Draft Indian Standard

SPECIFICATION FOR BODY LEVEL HEARING AIDS

(First Revision)

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
(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.

This standard was originally published in 1984 and had superseded IS: 4406-1967 'General requirements for hearing aids.' and IS: 4482-1967 'Specification for hearing aids.' First revision of this has been undertaken to refer latest IEC standards for test measurements. Major changes are as follows:

a) Amendment 1, 2 and 3 have been incorporated
b) Parameters 'Full-on acoustic gain', Comprehensive frequency response, Effect of gain control positions on frequency, difference frequency distortion, Effect of variation of battery voltage on distortion have been removed.

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.

1. SCOPE

1.1 This standard specifies the general and performance requirements of body level hearing aids.

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

3.0 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 Body Level Hearing Aid — A hearing aid normally worn on the body of a person.

4. CLASSIFICATION OF HEARING AIDS

4.1 The performance of hearing aids shall be classified on the basis of the following parameters:

a) Maximum OSPL 90,

b) HF Average OSPL 90, and

c) HF average full-on gain.

3.2 Hearing aids are classified into the three classes as per Table 1.

Table 1
Classification of Hearing aids
(Clause 3.2)

Characteristics	*Class of Hearing Aid*		
	Mild	Moderate	Strong
a) Maximum OSPL 90	115 dB	125 dB	135 dB (*see* Note)
b) HF Average OSPL 90	105 to 114 dB	114 to 124 dB	124 to 134 dB
c) HF-average full-on gain	40 dB (*Min)*	50 dB (*Min)*	60 dB (*Min)*

NOTE — Hearing aid with Maximum OSPL 90 greater than 135 dB SPL are likely to damage the ear. Hence their use should be under strict medical advice.

5. GENERAL REQUIREMENTS

5.1 Design and Workmanship

5.1.1 *Design* — The hearing aid shall be so designed:

a) as to avoid undesirable feedback,

b) as to minimize interference resulting from the proximity of the hearing aid to the source of electrical interference,

c) as to minimize effects due to change in temperature and relative humidity,

d) as to minimize effect due to body perspiration,

e) as to withstand shocks, drops and other mechanical damages likely to occur in normal use,

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

g) that the working voltages and currents of all components shall not exceed the manufacturer's ratings for these components, and

h) as to minimize the surface noise.

5.1.2 *Workmanship* — Layout of components, wiring, soldering and the workmanship shall conform to good engineering practices.

5.2 Power Supply — Unless otherwise specified the hearing aid shall be so designed as to be capable of operation from a battery of nominal voltage 1.5 V.

5.2.1 The battery should conform to R6 size of IS 8144:2018.

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

NOTE — The maximum overall sizes and mass for the hearing aids are specified in **5.5.**

5.3.1 The various controls, socket-outlets, etc., shall be so provided on the housing as not to interfere with the operation or functioning of the hearing aid in normal use.

5.3.2 A mechanical support shall be provided for attaching the aid on to the person's apparel such that it does not get easily dislodge and shall be of such a size and shape as not to appreciably disturb the hearing aid performance nor introduce spurious effects due to its own mechanical resonance in the sound field.

The support shall keep the hearing aid in a balanced position and shall not interfere with ease of operation of the controls or easy replacement of the battery.

5.3.3 The microphone shall be so mounted and housed as to minimize:

a) mechanical transfer of housing noise to the microphone; and

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

5.3.4 The design of the housing shall be such that it is possible to open the housing for maintenance purposes and to adjust the preset controls if provided without damaging or defacing the housing or the hearing aid components contained therein.

5.3.5 The housing shall 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.

5.3.6 The battery compartment shall be distinctly and indelibly marked to indicate the polarity of battery connections and battery voltage.

5.3.7 The battery contacts provided shall be made of corrosion resistant materials.

5.3.8 Adequate protection shall be provided to guard against damage to the housing and other hearing aid components from chemical discharge from the battery.

5.4 Earphone Receiver, Cord and Ear Plug — Each hearing aid shall be provided with a receiver of either air conduction type or bone conduction type. A lightweight flexible cord terminated on both ends by means of plugs conforming to IS 3720:1983 and of length at least 50 cm shall be provided with each hearing aid for connecting the hearing aid to the earphone receiver. An ear insert shall also be provided with each hearing aid.

