

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
Bureau of Indian Standards

AGENDA

13th Meeting of Ear, Nose and Throat Surgery Instruments Sectional Committee, MHD 04

Date: 02-08-2023	Time: 10:30 AM
Venue: Online (BIS WebEx Platform)	
Meeting No: 2515 365 3636	Password: Mhd4@13
Link:	
https://bismanak.webex.com/bismanak/j.php?MTID=m9669de65485fcec5792ba3f79de95193	
Chairperson:	Member Secretary:
Dr Rakesh Kumar,	Ms Gurpreet Kaur
Professor, AIIMS New Delhi	Scientist-B, MHD

ITEM 0 WELCOME ADDRESS AND OPENING REMARKS

ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING

The minutes of the last meeting were circulated to all the members after approval of the Chairperson vide email dated 25.10.2021. No comments have been received.

The Committee may formally confirm the minutes.

ITEM 2 PROCESS REFORMS IN STANDARDIZATION

2.1 BIS has instituted several process reforms in respect of formulation of Indian Standards. The process reforms introduced in the Standardization activities have been outlined in Annex-A.

2.2 Annual Meeting Calendar

As per guidelines, every Sectional Committee is required to meet once per quarter. In this regard, each committee needs to approve the annual meeting calendar in the beginning of the year. The annual calendar for MHD-04 is mentioned below.

Quarter	Q1	Q2	Q3	Q4
Date	19th Jul, 2023 (Wednesday)	13th Sept, 2023 (Wednesday)	6th Dec, 2023 (Wednesday)	6th Mar, 2024 (Wednesday)

The Committee may kindly note.

ITEM 3 SCOPE AND COMPOSITION OF COMMITTEE

3.1 Scope

To formulate Indian Standards for instruments used in ear, nose and throat surgery including ENT microsurgery instruments, ENT implants, vibrators, audiometers, hearing-aids tuning forks, hooks and elevators, diagnostic instrument, etc.

3.2 The present composition of MHD04 is given in [Annex-B](#) (Page 7-9). The Committee may review the composition according to following BIS guidelines:

- a) Consumer interests shall, as far as possible, predominate. In case, non-industry interests are less than two third, it may be reviewed to ensure that 2/3rd of the total representation on the committee is from non-industry.
- b) Only relevant organizations/government departments/consumer organizations and regulatory bodies that are related to the subject may be offered representation.
- c) Non-active members to be withdrawn
- d) Young professionals who can contribute in the working of the committee may be co-opted. The committee may deliberate on the same and advice.

The Committee may please note.

3.3 Members are also requested to **provide their latest details** like e-mail, phone no, enabling secretariat to make correspondence and send documents/Agenda/Minutes etc. through e-mail.

ITEM 4 DRAFT STANDARDS FOR FINALIZATION

The wide circulation stages for the following draft Indian Standards are complete. For documents from Sr No.1 to Sr. No. 23, no comments have been received and the documents can be finalized. For the documents from Sr No.24 to Sr No.25, comments have been received and are placed at [Annex-C](#) (Pages 10-11).

Sr No	Doc No.	Title	Remarks
1	18983	Forceps – Tonsil Artery, Curved (Scotts Pattern) – Specification (First Revision)	WC Completion: 12-08-2022
2	19166	Killian's Pattern Nasal Speculum – Specification (First Revision)	WC Completion: 16-10-2022
3	19194	Rhinoscopic Mirror (St Clair Thomsons Pattern) - Specification (First Revision)	WC Completion: 23-11-2022
4	19195	Laryngeal Forceps Part 1 Fine Grasping Crocodile Jaws Straight Specification (First Revision)	WC Completion: 20-10-2022
5	19196	Laryngeal Forceps Part 2 Oval Cup Specification (First Revision)	WC Completion: 20-10-2022
6	19199	Davis-Boyle Gag Frame and Tongue Plates Specification First Revision	WC Completion: 21-10-2022
7	19290	Myringotomy Knife Specification (First Revision)	WC Completion: 12-10-2022

