

**BUREAU OF INDIAN STANDARDS**  
**MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT**  
**(MHD)**

## **AGENDA**

<b>Sectional Committee</b>	<b>Meeting No:</b>	<b>Date, Day &amp; Time</b>
Neurosurgery Instruments, Implants & Accessories Sectional Committee (MHD 07)	17 <sup>th</sup>	26 September 2024 11 : 00 AM Thursday
<i>via Webex platform</i>  <b>Meeting Link:</b> <a href="https://bismanak.webex.com/bismanak/j.php?MTID=md93ee6ee25542457eaf8c747a511a420">https://bismanak.webex.com/bismanak/j.php?MTID=md93ee6ee25542457eaf8c747a511a420</a>  <b>Meeting Number:</b> 2518 599 6943  <b>Password:</b> Mhd@07		
<b>Chairperson</b>  Dr. Daljit Singh Director, Professor & Head, Department of Neurosurgery B Pant Hospital, New Delhi	<b>Member Secretary</b>  Harshada Ganesh Kadam Scientist B/ Assistant Director, Bureau of Indian Standards	

### **ITEM 0      GENERAL**

#### **0.1      WELCOME ADDRESS BY MEMBER SECRETARY**

#### **0.2      OPENING REMARKS BY CHAIRPERSON**

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

1.1      The minutes of the Sixteenth meeting of Neurosurgery Instruments, Implants & Accessories Sectional Committee (MHD 07) held on 27 June 2024 approved by the Chairperson was circulated to all members through BIS portal as well as email vide letter no : : MHD 07/A2.16 dated 10 July 2024.

1.2      No comments have been received so far.

*The Committee may formally confirm the minutes.*

### **ITEM 2      SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE**

2.1 The present scope of Neurosurgery Instruments, Implants & Accessories Sectional Committee (MHD 07) is as follows:

- To formulate Indian Standards for Neurosurgery instruments, implants and accessories (cranial & spinal) and monitoring devices.

*The Committee may please note.*

2.2 The present composition of Neurosurgery Instruments, Implants & Accessories Sectional Committee (MHD 07) along with participation status of members is enclosed at [Annexure A](#).

2.3 The attendance of members in Sectional Committee meetings is essential for its efficient and effective functioning. Accordingly, any member remaining absent from two consecutive meetings and/or fifty percent or more meetings of the Sectional Committee in a year will become automatically disqualified to continue as the member of the Sectional Committee.

2.4 Requests have been received from the following for representation on the Committee:

Sl. No.	Organisation	Nomination
1.	Johnson and Johnson Pvt Ltd	Ms. Meenakshi Goal
		Ms. Aishwarya Chaudran
		Ms. Bhuwan Singla
2.	Karl Storz Endoscopy India Private Limited, New Delhi	Mr. Manish Thakore
		Mr. Kapil Rana
3.	Medtronic	Mr. Himanshu Makhija
		Mr. Sandeep Verma

*The Committee may please note.*

2.5 The above members have become inactive by virtue of non-participation in consecutive meetings and have been removed.

Sl. No.	Organisation
1.	HLL Life care Limited

*The Committee may please note.*

2.7 With a view to make the Committee more effective through active contribution of the members in standardization activities, non-participating members are liable to be dropped from the Committee in order to provide opportunity to other similar organizations/institutions that

may be interested to participate and contribute to the standardization efforts. Further, the Committee needs to be made fully representative of the various interests concerned considering that non-industry representation should not be less than two-third of the committee composition, as far as possible.

*The committee may please note and review the composition.*

2.8 The following Working Panels to be created:

- a) Neurosurgical instruments
- b) Neurosurgical implants
- c) Neurosurgical accessories
- d) Neurosurgical monitoring devices

*The committee may kindly approve.*

2.9 The following Working groups has been created:

- a) Neuro navigation system working group

<b>Sr. No</b>	<b>Name</b>	<b>Organization</b>	<b>Role</b>
<b>1.</b>	Mr. Naveen Khanna	AIMED	<b>Convener</b>
<b>2.</b>	Mr. Pranab kr Dutta	IIT kharagpur	<b>Expert</b>
<b>3.</b>	Dr. Harsh deora,	SBSSI	<b>Expert</b>
<b>4.</b>	Mr. K. Puhazhendi,	AIMED	<b>Expert</b>