5.5 Dimensions and Mass

5.5.1 *Dimensions* **—** The maximum permissible dimension for battery operated hearing aids are as follows:

Overall height	80 mm
Overall width	65 mm
Thickness (without the mechanical support)	20 mm

5.5.2 *Mass* **—** The mass of the hearing aid with mechanical support and excluding hearing aid batteries, cord and ear plug shall not exceed 60 g.

5.6 External Case — Each hearing aid complete with the cord, receiver, ear plug, and battery shall be supplied in an external carrying case of durable quality.

5.7 Controls

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

a) Battery 'ON-OFF' switch,

b) Gain control (or volume control),

c) Tone selector (see Note), and

d) Telephone coil (optional).

NOTE — If a preset tone selector is provided, it shall be easily accessible for adjustment without the necessity of opening the housing of the hearing aid (see **5.3.4**).

5.7.1.1 In many cases, some of the functions of the switches may be combined in one switch, for example, the battery switch combined with the tone selector. However, it is recommended that the 'ON-OFF' switch should be independent of the gain control.

5.7.2 *Marking of Control Setting on Hearing Aids* — Provisions of ANNEX C shall apply.

6. METHODS OF MEASUREMENT

6.1 The characteristics specified in this standard shall be measured in accordance with methods specified in IS/IEC 60118-0:2022

7. MARKING

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

a) The name or trade-mark of the manufacturer,
b) The model and serial number of the hearing aid, and
c) The class of hearing aid.

7.1.1 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 Regulations made there under. The details of conditions under which a license for the use of the Standard Mark may be granted to the manufacturers and producers may be obtained from the Bureau of Indian Standards.

7.2 The following information shall be furnished with each hearing aid:

a) Name or trade-mark of the manufacturer,

b) Type and rating of the battery,

c) Operating instructions,

d) Precaution to be taken in the use of hearing aid,

e) The type of hearing aid earphone receiver(s) supplied with the hearing aid, and

f) Any other useful information the manufacturer would like to furnish.

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 2. 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 on a limited number of samples selected in accordance with the sampling procedure given in ANNEX D, and which have passed routine tests.

The samples 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 2. The characteristics and requirements specified shall be satisfied irrespective of the type of cord or receiver being used.

9. Acoustic Coupler — The reference coupler in accordance with IS/IEC 60318-5:2006 shall be used.

TABLE 2 TEST SCHEDULE REQUIREMENTS
(Clauses 8.1.1 *and* 8.2)

Sl No.	Characteristics Requirement	METHOD OF MEASUREMENT	REQUIREMENTS FOR		
			Mild Class	Moderate Class	Strong Class
(1)	(2)	(3)	(4)	(5)	(6)
1.	Maximum OSPL 90 [*Refer to clause 3.22 of IS/IEC 60118-0:2022*] [Note- *Hearing aids with Maximum OSPL90 greater than 135dB SPL are likely to damage the ear. Hence their use should be under strict medical advice.*]	Refer to clause **7.3 and 10.4** of IS/IEC 60118-0:2022	115 dB	125 dB	135 dB
2.	HF Average OSPL 90 [*Refer to clause 3.18 & 3.23 of IS/IEC 60118-:2022*]	Refer to clause **7.3 and 10.4** of IS/IEC 60118-0:2022	105 to 114 dB	114 to 124 dB	124 to 134 dB
3.	HF-average full-on gain [*Refer to clause 3.18 & 3.26 of IS/IEC 60118-:2022*]	Refer to clause 7**.4 and 10.5** of IS/IEC 60118-0:2022	40 dB *(Min)*	50 dB *(Min)*	60 dB *(Min)*
4.	Basic frequency response	Refer to clause **7.5 and 10.6** of IS/IEC 60118-0:2022	Measured results shall be recorded		
5.	Frequency range	Refer to clause **7.5.2 and 10.7** of IS/IEC 60118-0:2022	The frequency range shall be at least between 250 Hz and 3 150 Hz [Note: For clarity, f1 ≤ 250 Hz and f2 ≥ 3 150 Hz]		
6.	Effect of tone control positions on frequency response (if applicable)		As specified by the manufacturer		
7.	Effect on the full-on acoustic gain of variation of battery voltage		Battery usage pattern in India is different from international norms. Battery is used even if voltage level is not maintained at 1.5 V so hearing aid shall still be capable of amplification but may not conform to any specifications given in these standards if battery voltage drops till 1.0 V.		
8.	Total harmonic distortion	Refer to clause **7.6 and 10.10** of IS/IEC 60118-0:2022	Shall not exceed 7 percent at RTS for the following 500 Hz at 70 dB input 800 Hz at 70 dB input 1 600 Hz at 65 dB input		

