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Standard

BEHIND THE EAR (BTE) HEARING AIDS — DIGITAL — SPECIFICATION

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B U R E A U O F I N D I A N S T A N D A R D S
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Audio, Video and Multimedia Systems and Equipment Sectional Committee, LITD 07

FOREWORD

This Draft Indian Standard would be adopted by the Bureau of Indian Standards, after the draft finalized by the Audio, Video and Multimedia Systems and Equipment Sectional Committee would be approved by the Electronics and Information Technology Division Council.

There is no ISO/IEC standard on this subject.

The Committee responsible for the formulation of this standard has reviewed the provisions of the international publications listed in Annex B and has decided that these may be used in conjunction with this standard till Indian Standards on these subjects are published.

The composition of the Committee responsible for the formulation of this standard is given in Annex E.

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.

Draft Indian Standard

BEHIND THE EAR (BTE) HEARING AIDS — DIGITAL — SPECIFICATION

1 SCOPE

This standard specifies the general and performance requirements of the BTE hearing aids — digital, which connects to the ear by means of an ear insert.

2 REFERENCES

The standards listed in Annex A and Annex B contain provisions, which through reference in this text constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreement based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A and Annex B.

3 TERMINOLOGY

For the purpose of this standard, the terms and definitions given in clause 3 of IEC 60118-7:2005 and the following shall apply

3.1 Behind the Ear (BTE) Hearing Aid — Digital — A hearing aid normally worn behind the ear of a person, which gets connected to the ear by means of an ear insert (ear tip or ear mould) and incorporates built-in digital processing.

4 CHARACTERISTICS OF BTE TYPE HEARING AID — DIGITAL

The characteristics of hearing aid are as follows:

Sl No.	*Characteristics*	*Requirements*
(1)	(2)	(3)
i)	Maximum OSPL 90	105 - 135 dB SPL
ii)	HF average OSPL 90	100 - 135 dB SPL
iii)	HF average full on gain 40 dB *Min* (at 50 dB input)	

5.GENERAL REQUIREMENTS

5.1 Design and Workmanship

5.1.1 *Guiding Principles of Design*

It is recommended that the hearing aid should be designed to,

a) avoid undesirable feedback;

b) minimize interference resulting from the

proximity of the hearing aid to the source of electrical interference;

c) minimize effect due to body perspiration;

d) ensure that under normal conditions of use, it shall not be possible to damage the hearing aid by inserting the battery with the polarity reversed;

e) ensure that the working voltages and current of all components shall not exceed the manufacturer's ratings for these components; and

f) minimize the surface noise and EMI/EMC and ensure that there are no sharp corners on body of hearing aid.

5.2 Power Supply

The hearing aid shall be so designed as to be capable of operation from a battery of nominal voltage 1.3 V.

5.3 Housing

5.3.1 The battery compartment shall be distinctly and indelibly marked to indicate the polarity (+ve) of battery connections. An ear insert (or soft ear tip with an elbow and tube/prebent tube) shall also be provided with each hearing aid.

5.3.2 *Dimensions*

The maximum permissible dimension for BTE hearing aids (without an ear tip/mould) are as follows:

Overall length : 60 mm Overall width : 25 mm Thickness : 15 mm

5.3.3 *Mass*

The mass of hearing aid excluding the battery, ear insert, adapter and ear tip/mould if any, shall not exceed 10g.

5.4 External Case

Each hearing aid complete with the ear insert shall be supplied in an external carrying case of durable quality.

5.5 Controls

5.5.1 The following controls shall be provided on each hearing aid:

a) 'ON — OFF' switch, to apply power either through a switch or through the battery compartment cover/door;

b) Gain control / Volume Control shall be provided; and

c) Provision for adjusting tone either by a tone control or through programming.

5.5.2 *Marking of Control Setting on Hearing Aids*

Provisions of Annex C shall apply.

6 METHODS OF MEASUREMENT

The characteristics specified in this standard shall be measured in accordance with applicable trade practices and conform to IEC 60118-7:2005 and ANNEX – Part 2.

