Draft Indian Standard

SPECIFICATION FOR

BODY LEVEL HEARING AIDS

0. FOREWORD

0.1 This Draft Indian Standard would be adopted by the Bureau of Indian Standards ~~2 February 1984~~, 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.

0.2 The object of this standard is to specify the general and performance requirements of body level hearing aids. The values laid down have been chosen keeping in view the use of indigenous materials and components to the maximum possible extent.

0.3 This standard, which supersedes the earlier standards IS: 4406-1967 'General requirements for hearing aids.' and IS: 4482-1967 'Specification for hearing aids.', covers the following new features:

a) The hearing aid has been classified into three types, namely, mild moderate and strong based on the hearing loss and the capability of the amplifier: and
b) Additional characteristics both electrical and environmental have been incorporated in this standard to assess the performance of the hearing aid.

0.4 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. TERMINOLOGY

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

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

3. CLASSIFICATION OF HEARING AIDS

3.1 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

~~Full-on acoustic gain,~~

c) HF average full-on gain.

3.2 Hearing aids are classified into the following three classes:

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
~~Full-on acoustic gain~~	~~45 dB (*Min*)~~	~~55 dB (*Min*)~~	~~65 dB (*Min*)~~
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.

4. GENERAL REQUIREMENTS

4.1 Design and Workmanship

4.1.1 *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.

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

4.2 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.

4.2.1 The battery should preferably conform to R6 size ~~of IS : 7218-1974 'Dry Batteries For Hearing Aids'~~

4.3 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 **4.5.**

4.3.1 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.

4.3.2 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.

4.3.3 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.

4.3.4 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.

4.3.5 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.

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

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

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

4.4 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 ‘Dimensions of Plugs for Hearing Aids’ 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.

4.5 Dimensions and Mass

4.5.1 *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

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

4.6 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.

4.7 Controls

4.7.1 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 ~~4.3.1.4~~).

4.7.1.1 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 preferably be independent of the gain control.

4.7.2 *Marking of Control Setting on Hearing Aids* — Provisions of Appendix A shall apply.

5. METHODS OF MEASUREMENT

5.1 The characteristics specified in this standard shall be measured in accordance with methods specified in IEC 60118-7:2005 and ANNEX – Part 2.

6. MARKING

6.1 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.

6.1.1 The hearing aid may also be marked with the Standard Mark.

NOTE — 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 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.

6.2 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.

7. TESTS

7.1 Classification of Tests

7.1.1 *Type Tests* — The procedure for type approval shall be in accordance with ~~IS : 2612-1965 'Recommendation for type approval and sampling procedures for electronic components'.~~ 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.

7.1.2 *Acceptance Tests* — The acceptance tests shall be carried out on a limited number of samples selected in accordance with the sampling procedure given in Appendix B, 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,

~~Full-on acoustic gain,~~

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.

7.1.3 *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.

7.2 Test Schedule — The test schedule for the performance characteristics, its methods of measurements and the requirements to be met are given in Table 1. The characteristics and requirements specified shall be satisfied irrespective of the type of cord or receiver being used.

8. Acoustic Coupler — The IEC reference coupler in accordance with IEC 60318-5 (2cm3 coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts) shall be used.

TABLE 1 TEST SCHEDULE REQUIREMENTS
(Clauses 7.1.1 *and* 7.2)

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 3.7 of IEC 60118-7:2005*] [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 **8.2** of IEC 60118-7:2005	115 dB	125 dB	135 dB
2.	HF Average OSPL 90 [*Refer to clause 3.2 & 3.8 of IEC 60118-7:2005*]	Refer to clause **8.2** of IEC 60118-7:2005	105 to 114 dB	114 to 124 dB	124 to 134 dB
	~~Full-on acoustic gain~~		~~45 dB *(Min)*~~	~~55 dB *(Min)*~~	~~65 dB *(Min)*~~
3.	HF-average full-on gain [*Refer to clause 3.2 & 3.9 of IEC 60118-7:2005*]	Refer to clause **8.3** of IEC 60118-7:2005	40 dB *(Min)*	50 dB *(Min)*	60 dB *(Min)*
4.	Basic frequency response	Refer to clause **8.4** of IEC 60118-7:2005	Measured results shall be recorded		
	~~b) Comprehensive frequency response~~				
5.	Frequency range	Refer to clause **8.4.2** of IEC 60118-7:2005	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]		
	~~Effect of gain control positions on frequency response~~		~~Measured results shall be recorded~~		
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 **8.6** of IEC 60118-7:2005	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		
	~~Intermodulation distortion/ Difference frequency distortion~~		~~Measured results shall be recorded~~		
	~~Effect of variation of battery voltage on distortion~~				
9.	Internal noise from the hearing aid in terms of equivalent input noise level	Refer to clause **8.7** of IEC 60118-7:2005	Shall not exceed 30 dB SPL at RTS		
10.	Battery current at RTS	Refer to clause **8.5** of IEC 60118-7:2005	5 mA *(Max)*	10 mA *(Max)*	15 mA *(Max)*
11.	Induction coil sensitivity (if applicable) (at 10 mA/m)	Refer to ANNEX – Part 2	75 dB *(Min)*	85 dB *(Min)*	95 dB *(Min)*
12.	AGC characteristics (if applicable):				
	a) Steady state input/output characteristics	Refer to clause **8.9.2** of IEC 60118-7:2005	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 **8.9.3** of IEC 60118-7:2005	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 : 9000 (Part 3/Sec 2) - 1977§ 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 : 9000 (Part 5)-1981‖ at 40°C severity for 1 cycle			
	ii) Drop test	IS : 9000 (Part 7/Sec 5)- 1979¶, 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.		

