Draft Indian Standard

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

ICS 33.160.25

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FOREWORD
(Formal Clauses to be added later on)

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

There is no ISO/IEC standard on this subject.
This standard was originally published in 2013. First revision of this has been undertaken to refer latest IEC standards for test measurements. Major changes are as follows:

a) Scope has been updated by incorporating word 'insert'.
b) Referred standards have been updated. IS/IEC 60118-0:2022 has been referred replacing IS 10776
c) Characteristic - HF average full gain is at 50 dB instead of existing 50/60dB input.
d) Reference for acoustic coupler has been included.

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.

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.

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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 3 of IS/IEC 60118-0:2022 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. (1)	*Characteristics* (2)	*Requirements* (3)
i)	Maximum OSPL 90	105 - 135 dB SPL
ii)	HF average OSPL 90	100 - 135 dB SPL
iii)	HF average full on gain (at 50 dB input)	40 dB *Min*

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 IS/IEC 60118-0:2022.

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 may also be marked with the Standard Mark. The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 2016 and the Rules and Regulation made there under. Details of conditions under which a license for the use of Standard Mark may be granted to manufacturers and producers may be obtained from the Bureau of Indian Standards.

7.3 Each hearing aid shall 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

8.1 Classification of Tests

8.1.1 *Type Tests*

The procedure for type approval shall be in accordance with IEC 61193-2:2007. 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 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.

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.

8.2 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 ≥ 4500 Hz Else if Hearing aid has Maximum OSPL 90 between 115-135dB SPL then f1 ≤ 200 Hz and f2 ≥ 4000 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 1600 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/IEC 60068-2-2:2007] 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 reference coupler in accordance with IS/IEC 60318-5:2006 shall be used.

ANNEX A

(*Clause* 2)

LIST OF REFFERED INDIAN STANDARDS

IS No.	*Title*	*IS No.*	*Title*
IS/IEC 60118-0:2022	Electroacoustics Hearing Aids Part 0 Measurement of the Performance Characteristics of Hearing Aids	4905 : 2015	R andom Sampling and Randomization Procedures (First Revision)
IS/IEC 60068-2-2:2007	Environmental Testing Part 2: Tests - Test B Section 2: Dry Heat		
IS/IEC 60318-5:2006	Electroacoustics Simulators of Human Head and Ear –Part 5- 2cm^3 coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts		

ANNEX B

(*Foreword* and *Clause* 2)

LIST OF REFERRED INTERNATIONAL STANDARDS

Sl No.	*International Standard*	*Title*
1	IEC 61193-2:2007	Quality assessment systems - Part 2: Selection and use of sampling plans for inspection of electronic components and packages

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 be 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