*The Committee may kindly note.*

- b) Bipolar counter working group (Need to Formulate)

*The committee may kindly approve.*

### **ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION**

3.1 There are currently no indigenous standard for finalization drafts.

*The Committee may kindly note.*

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

4.1 The following 'P draft' are new indigenous standard under circulation.

<b>Sl. No.</b>	<b>Document No./ Standard No.</b>	<b>Title</b>	<b>Last date for Comments</b>	<b>Remarks</b>
1.	MHD/07/26392	Specification for Single Channel Physiological Recorder	20-Sep-2024	<i>New Indigenous Standard</i>
2.	MHD/07/26390	Specification for Intracranial Pressure Monitors	20-Sep-2024	<i>New Indigenous Standard</i>
3.	MHD/07/26391	Specification for Electroconvulsive Therapy Machine	20-Sep-2024	<i>New Indigenous Standard</i>
4.	MHD/07/26388	Specification For Algometer	20-Sep-2024	<i>New Indigenous Standard</i>

*The Committee may kindly approve.*

4.2 The comments on WC drafts shall be made only through the Standardization Portal. The BIS portal provides a very user friendly interface and helps faster compilation and analysis of comments. In case of any difficulties in accessing the portal, the members may contact the Member Secretary for necessary guidance.

*The Committee may kindly discuss.*

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

5.1 The following indigenous subject drafts are under preparation.

<b>Sl. No.</b>	<b>Project Title.</b>
1.	Computer Assisted Surgical Systems - Surgical Navigation System or Surgery
2.	Stereotactic System
3.	Endoscopic Brain System
4.	Spine Implant
5.	Intracranial Stents
6.	Leyla retractor and flow diverters
7.	Bipolar Cautery
8.	Vagal Nerve Stimulator
9.	IONM -Intra operative neuro monitoring system
10.	Coil for aneurysm

5.2 One new subjects were allocated to interns, working drafts have been received.

Sl. No.	Title
1.	Leyla retractor

*The Committee may kindly deliberate.*

### 5.3 Structure of Technical Committee – Working Group

#### a) Neuro navigation system working group

Sr. No	Name	Organization	Role
5.	Mr. Naveen Khanna	AIMED	Convener
6.	Mr. Pranab kr Dutta	IIT kharagpur	Expert
7.	Dr. Harsh deora,	SBSSI	Expert
8.	Mr. K. Puhazhendi,	AIMED	Expert

*The Committee may kindly note.*

#### b) Bipolar counter working group (Formulation)

### 5.3 Structure of Technical Committee – Panel in TC

- e) Neurosurgical instruments
- f) Neurosurgical implants
- g) Neurosurgical accessories
- h) Neurosurgical monitoring devices

*The Committee may kindly deliberate for the creation of Panels in TC.*

### 5.5 Commenting on P-Drafts by Members of Technical Committee

5.5.1 P-Draft is the stage where members of the concerned technical committee can support or reject the project or offer comments for improvement. Therefore, abstaining from commenting on the P-Draft by a member has serious implications on the quality of the draft. BIS had issued directions regarding commenting on P-Drafts wherein any member not commenting on two consecutive and/or one-fourth of the P-Drafts circulated by the Technical Committee in a year will automatically be disqualified to continue as a member.

5.5.2 The members may examine the P-Draft document(s) whenever under circulation and offer comments as per the following options:

- (a) Agree
- (b) Agree (with comments\*)

- (c) Don't agree (with comments\*)
- (d) No Comments, as it is not related to my area of expertise.

5.5.3 The comments on P- Drafts shall be made only through the Standardization Portal.

*The Committee may kindly note.*

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

6.1 No comments have been received on published Indian Standards.

*The committee may kindly note.*

## **ITEM 7 NEW SUBJECTS**

7.1 The committee may identify the emerging fields in the area under its scope and decide formulation of Indian Standards on the same. The Committee may also define thrust area which should take into consideration the standards development required in the given context keeping in view the social, environmental and economic consideration.

*The Committee may kindly note.*

7.2 The Department of Pharmaceuticals (DoP) is the nodal department for the strategic Implementation of National Medical Devices Policy (NMDP), 2023. One of the action points under the roadmap for implementation of strategies under the NMDP include adoption and Expansion of Indian Standards for Medical Devices. In this regard, DoP had constituted a Committee for prioritizing the setting of Indian Standards for Medical Devices and deliberated on the list of Medical Devices where Indian Standards need to be formulated.