§Basic environmental testing procedures for electronic and electrical items:
Part 3 Dry heat test, Section 2 Dry heat test for non-heat dissipating items with sudden change of temperature.
‖Part 5 Damp heat (cyclic) test.
¶Part 7 Impact test, Section 5 Free fall, repeated.

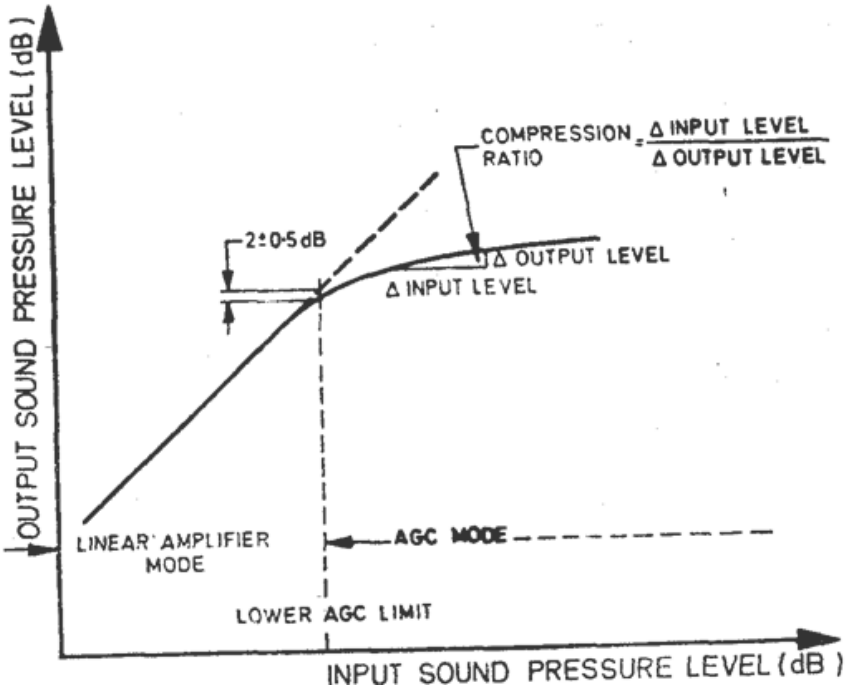

FIG. 1 EXAMPLE OF STEADY STATE INPUT/OUTPUT GRAPH

APPENDIX A

(Clause 4.7.2)

MARKING OF CONTROL SETTINGS ON HEARING AIDS

A-0. GENERAL

A-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.

A-0.2 The markings should preferably 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.

A-1. BATTERY SWITCH

A-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.

A-2. INPUT SELECTOR

A-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.

A-3. TONE SELECTOR

A-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

A-3.1.1 In case where several forms of high frequency or low-frequency emphasis are to be marked the letter symbols stated in **A-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.

A-4. GAIN CONTROL (OR VOLUME CONTROL)

A-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 space does not allow the use of numbers, marks shall be such that a greater number of marks indicates a higher gain.

A-5. OUTPUT LIMITING SELECTOR

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

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

A-6. OUTPUT LIMITING CONTROL

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

A-7. COMBINED SWITCHES

A-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 **A-1**, and the relevant markings specified in **A-2** to **A-6** shall be used.

APPENDIX B

(Clause *7.1.2*)

SAMPLING AND CRITERIA FOR CONFORMITY

B-1. LOT

B-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.

B-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 2.

———————————————————————

TABLE 2 SAMPLE SIZE AND ACCEPTANCE NUMBER

(Clauses *B-1.2 and B-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

B-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.

B-2. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

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

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~~ 200 Hz to ~~10000~~ 5 000 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 centre 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 characteristic 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~~ 200 Hz to ~~10000~~ 5 000 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~~ 200 Hz to ~~10000~~ 5 000 Hz can be derived.