7 MARKING

7.1 Each hearing aid shall be indelibly and clearly marked with the following information:

a) Name and/or trade-mark of the manufacturer;

b) Model; and

c) Serial Number

7.2 *BIS Certification Marking*

The hearing aid and/or the hearing aid manual may also be marked with the Standard Mark.

7.2.1 The use of the Standard Mark is governed by the

provisions of the *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions under which a licence for the use of the Standard Mark may be granted to the manufacturers or producers may be obtained from the Bureau of Indian Standards.

7.3 Each hearing aid must be packed with an instruction manual to furnish,

a) name or trade-mark of the manufacturer;

b) type and rating of the battery;

c) precaution to be taken in the use of hearing aid;

d) method of adjusting gain control; and

e) any other useful information the manufacturer would like to furnish.

7.4 The manufacturer shall specify the maximum current consumption in the instruction manual.

8 TESTS

no single failure in any of the type tests. If any failure occurs in the type tests, twice the number of samples shall be subjected to type tests. There shall be no single failure in any of the type tests.

NOTE — Recommendation for type approval and a sampling procedure for electronic components

8.1.2 *Acceptance Tests*

The acceptance tests shall be carried out based on sampling plan as given in Annex D. The hearing aids shall be subjected to the following tests in the order given below:

a) Maximum OSPL 90;

b) HF Average OSPL 90;

c) Frequency range;

d) HF — average full on gain;

e) Total harmonic distortion;

f) Internal noise from the hearing aid in terms of equivalent input noise level; and

g) Battery current.

8.1.3 *Routine Tests*

Each and every hearing aid shall be subjected to the following tests:

a) Maximum OSPL 90;

b) HF Average OSPL 90;

c) HF — average full-on gain;

d) Frequency range; and

e) Total harmonic distortion.

8.1 Classification of Tests

8.1.1 *Type Tests*

The procedure for type approval shall be in accordance with ~~IS 10673~~ (*see* Note). The minimum number of samples for type tests shall be three. The sequence of type tests shall be as given in Table 1. There shall be

8.2 Test Schedule

The test schedule for the performance characteristics, its methods of measurements and the requirements to be met are given in Table 1.

9 RECOMMENDED GOOD MANUFACTURING PRACTICES

9.1 Under normal conditions of use, it should not be possible to damage the hearing aid by inserting the batteries with polarity reversed.

9.2 Working voltages and currents in all components should not exceed the manufacturer's ratings for these components.

9.3 Use of mercury batteries is not desirable.

9.4 Housing

The hearing aid including the battery should be contained in compact lightweight housing of a size easily carried on a person. The design should be such as to provide for hearing aid reasonable protection from dust.

Table 1 Test Schedule Requirements
(*Clauses* 8.1.1 *and* 8.2)

Sl No. (1)	Characteristics (2)	Requirement (3)
i)	Maximum OSPL 90	105-135 dB SPL Maximum OSPL 90 of > 135dB SPL is likely to damage the ear, hence should be prescribed under supervision of qualified audiologist
ii)	HF average OSPL 90	100-135 dB SPL
iii)	HF average full on gain (at 50 dB input)	40 dB *Min*
iv)	Frequency range	If Hearing aid has Maximum OSPL 90 between 105-115dB SPL then f1 ≤ 200 Hz and f2 ≥ 4 500 Hz Else if Hearing aid has Maximum OSPL 90 between 115-135dB SPL then f1 ≤ 200 Hz and f2 ≥ 4 000 Hz
v)	Effect of tone control positions on frequency response	As specified by the manufacturer
vi)	Total harmonic distortion	Shall not exceed 7 percent at 500 Hz, 800 Hz and 1 600 Hz at RTG position, respectively
vii)	Internal noise from the hearing aid in terms of equivalent input noise level	Shall not exceed 30 dB SPL
viii)	Induction coil sensitivity (if telecoil is provided) (at 10 mA/m)	75 dB *Min*
ix)	AGC characteristics (if applicable): a) Steady state input/output characteristics b) Dynamic output characteristics	 a) With the measured and specified curves matched at the point corresponding to 70 dB input SPL, the measured curve at 50 and 90 dB input SPL from the curve specified by the manufacturer for the model by more than ±5 dB b) The attack and release times shall each be within ±5 milliseconds or ±50 percent whichever is larger, of the values specified by the manufacturer for the model
x)	Environmental tests: a) Climatic tests, dry heat at 40°C for 2 h [as per IS 9000 (Part III)] b) Drop test, height of drop 2.0 m on hardwood plane in original individual packing by the manufacturers as intended for end user	 a) After all the tests, the hearing aid shall be subjected to the tests specified as acceptance test and shall meet the requirements laid down in the table b) After one drop from 1.5 m without packing hearing aid shall still be capable of amplification but may not conform to any specifications given in these standards

