

**BUREAU OF INDIAN STANDARDS**  
**MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT**

**(MHD)**

**MINUTES**

<b>Sectional Committee</b>		<b>Meeting No:</b>	<b>Date, Day &amp; Time</b>
Ear, Nose, Throat and Head & Neck Surgery (ENT - H&N) Instruments Sectional Committee, (MHD 04)		Seventeenth	25 Sep 2024 Wednesday, 3:00 PM
<b>Chairperson</b>	Dr. Rakesh Kumar, Professor, Dept. of Otorhinolaryngology and HNS, AIIMS New Delhi  <b>Chaired by</b> Dr. Surinder K Singhal Dr. Kapil Sikka		
<b>Member Secretary</b>	Karthik Reddy Katipally, Scientist B/Assistant Director, Bureau of Indian Standards.		

The list of participants is given in *Annexure-A*.

**ITEM 0 GENERAL**

**0.1** Welcome address by Member Secretary.

The Member Secretary informed the committee members that Dr. Rakesh Kumar, Chairperson of MHD04, is currently occupied with other work. In his absence, Dr. Surinder K. Singhal chaired the meeting.

The Member Secretary extended a warm welcome to Dr. Surinder K. Singhal, and all the members attending the Seventeenth Meeting of the Ear, Nose, Throat, and Head & Neck Surgery (ENT - H&N) Instruments Sectional Committee.

**0.2** Opening remarks by Chairperson

Dr. Surinder K. Singhal warmly welcomed all Committee Members and expressed his delight at their active participation. He emphasized the importance of standardization in advancing the nation and encouraged all members to engage actively in the deliberations to ensure the meeting's success.

**ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING**

The Committee formally confirmed the minutes of the last meeting of of Ear, Nose, Throat and Head & Neck Surgery (ENT - H&N) Instruments Sectional Committee, MHD 04 held on 26th June 2024.

## ITEM 2 SCOPES AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The Committee noted the contents of Item 2.1 of the agenda.

2.2 The Committee noted the contents of Item 2.2 of the agenda.

2.3 The committee deliberated on the current composition of the working panels under MHD04 and approved the composition as follows:

**a) Otology (Ear) Panel** – Experts informed the committee that Dr. N. K. Mohindroo is superannuated and recommended BIS secretariat to contact Dr. Ramesh Azad, Professor & Head MS-ENT for nomination of experts in the panel.

Sr. No	Name	Organization	Role
1.	Dr Jaimanti Bakshi	PGIMER, Chandigarh	Convener
2.	Dr N.K.Mohindroo	IGMC, Shimla	Expert
3.	Dr Vikas Kakkar	Ex-PGIMS, Rohtak	Expert
4.	Mr. Karan Narang	ALPS International, New Delhi	Expert
5.	Mr. Alok Narang	ALPS International, New Delhi	Expert

**b) Rhinology (Nose) Panel** - Experts informed the committee that Dr. Kanwar Sen is superannuated and recommended BIS secretariat to contact Dr Ram Manohar Lohia Hospital for nomination of experts in the panel.

Sr. No	Name	Organization	Role
1.	Dr Rakesh Kumar	AIIMS, New Delhi	Convener
2.	Dr Prem Sagar	AIIMS, New Delhi	Expert
3.	Dr Arvind Kumar	AIIMS, New Delhi	Expert

### C) Head and Neck Surgery (HNS) Panel

Sr. No	Name	Organization	Role
1.	Dr Surinder Singhal	Government Medical College & Hospital, Chandigarh	Convener
2.	Dr Jaimanti Bakshi	PGIMER, Chandigarh	Expert
3.	Dr Kapil Sikka	AIIMS, New Delhi	Expert
4.	Dr. Vipin Arora	GTB Hospital, New Delhi	Expert

5.	Dr Ravi Meher,	Maulana Azad Medical College, New Delhi	Expert
6.	Dr.Richa Vaish	Tata Memorial Hospital, Mumbai	Expert

**D) Laryngology (Throat) Panel** - The committee recommended that the BIS Secretariat reach out to Dr. Arvind Kairo, Dr. Smriti Panda, and Mr. Vijay Aggarwal regarding their panel membership, and ensure the inclusion of relevant experts in future meetings.