8	19297	Meatal Skin Incision Knife Specification (First Revision)	WC Completion: 11-10-2022
9	21527	Eustachian Catheter Specification First Revision	WC Completion 28-07-2023
10	21739	Mollison's Pattern Self-Retaining Mastoid Retractor — Specification (First Revision)	WC Completion: 07-05-2023
11	21746	Cawthorne's Pattern Cerumen Hook – Specification (First Revision)	WC Completion: 14-05-2023
12	21747	Farabeuf's Pattern Elevator – Specification (First Revision)	WC Completion: 20-05-2023
13	21750	Dundas Grant's Pattern Seeker – Specification (First Revision)	WC Completion: 21-05-2023
14	21755	Heath's Pattern Granulation Forceps – Specification (First Revision)	WC Completion: 21-05-2023
15	21821	Zoellner's Pattern Downward Cutting Knife — Specification (First Revision)	WC Completion: 28-05-2023
16	21823	Zoellner's Pattern Upward Cutting Knife — Specification (First Revision)	WC Completion: 01-06-2023
17	21824	Shea's Pattern 25°, 45°, and 90° Angle Fenestra Hook for Ear Surgery – Specification (First Revision)	WC Completion: 01-06-2023
18	21825	Shea's Pattern Left and Right Elevators for Ear Surgery – Specification (First Revision)	WC Completion: 02-06-2023
19	21827	Crocodile Jaw Stapedectomy Scissors – Specification (First Revision)	WC Completion: 04-06-2023
20	21829	Round Cup, Elongated Cup and Oval Cup Jaws Stapedectomy Forceps – Specification (First Revision)	WC Completion: 04-06-2023
21	21831	Serrated, Smooth and Mc Gee Wire Closing Jaws Stapedectomy Forceps – Specification (First Revision)	WC Completion: 04-06-2023
22	21847	Aural and Nasal Dressing Forceps – Specification (Second Revision)	WC Completion: 01-07-2023
23	21848	Aural Specula – Specification (First Revision)	WC Completion 28-07-2023
24	21654	Mallets for Ent Surgery (First Revision)	WC Completion: 01-05-2023
25	21655	Jenkins Pattern Mastoid Gouge Specification (First Revision)	WC Completion: 01-05-2023
26	21659	PTFE Piston Cutting Jig Specification (First Revision)	WC Completion: 01-05-2023
27	21736	Lempert's Pattern Endaural Retractor — Specification (First Revision)	WC Completion: 06-05-2023
28	21743	Gardiner Brown's Pattern Tuning Forks — Specification (First Revision)	WC Completion: 08-05-2023

The committee may please note.

ITEM 5 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

The P-draft documents currently under MHD-04 are as listed.

Sr No.	Doc No.	Title	Remarks
1	19126	Aspirating Bronchoscope, Negus Pattern – Specification (First Revision)	IS 15732 (Part 2):2019/ ISO 8600-2:2015 published under MHD-01
2	19128	Oesophagoscope, Negus Pattern – Specification (First Revision)	
3	21279	Fibrin Glue – Specification	Comments received from Ms Priyadarshini A, AMTZ 1) The Extraction of Fibrin Glue: The Donor of the fibrin glue must be selected according to standards of Blood Center Donor who is free of infectious diseases, Hb should be assessed etc. 2) The Fibrin Glue need not be made from Human Blood only. Synthetic plasma must be given an option for inclusion with appropriate assessment. 3) Package should have the details of the product should declare the components of potential hypersensitivity. 4) Quantity: The product should be available in a package of 1ml, 2ml or 4ml. 5) BIS marking is on the casing label? Or on the product?
4	21280	Grommet – Specification	Comments received from Ms Priyadarshini A, AMTZ 1) The Grommet should be Green or Blue (not white, brown, red, pink, or yellow- to avoid confusion with body fluids or ear drum.) 2) Can Grommet be considered as "implant"; since it stays in the body for more than 6 months in CSOM cases. If so the standards of Implants must be taken into consideration.
5	21830	PTFE Teflon Piston Depth Gauge – Specification First Revision	

The committee may kindly deliberate.

ITEM 6 DRAFTS UNDER PREPARATION

6.1 Under the BIS-Internship Program, 15 Interns have been engaged under MHD. The scope of their project work involves *preparation of pre-standardisation document for New Work Item proposals for standard formulation*. The following new subjects under MHD-04 have been assigned to the Interns and are under process:

- a. ENT Workstation
- b. Oscillating Saw System
- c. Otology Drill System
- d. Xenon Head Light with Micro Camera
- e. Olfactometer (BS EN 13725:2022)

6.2 The following drafts are under preparation:

- a. External Nasal Splint – Specification
- b. Ossicular reconstruction prosthesis – General Requirements
- c. Video nystagmography (VNG) — Specification

The Committee may kindly deliberate and provide further inputs.

ITEM 7 COMMENTS ON PUBLISHED STANDARDS

No comments on published standards have been received.

ITEM 8 NEW SUBJECTS

BIS carried out an Exposure Visit to HRS Navigation, Bangalore. They manufactured surgical navigation systems which included **ENT Navigation System**, a prospective subject that could be taken up for formulation.

The committee may please note

ITEM 9 TECHNICAL ISSUES

The following standards to be considered for withdrawal:

Sr No.	IS No.	Title
1	IS 6463: 1972	Burs, Antrum (Tilley's Pattern)
2	IS 7711: 1975	Curette, Adenoid, Beckmann's Pattern
3	IS 8199: 1976	Tracheostomy Tubes, Fuller's Pattern

The Committee may kindly deliberate.