9.5 The various controls, outlets, etc, should be so provided on the housing as not to

interfere with the operation or functioning of the hearing aid in normal use and yet be accessible without difficulty while wearing the aid.

9.6 The microphone should be so mounted and housed as to minimize,

a) mechanical transfer of housing noise to the microphone.

b) acoustic, magnetic or mechanical coupling between receiver and microphone giving rise to feed back or instability of the amplifier within the rated sensitivity, gain or output.

c) mounting microphone at the bottom is not desirable.

9.7 The battery contacts provided should be of corrosion resistant materials.

9.8 Workmanship

Layout of components, wiring and soldering, etc, should conform to good engineering practices.

9.9 The design of the housing should be such that it is possible to open the housing for maintenance purpose

and to adjust the preset controls, if provided without damaging or defacing the housing or the hearing aid components contained therein

9.10 The housing should be so designed that the method of battery replacement does not require the use of tools, either to open/close the battery compartment or to replace the batteries.

9.11 Information whether the device is to be programmed using trimmer controls or /computer software should be mentioned in the user manual.

9.12 Tone Selector

If a preset tone selector is provided, it shall be easily accessible for adjustment unless taken care of by programs in the hearing aid.

9.13 Each hearing aid should be supplied with at least two different sizes of ear inserts.

10 Acoustic Coupler

The IEC reference coupler in accordance with IEC 60318-5 ($2cm^3$ coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts) shall be used.

ANNEX – Part 2

1. Object

1.1 The purpose of this Annex is to describe a method of determining the physical performance of hearing aids using an induction pick-up coil within an audio-frequency magnetic field. The methods specified in this publication give information on the measurement in Sub-clauses 4.4 and 4.5.

2. Explanation of terms

Terms other than those below are specified in IEC Publication IEC 60118-7:2005 Electroacoustics - Hearing aids - Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes.

2.1 Test point

A position in the test enclosure at which the strength of the magnetic field is defined.

2.2 Test Space

A space, the centre of which is the test point and within which the magnetic field strength is between stated limits for magnitude and direction, and where the hearing aid is to be placed for test.

2.3 Frequency Response

The sound pressure level measured in the coupler expressed as a function of frequency under specified test conditions.

2.4 Sensitivity

The sound pressure level in the coupler under essentially linear input-output conditions at a specified magnetic input field strength and at a specified frequency.

2.5 Maximum sensitivity

The maximum obtainable sound pressure level in the coupler under essentially linear input-output conditions at a specified magnetic input field strength and at a specified frequency, allowing all possible settings of the hearing aid controls and with the hearing aid oriented relative to the test field in such a way that the magnetic induction in the induction pick-up coil has its maximum value.

3. Test equipment

3.1 General

Throughout this standard, all sound pressure levels are referred to 20 μPa and measured according to IEC Publication IEC 60118-7:2005. Magnetic field strength is expressed in A/m or mA/m.

3.2 Test Space

When the input signal to the hearing aid under test is turned off, the residual output level, due to ambient hum, noise and stray fields in the test space, shall drop at least 10 dB and preferably 20 dB or more from the output level with the signal on.

3.3 Magnetic field source

3.3.1 The magnetic field source shall not contain any ferromagnetic material.

3.3.2 The magnetic field source shall be provided with a calibration expressing the relationship between the magnetic field strength in A/m at the test point and the input current in amperes.

