pass reinspection.

6.2 Periodic inspection

6.2.1 Scope of application

a) for products of continuous normal production, the sampling inspection which is carried out by the quality inspection department of the manufacturer or the quality monitoring department of a superior level in order to determine whether the production process can ensure the continuous stability of product quality;

6.2.8.3 All product lots in storage, which are produced in a period, shall only be put into use after corrective measures are taken and resampling is carried out for the inspection of rejection items, until the inspection item is acceptable.

6.2.9 Handlings of samples

No samples shall not be put into storage or use as acceptable products after periodic inspection.

7 Marking, packaging, transportation and storage

7.1 Marking

7.1.1 The enclosure of products shall be marked with manufacturer name or registered trademark and product model number.

7.1.2 The consumer package shall be provided with manufacturer name, address, zip code, telephone number, product name, model number, registered trademark, reference standard, etc.

7.1.3 All hearing aids which pass the inspection shall be accompanied by a mark of conformity (such as a certificate of compliance); the production lot number (or date) and inspection lot number (or date) shall be indicated; the marking shall include the signature and seal of the inspection personnel.

7.2 Packaging

7.2.1 The packaging box shall contain certificate of compliance, instructions for use, accessories and other related technical documents (such as warranty cards) (the instructions for use and other related documents shall comply with relevant national regulations).

7.2.2 The types and capacities of packages for transportation shall be designed by the manufacturer by itself, but they shall ensure products are in a perfect condition after normal transportation and handling. A packing list shall be enclosed in the packaging box.

7.3 Transportation and storage

7.3.1 Packaged hearing aids can be transported using general freight transportation method, but they shall be protected from direct exposure to sunlight, rain and snow or mechanical impacts.

7.3.2 For long-term storage, hearing aids shall be stored in a well-ventilated warehouse, where the temperature is 0°C ~ 38°C, the relative humidity is not greater

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