ITEM 10 INTERNATIONAL ACTIVITIES

BIS being the National Standards Body, represents India in various Technical Committees of ISO and IEC. In order to achieve global harmonization and to align with the International Standards of ISO/IEC available on the specific subject, various sectional committees of BIS are in liaison with technical committees of ISO/IEC. BIS holds O-membership i.e., observer status in ISO/TC 150/SC 6 (Implants for Surgery: Active implants). MHD-04 experts can be

nominated under the Working Group WG3 under this Subcommittee which deals with the subject of ‘Cochlear Implants’.

The Committee may please note.

ITEM 11 PROGRAMME OF WORK

The present programme of work of the Sectional Committee is given at:
https://www.services.bis.gov.in/php/BIS_2.0/bisconnect/pow_details

The Committee may please note.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

The issues arising out of previous meetings have been discussed in corresponding agenda items.

ITEM 13 ANY OTHER BUSINESS

ANNEX-B**Composition of Sectional Committee**

Sr. No.	Organization	Member Name	Role
1	All India Institute of Medical Sciences, New Delhi	Dr. Rakesh Kumar	Chairperson
2	Ali Yavar Jung National Institute of Speech and Hearing Disabilities (Divyangjan), Noida	Ms Alka Sapru Joshi	Alternate Member
3	Ali Yavar Jung National Institute of Speech and Hearing Disabilities (Divyangjan), Noida	Dr Rajeev Ramkrishna Jalvi	Principal Member
4	All India Institute for Speech and Hearing, Mysuru	Dr. T K Prakash	Alternate Member
5	All India Institute for Speech and Hearing, Mysuru	Dr. S R Savithri	Principal Member
6	All India Institute of Medical Science, Jodhpur	Dr. Bikram Choudhury	Alternate Member
7	All India Institute of Medical Science, Jodhpur	Dr. Amit Goyal	Principal Member
8	All India Institute of Medical Sciences, New Delhi	Dr. Prem Sagar	Principal Member
9	All India Institute of Medical Sciences, New Delhi	Dr Arvind Kumar	Young Professional
10	All India Institute of Medical Sciences, Bhopal	Dr Vikas Gupta	Principal Member
11	All India Institute of Medical Sciences, Bhopal	Dr Ganakalyan Behera	Alternate Member
12	B. Braun Medical India Private Limited, New Delhi	Dr. Anmol Kumar Ray	Principal Member
13	B. Braun Medical India Private Limited, New Delhi	Ms Gayatri Garg	Alternate Member
14	B. Braun Medical India Private Limited, New Delhi	Shri Arihant Jain	Young Professional
15	Bombay Hospital and Medical Research Centre, Mumbai	Dr Rajesh Choumal	Alternate Member
16	Bombay Hospital and Medical Research Centre, Mumbai	Dr D. P. Vyas	Principal Member
17	CSIR - Central Scientific Instruments Organisation, Chandigarh	Shri Dhirendra Bansal	Principal Member
18	CSIR - Central Scientific Instruments Organisation, Chandigarh	Shri Sanjeev Kumar	Alternate Member
19	CSIR - Central Scientific Instruments Organisation, Chandigarh	Dr H. K. Sardana	Principal Member
20	Central Drugs Standard Control Organization, New Delhi	Dr. Ravi Kant Sharma	Alternate Member
21	Central Drugs Standard Control Organization, New Delhi	Shri Arvind Hiwale	Alternate Member
22	Christian Medical College, Vellore	Dr Naina Picardo	Alternate Member