Sr.No	Name	Organization	Role
1.	Dr Vikas Gupta	All India Institute of Medical Sciences, Bhopal	Convener
2.	Dr Nitin Gupta	Government Medical College & Hospital, Chandigarh	Expert

2.4 The Committee noted the contents of Item 2.4 of the agenda.

2.5 The Committee approved the Co-option request received from Directorate General of Health Services, Ministry of Health & Family Welfare.

2.6 The Committee noted the contents of Item 2.6 of the agenda.

### ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

3.1 The Committee finalized the following documents and recommended to resolve the comments on ENT Workstation and Otology Drill in consultation with relevant stakeholders by 15<sup>th</sup> October 2024. Followed by Wide- circulation of one month. If no comments are received documents will proceed for finalization in consultation with chairperson.

Sl. No	Document No.	Title	Last date for comments	Comments received (Yes/No)
1	MHD/04/26103. Revision of (IS 7712: 1975)	Specification for Curette Adenoid St Clair Thomsons Pattern	05 Aug, 2024	No
2	MHD/04/26089. Revision of (IS 7710: 1975)	Specification for Snare Tonsil Eves Pattern	04 Aug, 2024	No
3	MHD/04/25984. Revision of (IS 10308: 1982)	Specification for Tracheostomy Tubes and Guides Cubleys Pattern	25 July, 2024	No
4	MHD/04/25979. Revision of (IS 13169: 1991)	ENT Surgery Instruments Head Mirror-Specification	25 July, 2024	No
5	MHD/04/25987. Revision of (IS	Ent Surgery Instruments - Tracheostomy Tubes Chevaliar	25 July, 2024	No

	13179: 1991)	Jack Sons Pattern-- Specification		
6	MHD/04/25980. Revision of (IS 10272: 1982)	Specification for Draffin Suspension Apparatus	25 July, 2024	No
7	MHD/04/25933. Revision of (IS 6465: 1972)	Specification for Trocar Antral With Cannula Tilley Lichtwitz Pattern	22 July, 2024	No
8	MHD/04/25927. Revision of (IS 8093: 1976)	Specification for Curette Ballances Pattern	22 July, 2024	No
9	MHD/04/25923. Revision of (IS 4994: 1968)	Specification for Forceps Redressing Walshams Right Left and Straightening	22 July, 2024	No
10	MHD/04/25934. Revision of (IS 6514: 1972)	Specification for Nasal Cartilage Knife Ballengers Pattern	22 July, 2024	No
11	MHD/04/25929. Revision of (IS 8315: 1977)	Specification for Forceps Redressing ASCHs Pattern	22 July, 2024	No
12	MHD/04/25925. Revision of (IS 5377: 1969)	Specification for Speculum Nasal Thudichums	22 July, 2024	No
13	MHD/04/25922. Revision of (IS 5412: 1969)	Specification for Saws Nasal Josephs Pattern	22 July, 2024	No
14	MHD/04/25938. Revision of (IS 7756: 1975)	Specification For Depressor Tongue Lacks Pattern	22 July, 2024	No
15	MHD/04/25494. Revision of (IS 7713: 1975)	Specification For retractor Light Model Weislanders Pattern	30 May, 2024	No

#### **ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION**

4.1 The Committee approved Wide circulation of the following documents for 60 days and recommended to review Ossicular Reconstruction Prosthesis and ENT Navigation System drafts by 15th October 2024. Followed by Wide- circulation of two months.

The committee also recommended to have a discussion on the inclusion of an electromagnetic-based navigation system or the creation of a separate standard for the electromagnetic-based navigation system. The following members are recommended to be part of this discussion:

- Dr. Rakesh Kumar
- Dr. Surinder Singhal
- Dr. Jaimanti Bakshi

- Dr. Vikas Gupta
- Representatives from Medtronic India Pvt. Ltd., HRS Navigation, and Karl Storz Endoscopy