3.3.3 The magnetic field source shall be of such shape and dimensions that inside a sphere of diameter 10 cm of which the centre is the test point, the deviation from nominal values in magnitude and direction is less than ±5 % and ±10°, respectively.

Note. - A square loop with a side length a greater than 0.5 m or a circular loop with a diameter d greater than 0.56 m will meet these specifications.

3.3.4 The total harmonic distortion of the magnetic field shall not exceed 1%.

Note. - This condition will be met if the distortion of the input current is less than 1%.

3.3.5 The magnetic field strength at the test point shall be maintained within an overall accuracy of ±1.5 dB.

4 Test procedure

4.1 Strength of magnetic field source

The magnetic field strength produced by the magnetic field source is computed from the geometry of the source.

Notes 1. – For example, the magnetic field strength in the centre of a square loop with a side of a meters and carrying a current of i amperes is given by:

$$H = \frac{2\sqrt{2}}{\pi} . \frac{i}{a} \, A/m$$

In the centre of circular loop with a diameter of d meters carrying a current of i amperes, the magnetic field strength is given by:

$$H = \frac{i}{d} \, A/m$$

2. -One way to secure essentially constant current conditions is to drive the magnetic field source from a source having a constant e.m.f. and an internal impedance at least 100 times greater than the magnetic field source input impedance in the frequency range 100 Hz to 10000 Hz, which, in the case of a low impedance generator, may be accomplished by a resistor connected in series with the output terminals of the generator.

3. -The test space shall be remote from any field-disturbing iron or other ferromagnetic material or other material in which eddy currents can be induced, that could give rise to a field-disturbance.

4.2 Locating the hearing aid for test

4.2.1 The support for the hearing aid shall be non-metallic.

4.2.2 The hearing aid shall be placed in the center of the test space and oriented in a way that maximum signal pick-up is obtained. The orientation should be stated.

4.3 Normal operating conditions for the heating aid

The normal hearing aid operating conditions applicable to measurements are prescribed in IEC Publication IEC 60118-7:2005. As the material and the construction of the power source might influence the results, the actual type of source should be stated.

4.4 Frequency response

As the tone control settings or gain control characteristics are likely to have the same effect upon the frequency response whether the hearing aid is connected to the microphone input or to the induction pick-up coil input, it is necessary to measure the frequency response only under normal operating conditions.

The test procedure is:

a) Adjust the magnetic field at the test point to 10 mA/m ±5% at 1600 Hz or 2500 Hz when appropriate.

b) Adjust the gain control to the reference test gain control position (see IEC Publication IEC 60118-7:2005). Set other controls into desired positions. If the hearing aid does not have sufficient gain to permit this, set the gain control at maximum.

c) Vary the frequency of the source over the frequency range 100 Hz to 10000 Hz, keeping the magnetic field constant at 10 mA/m.

Note. - In certain cases - for example, if a significant degree of non-linearity should occur - it may be necessary to employ a lower input magnetic field strength or a lower position of the gain control to define the frequency response.

When non-linearity does not occur, a higher input magnetic field strength may be employed to obtain a better signal-to-noise ratio.

When either is done, the test conditions shall be stated.

d) For continuous recording, the sweep rate shall be such that the response does not differ by more than 1.0 dB from the steady-state value at any frequency.

e) The frequency response is plotted as the coupler sound pressure level versus frequency at a constant magnetic input field strength. The magnetic input field strength shall be stated.

4.5 Sensitivity

4.5.1 The sensitivity is expressed as the output sound pressure level at a magnetic field strength of 1 mA/m.

Note. – Expressing the sensitivity at a magnetic field strength of 1 mA/m does not necessarily mean that the sensitivity is measured at a magnetic field strength of 1 mA/m.

4.5.2 Maximum sensitivity

The test procedure is:

Turn the gain control full on; set other controls, if any, in such a position that maximum gain is obtained and measure the coupler sound pressure level at an input signal sufficiently low to provide essentially linear input-output conditions. When possible, a value of 1 mA/m or 10 mA/m is recommended.