23	Christian Medical College, Vellore	Dr Suma Susan Mathews	Principal Member
24	Directorate General Armed Forces Medical Service, New Delhi	COL AJAY MALIK	Alternate Member
25	Directorate General Armed Forces Medical Service, New Delhi	COL A K MISHRA	Principal Member
26	Dr Ram Manohar Lohia Hospital, New Delhi	Dr Kanwar Sen	Alternate Member
27	Eagle Medical Systems Private Limited, New Delhi	Shri Ramesh Bhasin	Principal Member
28	Government Medical College and Hospital	Dr Herman Guild M John	Alternate Member
29	Government Medical College and Hospital	Dr Shibu George	Principal Member
30	Government Medical College & Hospital, Chandigarh	Dr Surinder K Singhal	Principal Member
31	Government Tamil Nadu, R M Hospital, Thanjavur	Dr K Balasubramanian	Principal Member
32	India Audio Centre, Chandigarh	Shri Kashmir S. Rana	Alternate Member
33	India Medtronic Private Limited, Gurugram	Ms Latika Vats	Principal Member
34	India Medtronic Private Limited, Gurugram	Shri Sanjeev Minhas	Alternate Member
35	Indian Audio Centre, Chandigarh	Shri Sandeep Kamboj	Principal Member
36	Indian Institute of Technology Kanpur, Kanpur	Dr A. R. Harish	Principal Member
37	Jawaharlal Nehru Medical College, Aligarh	Dr Aftab Ahmed	Alternate Member
38	Jawaharlal Nehru Medical College, Aligarh	Dr Mohammad Aftab	Principal Member
39	Kalam Institute of Health Technology, Vishakhapatnam	Shri Dilip Kumar Chekuri	Alternate Member
40	Kalam Institute of Health Technology, Vishakhapatnam	Dr Jitendar Sharma	Principal Member
41	Kalam Institute of Health Technology, Vishakhapatnam	Manoj G	Young Professional
42	King George's Medical University, Lucknow	Dr H. P. Singh	Alternate Member
43	King George's Medical University, Lucknow	Dr Anupam Mishra	Principal Member
44	Mahatma Gandhi Memorial Medical College, Indore	Dr Prof Y K Maru	Principal Member
45	Maulana Azad Medical College, New Delhi	Praveen K Rathore	Principal Member
46	Maulana Azad Medical College, New Delhi	Dr Ravi Meher	Alternate Member
47	Ministry of Railways, New Delhi	Dr Divya Aggarwal	Principal Member

48	Ministry of Railways, New Delhi	Dr Deepak Dalmia	Alternate Member
49	Office of Development Commissioner (MSME), New Delhi	Shri Susanta Kumar Som	Alternate Member
50	Office of Development Commissioner (MSME), New Delhi	Ms. Maitreyee Talapatra	Principal Member
51	Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak	Dr. Aditya Bhargava	Principal Member
52	Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak	Dr. Vijay Kumar Kalra	Alternate Member
53	Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak	Dr. Nikhil Arora	Young Professional
54	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr Jaimanti Bakshi	Alternate Member
55	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr Anurag Ramavat	Alternate Member
56	Sawai Man Singh(SMS) Medical College and Attached Hospitals, Jaipur	Dr. Pawan Singhal	Alternate Member
57	Sawai Man Singh(SMS) Medical College and Attached Hospitals, Jaipur	Dr. Sunita Agarwal	Principal Member
58	Speedway Surgical Company, Delhi	Shri Jatin Pahwa	Alternate Member
59	Vaansari Marketing Services, Chennai	Dr R Nareshkumar	Principal Member
60	Vaansari Marketing Services, Chennai	Shri Sundarapandian R	Alternate Member
61	In Personal Capacity	Dr Vikas Kakkar	Personal Capacity

ANNEX-C

Comments received on draft documents

Sr No.	Document	Organization	Comment Received
3	21655 Mastoid Gouge – Jenkin’s Pattern (First Revision of IS 5732)	Anup Chandra	In cl 6, for hardness test method IS 1501 different parts to be referred.
4	21659 PTFE Piston Cutting Jig (First Revision of IS 9718)	Anup Chandra	PTFE Piston Cutting Jig 1. For Testing: a. Cl 5.1 IS 16491 or IS 12937 b. Cl 5.2 Etching by Laser May Be added c. Cl 6 IS 1501 Different Parts for Vickers Hardness 2. In Fig.1, suitable tolerance for hole diameter can be provided by selecting from IS 919
5	21736 Endaural Retractor, Lempert’s Pattern (First Revision of IS 5747)	Anup Chandra	The updated standard may provide more references like: 1. For Figure 1 , standard for screws M2.5 and M6. 2. 2.5 mm holes, provide Indian standard. 3. Standard for rods may also be provided along with SS 316. 4. Clause 5.3- Pivot standard may be included. 5. Clause 6, Vickers’ Hardness to conform with IS 1501 (all parts). Include application in Foreword.
6	21743 Tuning Forks, Gardiner Brown’s Pattern (Second revision of IS 6464)	Anup Chandra	CL 4.2: Type and place at which grooves can be shown in fig 1. CL 4.3: Which part is riveted and silver soldered is not shown in fig. There are few Indian standards select the correct one: IS 103 and IS 964 may be added. In Fig, tolerance on dimension is not mentioned. IS 2102 may be added. CL 7.1 The test may be elaborated. CL 7.2 Suitable Indian standards may be added like IS10995. ISO 37301 for compliance management may be added suitably.
\\7	21654 Mallets for ENT Surgery	Anup Chandra	Material for finishing: Add IS 2338 (Part 1) and (Part 2), IS 11106 In fig 1, add dimensional tolerance and

	(First Revision of IS 5723: 1970)		add Indian standard for M6 thread. Cl 6: Add IS 1501 different part for Vickers hardness Cl 8.1 (c) Stainless steel grade
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