9.	Internal noise from the hearing aid in terms of equivalent input noise level	Refer to clause **8.3 and 10.11**of IS/IEC 60118-0:2022	Shall not exceed 30 dB SPL at RTS		
10.	Battery current at RTS	Refer to clause **8.7 and 10.9** of IS/IEC 60118-0:2022	5 mA *(Max)*	10 mA *(Max)*	15 mA *(Max)*
11.	Induction coil sensitivity (if applicable) (at 10 mA/m)	Refer clause 9 **of** IS/IEC 60118-0:2022	75 dB *(Min*)	85 dB *(Min*)	95 dB *(Min*)
12.	AGC characteristics (if applicable):				
	a) Steady state input/output characteristics	Refer to clause **8.5.2** of IS/IEC 60118-0:2022	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 shall not differ in output SPL from the curve specified by the manufacturer for the model by more than ± 5 dB. An example of the curve is given in Fig. 1		
	b) Dynamic output characteristics	Refer to clause **8.5.3** of IS/IEC 60118-0:2022	The attack and recovery times shall each be within ± 5 milliseconds or ± 50% whichever is larger, of the values specified by the manufacturer for the model.		
13.	Environmental tests:				
	i) Climatic tests				
	a) Dry heat	IS/IEC 60068-2-2:2007 at 40°C for 2 h	After all the tests, the hearing aids shall be subjected to the tests specified as Acceptance Tests and shall meet the requirements laid down in the table		
	b) Damp heat (Cycling)	IS/IEC 60068-2-30 : 2005 at 40°C severity for 1 cycle			
	ii) Drop test	Height of drop 0.5 meter, No. of drops 6 on hardwood plane	NOTE — Minor dents or cracks which do not effect the conformance of the hearing aid should not be taken as criteria of failure for the drop test.		

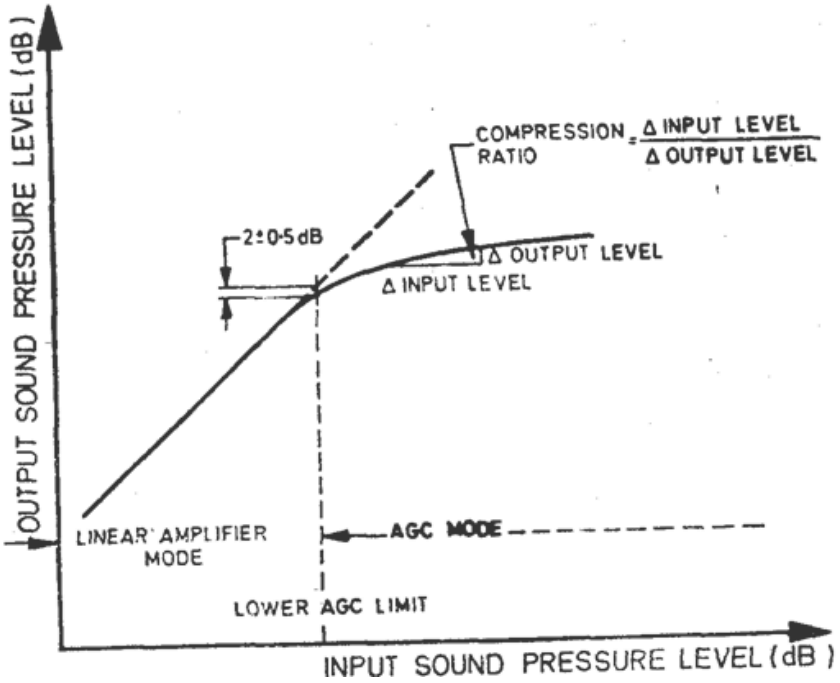

FIG. 1 EXAMPLE OF STEADY STATE INPUT/OUTPUT GRAPH

ANNEX A

(*Clause* 2)