Note. - In cases where the gain control position has no influence on the frequency response, it is necessary only to measure the maximum sensitivity at only one frequency, e.g. 1600 Hz or 2500 Hz when appropriate. From the result of this measurement, in conjunction with the frequency response the maximum sensitivity at all frequencies within the frequency range 100 Hz to 10000 Hz can be derived.

ANNEX A

(*Clause* 2)

LIST OF REFFERED INDIAN STANDARDS

IS No.	*Title*
~~10673 : 1983~~	~~Sampling Plans and Procedures for Inspection by Attributes for Electronic Items (superseding IS 2612 : 1965)~~
9000 (Part III) : 1977	Basic environmental testing procedures for electronic and electrical items: Part III Dry heat test
~~10776~~	~~Methods of measurement of electro-acoustical characteristics of hearing aids~~
~~(Part 1) : 1984~~	~~General measurements for air- conduction hearing aids (superseding IS 3641 : 1976)~~
~~(Part 2) : 1984~~	~~Additional measurements for hearing aids with induction pick- up coil input~~
4905 : 2015	Random Sampling and Randomization Procedures

ANNEX B

(*Foreword* and *Clause* 2)

LIST OF REFERRED INTERNATIONAL STANDARDS

Sl No.	*International Standard*	*Title*
1	IEC 60118-7 : 2005	Electroacoustics — Hearing aids — Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes

ANNEX C

(*Clause* 5.5.2)

MARKING OF CONTROL SETTINGS ON HEARING AIDS

C-0 GENERAL

C-0.1 The object of this Annex is to provide uniformity in markings used on hearing aids. Because of their small size or for other reasons, marking shall be as given in this Annex are to be adopted.

C-0.2 The markings should be preferably in easily readable characters and aiming on a ready identification for the various control settings.

C-1 BATTERY SWITCH (IF PROVIDED) C-2 INPUT SELECTION

If provided, shall be explained in the manual.

C-2.1 Selection

Patient should be able to shift easily between Mic and

Telecoil (if provided), using either,

a) static switch (like OTM switch); or
b) momentary switch (press for change).

C-3 TONE CONTROL (IF PROVIDED)

The marking shall be as follows:

Function	: Marking
Normal or no emphasis	: N
Low frequency suppressor	: H or NL

C-4 GAIN CONTROL OR VOLUME CONTROL

The device shall have a gain control (or volume control) whose setting shall be clearly explained in the instruction manual.

C-5 OUTPUT LIMITING CONTROL (IF PROVIDED)

ANNEX D

(*Clause* 8.1.2)

SAMPLING AND CRITERIA FOR CONFORMITY

D-1 LOT

D-1.1 In a consignment, all the hearing aids of the same category, manufactured from the same material under similar conditions of production shall be grouped together to constitute a lot.

D-1.2 The number of hearing aids to be selected from the lot shall depend upon the size of the lot and shall be in accordance with col 2 of Table 2.

D-1.2.1 These hearing aids shall be selected from the lot at random. In order to ensure the randomness of selection, procedures given in IS 4905 may be followed.

D-2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

All the hearing aids selected from the lot at random according to col 2 and col 3 of Table 2 shall bevvvv subjected to the acceptance tests. A hearing aid failing to meet the requirements of any of these acceptance tests shall be termed as 'defective'. The lot shall be considered as conforming to the requirements of acceptance tests, if the number of defectives found in the sample is less than or equal to the corresponding acceptance number given in col 4 of Table 2, otherwise the lot shall be rejected.

Table 2 Sample Size and Acceptance Number

(*Clauses* D-1.2 *and* D-2)

Sl No.	Lot Size	Sample Size	Acceptance Number
(1)	(2)	(3)	(4)
1	Up to 50	8	0
2	51 - 100	13	1
3	101 - 300	20	1
4	301 - 500	32	2
5	501 and above	50	3

ANNEX E
(*Foreword*)
COMMITTEE COMPOSITION