<b>Sl. No.</b>	<b>Document No./ Standard No.</b>	<b>Title</b>	<b>Remarks</b>
3	IS 8316 : 1977	Retractor, Hajek's Pattern	<i>Revision</i>
4	IS 8327 : 1977	Forceps, Nodule, Vocal, Chevalier Jackson's Pattern	<i>Revision</i>
5	IS 8343 : 1977	Forceps, Biopsy, Peterson's Pattern	<i>Revision</i>
6	IS 8734 : 1978	Forceps, Cutting and Removing Large Specimens, Chevalier Jackson's Pattern	<i>Revision</i>
7	IS 8735 : 1978	Tube, Suction, Yankauer's Pattern	<i>Revision</i>
8	IS 8743 : 1994	ENT surgery instruments - Forceps, direct bronchoscopy, with alligator jaws and tenaculum points, Irwin Moore's pattern	<i>Revision</i>
9	IS 8825 : 1978	Specification for cannula, suction irrigation with locking device, microlaryngeal	<i>Revision</i>
10	IS 8837 : 1978	Specification for suction tubes with stylet microlaryngeal surgery	<i>Revision</i>
11	IS 8838 : 1978	Specification for forceps, cup, straight, microlaryngeal surgery	<i>Revision</i>
12	IS 8839 : 1978	Specification for forceps, cup upwards, microlaryngeal surgery	<i>Revision</i>
13	IS 8840 : 1978	Specification for scissors, microlaryngeal surgery	<i>Revision</i>

4.2 The Committee noted the contents of Item 4.2 of the agenda.

#### **ITEM 5 DRAFT UNDER PREPARATION**

5.1 The Committee recommended to circulate drafts of Light Source and Microdebrider within committee for 15 days and recommended to circulate Audiometry Room draft as P-draft for one month. Committee recommended to consult manufacturers for the drafts on Oscillating Saw and External Nasal Splint.

5.2 The Committee noted the contents of Item 5.2 of the agenda.

#### **ITEM 6 COMMENTS ON PUBLISHED STANDARDS**

The Committee recommended that Otology Panel will review the comments received on IS 17407:2020 by 24<sup>th</sup> October 2024. Based on the recommendation of Panel, decision on revision will be taken in consultation Chairperson by end of October 2024.

#### **ITEM 7 NEW SUBJECTS**

7.1 The Committee noted the contents of Item 7.1 of the agenda.

7.2 The committee noted the importance of formulation of standards on the following subjects. Recommendations of the committee are as follows:

Sr. No.	Name of Equipment	Remarks	
1	Micro debrider	Details in Item 5.1	
2	Nasal Endoscopes	These subjects are assigned to Laryngology Panel for standard formulation.	
3	Flexible Video-Rhino-Laryngoscope (FOL)	The panel will convene meetings and provide recommendations on the formulation of standards for these projects after reviewing the existing ISO and IEC standards. Relevant stakeholders will be invited to attend the meetings.  Karl Storz endoscopy and Serwell MediEquip volunteered to provide inputs on these subjects.	
4	Otoendoscopes		
5	Flexible Fibre optic bronchoscope		
6	Oesophagoscope		
7	Stroboscope		
8	Microlaryngoscope		
9	Plasma Ablation System (Coblation System)		
10	LED head light		Karl Storz endoscopy and Serwell MediEquip volunteered to provide preliminary draft on this subject.
11	Navigation system		Details in Item 4.1
12	Camera monitor system for endoscopic sinus surgery	These subjects are assigned to Rhinology Panel for standard formulation. The panel will convene meetings and provide recommendations on the formulation of standards for these projects after reviewing the existing ISO and IEC standards. Relevant stakeholders will be invited to attend the meetings.  Karl Storz endoscopy and Serwell MediEquip volunteered to provide inputs on these subjects.	
13	Pure Tone Audiometer with Speech audiometers	These subjects are assigned to Otology Panel for	

14	Tympanometer	standard formulation. The panel will convene meetings and provide recommendations on the formulation of standards for these projects after reviewing the existing ISO and IEC standards. Relevant stakeholders will be invited to attend the meetings.  Mr. Tarlochan Dev(Labat Asia) and ALPS international volunteered to provide inputs on these subjects.
15	Automated otoacoustic emission recorder	
16	Automated auditory brain stem recorder	
17	Evoked Potential system (for Brain Stem Evoked Response audiometry and Auditory steady state responses and vestibular evoked myogenic potentials)	
18	Videonystagmography system	These subjects are assigned to Laryngology Panel for standard formulation. The panel will convene meetings and provide recommendations on the formulation of standards for these projects after reviewing the existing ISO and IEC standards. Relevant stakeholders will be invited to attend the meetings.
19	Tracheostomy tubes (cuffed and plain)	
20	ENT treatment unit (ENT Workstation)	Details in Item 3.1

## **ITEM 8 TECHNICAL ISSUES**

The Committee noted the contents of Item 8 of the agenda.

## **ITEM 9 INTERNATIONAL ACTIVITIES**

The Committee noted the contents of Item 9 of the agenda.

## **ITEM 10 PROGRAMME OF WORK**

The Committee noted the contents of Item 10 of the agenda.