LIST OF REFFERED INDIAN STANDARDS

IS No.	*Title*
3720 : 1983	Dimensions of plugs for hearing aids (First Revision)
4905 : 2015	Random Sampling and Randomization Procedures (First Revision)
8144 : 2018	Multipurpose dry batteries - Specification (Second Revision)
IS/IEC 60118-0:2022	Electroacoustics Hearing Aids Part 0 Measurement of the Performance Characteristics of Hearing Aids
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
IS/IEC 60068-2-30 : 2005	Environmental testing Part 2 Tests Section 30 Test Db: Damp heat cyclic (12 h+ 12 h cycle)

ANNEX B

(*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 5.7.2)

MARKING OF CONTROL SETTINGS ON HEARING AIDS

C-0. GENERAL

C-0.1 The object of this appendix is to provide uniformity in markings used on hearing aids. Because of their small or for other reasons hearing aids may not all be thus marked, but if they are, the markings given in this appendix are to be adopted.

C-0.2 The markings should be in easily readable characters and aiming on a ready identification for the various control settings. The markings of settings by use of colour coding, for example, by using dots of different colours should be avoided.

C-1. BATTERY SWITCH

C-1.1 The markings shall be as follows:

Function	*Marking*
OFF	0
ON	1

NOTE — The marking of the 'ON' position is used only when the hearing aid is provided with a separate battery switch.

C-2. INPUT SELECTOR

C-2.1 The markings shall be as follows:

Function	*Marking*
Microphone	M
Pick-up coil	T

NOTE — If a position is provided where both microphone and pick-up coil are connected, this shall be marked MT.

C-3. TONE SELECTOR

C-3.1 The markings shall be as follows:

Function	*Marking*

Normal or no emphasis	N
High frequency emphasis (or low-frequency suppression)	H
Low frequency emphasis (or high frequency suppression)	L

C-3.1.1 In case where several forms of high frequency or low-frequency emphasis are to be marked the letter symbols stated in **C-3.1** shall be followed by numbers such as H_1, H_2, etc., L_1, L_2, etc. The number used shall be such that increasing numbers indicate increased emphasis on the frequency range in question.

C-4. GAIN CONTROL (OR VOLUME CONTROL)

C-4.1 The setting of the gain control (or volume control) shall be indicated by numbers on the control knob or on the hearing aid in such a way that the higher number indicates a higher gain. In cases where restricted pace does not allow the use of numbers, marks shall be such that a greater number of marks indicates a higher gain.

C-5. OUTPUT LIMITING SELECTOR

C-5.1 The output limiting selector shall be marked as follows:

Function	Marking
No limiting	None
Automatic volume control	AV
Peak clipping	PC

C-6. OUTPUT LIMITING CONTROL

C-6.1 The control for adjusting the level of maximum output shall be indicated in accordance with C-**5.1** and the setting shall be indicated by numbers in such a way that a higher number indicates a higher output level.

C-7. COMBINED SWITCHES

C-7.1 Where the battery switch is combined with another switch or control, the position corresponding to the 'OFF' position shall be marked as indicated in **C-1**, and the relevant markings specified in **C-2** to **C-6** shall be used.

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 1 and 2 of Table 3.

TABLE 3 SAMPLE SIZE AND ACCEPTANCE NUMBER

(Clauses *D-1.2 and D-2.1*)

LOT SIZE	SAMPLE SIZE	ACCEPTANCE NUMBER
(1)	(2)	(3)
Up to 50	8	0
51 to 100	13	1
101 to 300	20	1
301 to 500	32	2
501 and above	50	3

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 : 2015 ‘Random sampling and randomization procedures (First Revision)’ may be followed.

D-2. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

D-2.1 All the hearing aids selected from the lot at random according to col 1 and 2 of Table 3 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 3 of Table 3; otherwise, the lot shall be rejected.