



उत्पाद मैनुअल
आई एस 10775 : 1984 के अनुसार
बॉडी लेवल हीयरिंग एड्स के लिए

दस्तावेज संख्या - पी एम/आई एस 10775/ 1/ जुलाई 2021

भारतीय मानक ब्यूरो की स्कीम-1 (अनुरूपता मूल्यांकन) विनियम, 2018 के तहत यह उत्पाद मैनुअल प्रमाणीकरण के प्रचालन में रीति और पारिश्रिता की सुसंगतता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसी द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस प्रमाणीकरण लाइसेंस/ प्रमाणपत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज का उपयोग किया जा सकता है।

**PRODUCT MANUAL FOR
BODY LEVEL HEARING AIDS
ACCORDING to IS 10775 : 1984**

Document No.- PM/IS 10775/ 1 / July 2021

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

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1.	Product	:	IS 10775: 1984
	Title	:	Body Level Hearing Aids
	No. of Amendments	:	3
2.	Sampling Guidelines:		
a)	Raw material	:	Plugs for hearing aids – IS 3720
b)	Grouping guidelines	:	Please refer ANNEX – A
c)	Sample Size	:	11 (8 for all acceptance tests and 3 for Type tests)
3.	List of Test Equipment	:	Please refer ANNEX – B
4.	Scheme of Inspection and Testing	:	Please refer ANNEX – C
5.	Possible tests in a day:		
	As the licence is operated on Factory Testing basis due to unavailability of TPTL, complete testing of a sample shall be done in factory. 2 days are required for complete factory testing.		
6.	Scope of the Licence:		
	“Licence is granted to use Standard Mark as per IS 10775: 1984 with the following scope:		
	Name of the product	Body Level Hearing Aids	
	Class	Mild/Moderate/Strong	
	Any other aspect required as per the Standard	With/ without induction coil	

ANNEX A

Grouping guidelines

1. Body Level Hearing Aids are classified into three Classes, viz, Mild, Moderate and Strong, based on the hearing loss and the capability of the amplifier.
2. For considering GOL/CSoL, Body Level Hearing Aids of each Class intended to be covered in the licence shall be drawn for testing.
3. For each Class, if Body Level Hearing Aid with Induction Coil is tested, Body Level Hearing Aid without Induction Coil may also be covered.
4. The Firm shall declare the varieties of various Body Level Hearing Aids they intend to cover in the Licence. The Scope of Licence may be restricted based on the Manufacturing capability and Testing facilities of the Manufacturer.
5. During the operation of the Licence, BO shall ensure that all the Varieties covered in the Licence are tested in rotation to the extent possible.

ANNEX B**List of Test Equipment***Major test equipment required to test as per the Indian Standard*

Sl. No.	Tests used in with Clause Reference	Test Equipment
01	Clauses 7.1 and 7.2 Table 1 (1 -16)	Hearing Instrument Analyzer & Test System
02		Test Chamber Sound proof chamber that encloses the instrument to be tested
03		Test Chamber Cable Connects the Test Chamber to the Hearing analyzer with coupler
04		Ear-Level Adapter (BTE) Snaps into the 1/4" (6.35 mm) diameter cavity of the Hearing Analyzer
05		Sound Level Calibrator
06		Microphone Adapter
07	4.5.2	Digital Weighing Scale
08	4.5.1	Vernier Caliper
09	4.5.1	Micrometer
10	7.1.2(h)	Battery Substitution Pill
11	7.1 & 7.2 and 17(ia) of Table 1	Heating Chamber or Incubator
12	7.1 & 7.2 and 17(ib) of Table 1	Humidity Chamber
13	17(ii) of Table 1	Drop test Apparatus

The above list is indicative only and may not be treated as exhaustive.

ANNEX C

Scheme of Inspection And Testing

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipment.

2. TEST RECORDS – The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. LABELLING AND MARKING – As per the requirements of IS 10775:1984

4. CONTROL UNIT – Body Level Hearing Aids of the same class and design manufactured in a day shall constitute a control unit.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

5.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

6. REJECTIONS – Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE 1

(1)				(2)	(3)		
Test Details				Test equipment requirement R: required (or) S: Sub-contracting permitted	Levels of Control		
Cl.	Requirement	Test Method Clause	Ref		No. of Sample	Frequency	Remarks
4.1	Design and Workmanship	4.1	IS 10775	R	Each Hearing Aid		--
4.2	Power Supply	4.2	IS 10775	R			--
4.3	Housing	4.3	IS 10775	R			--
4.4	Earphone receiver, cord and ear plug	4.4	IS 10775	R			--
4.5.1	Dimensions	4.5.1	IS 10775	R			--
4.5.2	Mass	4.5.2	IS 10775	R			--
4.6	External Case	4.6	IS 10775	R			--
4.7	Controls	4.7	IS 10775	R			--
7.1.2.a, 7.1.3. a	Maximum Saturation Sound Pressure level (OSPL 90)	7.1.2.a, 7.1.3. a	IS 10775	R			--
7.1.2.b, 7.1.3.b	HF Average OSPL 90	7.1.2.b, 7.1.3.b	IS 10775	R			--
7.1.2.e, 7.1.3.c	HF – average full-on gain (at 50/60 dB input)	7.1.2.e, 7.1.3.c	IS 10775	R			--
7.1.2.c, 7.1.3. d	Frequency range	7.1.2.c, 7.1.3. d	IS 10775	R			--
7.1.2.f, 7.1.3. e	Total Harmonic Distortion	7.1.2.f, 7.1.3. e	IS 10775	R			--
7.1.2.d	Full on acoustic gain	7.1.2.d	IS 10775	R	One	Each control unit	
Sl 15, (Table 1)	Induction Coil Sensitivity (if provided)	Sl 15, (Table 1)	IS 10775	R	One	Once a week for each class and design	--

7.1.2. g	Internal noise from the hearing aid in terms of equivalent input noise level	7.1.2. g	IS 10775	R	one	Once a week for each class and design	--
7.1.2. h	Battery Current	7.1.2. h	IS 10775	R	one	Once a week for each class and design	--
SI 5, (Table 1)	a) Basic frequency response b) Comprehensive frequency response	SI 5, (Table 1)	IS 10775	R	one	Once a week for each class and design	
SI 7, (Table 1)	Effect of Gain control positions on Frequency Range	SI 7, (Table 1)	IS 10775	R	one	Once a week for each class and design	
SI 8, (Table 1)	Effect of Tone control positions on Frequency Range (if applicable)	SI 8, (Table 1)	IS 10775	R	one	Once a week for each class and design	--
SI 9, (Table 1)	Effect on the full-on acoustic gain of variation of battery voltage	SI 9, (Table 1)	IS 10775	R	one	Once a week for each class and design	--
SI 11, (Table 1)	Intermodulation distortion/ Difference frequency distortion	SI 11, (Table 1)	IS 10775	R	one	Once a week for each class and design	--
SI 12, (Table 1)	Effect of variation of battery voltage on distortion	SI 12, (Table 1)	IS 10775	R	one	Once a week for each class and design	--
SI 16, (Table 1)	AGC Characteristics (if applicable)	SI 16, (Table 1)	IS 10775	R	one	Once a week for each class and design	--
SI 17, (Table 1)	Environmental tests: Climatic tests	IS 9000 (Pt 3/ Sec 2) & IS 9000 (Pt 5)		R	one	Once in three months for each class and design	--
SI 17, (Table 1)	Environmental tests: Drop test	IS 9000 (Pt 7)		R	one		--

Note: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.