## **ITEM 11 REVIEW OF INDIAN STANDARDS**

11.1 The Committee took note of the contents of Item 11.1 on the agenda. It was informed that the deliberation and decision on IS 11319: 1985, *Oesophagoscope, Negus' Pattern*, would be made by the Laryngology panel in conjunction with decisions on other endoscopic instruments.

## **ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS**

The Committee noted the contents of Item 12 of the agenda.

### ITEM 13 DATE AND PLACE OF NEXT MEETING

Member Secretary appraised the committee members that the next meeting has been scheduled on 18<sup>th</sup> December 2024 as per the approved Annual Meeting calendar 2024-2025.

### ITEM 14 ANY OTHER BUSINESS

The Committee approved the formation of working panel on sustainability of stainless steel surgical instruments, with initial members as listed below. The Committee recommended to adhere to the following timeline:

1. Meetings of WP/JWGs – to be completed in October 2024
2. P draft – 1 Nov 2024 (15 days circulation)
3. WC draft – 1 Dec 2024 (45 days circulation)
4. F draft – 15 Feb 2025
5. Printing – 6 March 2025
6. Releasing the document – 15 March 2025

Sl. No	Committee/ Expert	Organization	Name
1	MHD 01	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Amit Sharma
2	MHD 02	Association of Indian Medical Device Industry, New Delhi	Mr. Anuj Dureja
3	MHD 03	Bureau of Indian Standards, New Delhi	Ms. Gurpreet Kaur Bhombra
4	MHD 04	All India Institute of Medical Sciences, Bhopal Karl Storz Endoscopy India Private Limited, New Delhi	Dr. Vikas Gupta Mr. Kapil Rana
5	MHD 05	Iscon Surgicals Limited, Jodhpur	Mr. Kuldeep Sharma
6	MHD 06	Meril Life Sciences Private Limited, Vapi	Ms. Gayathri Nair
7	MHD 07	Association of Indian Medical Device Industry, New Delhi	Mr. Naveen Khanna
8	MHD 08	J. Morita Corporation, Mumbai	Mr. Lokesh jadav

9	MHD 13	National Meditek, New Delhi	Mr. Sanchit Bhatia
10	Other Expert	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum	Dr. Gijo Raj

**Annexure-A**

<b>Sl. No.</b>	<b>Organization</b>	<b>Member Name</b>
1.	All India Institute of Medical Sciences, New Delhi	Dr. Rakesh Kumar
2.	ALPS International, New Delhi	Mr. Karan Narang
3.	ALPS International, New Delhi	Mr. Alok Narang
4.	All India Institute of Medical Sciencesm, Bhopal	Dr. Vikas Gupta
5.	All India Institute of Medical Sciencesm, Bhopal	Dr. Ganakalyan Behera
6.	Association of Indian Medical Device Industry, New Delhi	Mr. Tarlochan Dev
7.	Government Medical College & Hospital, Chandigarh	Dr. Surinder K Singhal
8.	Happy Reliable Surgeries Private Limited, Bangalore	Mr. Hemant Savale
9.	India Medtronic Private Limited, Gurugram	Mr. Saurabh Sable
10.	India Medtronic Private Limited, Gurugram	Mr. Sandeep Verma
11.	India Medtronic Private Limited, Gurugram	Ms. Chhaya Asthana (Invitee)
12.	Indian Institute of Technology Kanpur, Kanpur	Dr. A. R. Harish
13.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Amit Sharma
14.	Kalam Institute of Health Technology, Vishakhapatnam	Dr. Arjun Thimmaiah
15.	Kalam Institute of Health Technology, Vishakhapatnam	Ms. Shusmita Roy (Invitee)
16.	Karl Storz Endoscopy India Private Limited, New Delhi	Mr. Kapil Rana
17.	Karl Storz Endoscopy India Private Limited, New Delhi	Mr. Sandeep Sethi
18.	Karl Storz Endoscopy India Private Limited, New Delhi	Mr. Abhisekh Singh (Invitee)
19.	Serwell MediEquip, Chennai	Mr. T. Jebin Samuel
20.	Tata Memorial Center (Hospital), Mumbai	Dr. Richa Vaish
21.	Tata Memorial Center (Hospital), Mumbai	Mr. Vijay Yashwant Mestri
22.	In Personal Capacity	Dr. Jaimanti Bakshi
23.	In Personal Capacity	Dr. Kapil Sikka