With reference to Neurosurgery Instruments, Implants & Accessories there is a need to formulate Indian Standards on the following Medical devices:

<b>Sr. No</b>	<b>DOP Topics</b>
<b>1.</b>	Intra Operative Neuro Monitoring System
<b>2.</b>	Transcranial Magnetic Stimulation
<b>3.</b>	Epilepsy monitoring stimulator
<b>4.</b>	TMS System
<b>5.</b>	Electronic balances

*The Committee may kindly deliberate and decide*

## **ITEM 8 TECHNICAL ISSUES**

8.1 There are no specific technical issues to be discussed.

*The Committee may kindly note.*

## **ITEM 9. INTERNATIONAL ACTIVITIES**

### **9.1 Participating (P) Membership in ISO/IEC**

9.1.1 BIS participates in the International Standardization activities of the International Organization for Standardization (ISO) thereby contributing to International Standards development activities. It is a constant endeavor of the Sectional Committees to identify priority areas for participation in International technical committees that are of strategic importance to India and to identify relevant experts who would actively contribute to international standardization. The details of membership held in various Technical Committees/Subcommittees of ISO are given below:

<b>Sl. No.</b>	<b>Liaison Committee of ISO</b>	<b>Type of Membership</b>
1.	ISO TC 150/WG 15 - Neurosurgical implants	Participating Member
2.	ISO/TC 150/ SC 6/WG 5 - Implantable neuro stimulators	Participating Member

9.1.2 As a P-member, it is mandatory for India (BIS) to vote on all draft standards and other documents circulated by ISO seeking votes/comments. The members should carefully examine the documents taking into consideration nation's interests and send the comments to BIS keeping in mind that if these ISO Standards so finalized are adopted as Indian Standards in future, the Indian Medical Device Industry would not have any problem in its implementation. The experts who are not contributing to international standardization by submitting comments/feedback on work items and ballots will not be allowed to represent BIS (India) in ISO/ IEC Technical meetings.

*The Committee may kindly note.*

### **9.2 Participation of Working Group Experts in ISO Technical Committees**

9.2.1 Working Groups (WGs) are established by ISO/IEC Technical Committees for specific tasks. The Experts are nominated in these WGs by BIS ('P' Member National Standards Body – NSB) to deal with specific tasks allocated to the Working Group. Persistently Inactive Experts, meaning the absence of contributions through attendance to WG meetings or by correspondence, will be removed from the Working Groups by ISO Technical Committee. This removal of Inactive Experts would also reflect badly on the 'P' Member NSB. Therefore, participation of nominated Indian Experts at the Working Group level of ISO is of critical importance while being a part of BIS for Standards Development.

## **ITEM 10. PROGRAMME OF WORK**

10.1 The present Programme of Work of Neurosurgery Instruments, Implants & Accessories Sectional Committee (MHD 07) is available at BIS website [Program of work \(bis.gov.in\)](http://bis.gov.in)

*The Committee may kindly note.*

10.2 The progress of development of Indian Standards at various stages is given below:

Stage		No. of Documents
Under Print		07
Sl. No.	Document No	Title
1.	MHD/07/25865	Specification For Forceps Dressing Bayonet Shape Gushing's Pattern
2.	MHD/07/25836	Neurosurgical Instruments - Needle Holder - Shape and Dimensions
3.	MHD/07/25834	Neurosurgical Instruments- Forceps Artery Dandy's Pattern-Shape and Dimensions
4.	MHD/07/25867	Specification For brain cannula
5.	MHD/07/25835	Neurosurgical Instruments -Forceps Artery Straight and Curved on Flat Hugh Cairns Pattern - Shape and Dimensions
6.	MHD/07/25866	Specification For Guide Saw De Martels Pattern
7.	MHD/07/25864	Rongeur, Cranial, Dahlgren's Pattern Specification

Stage		No. of Documents
Under Development		04
Sl. No.	Document No	Title
1.	MHD/07/26390	Specification for Intracranial Pressure Monitors
2.	MHD/07/26391	Specification for Electroconvulsive Therapy Machine
3.	MHD/07/26388	Specification For Algometer
4.	MHD/07/26392	Specification for Single Channel Physiological Recorder

## ITEM 11. REVIEW OF INDIAN STANDARDS

### 11.1 Review of Pre-2000 Standards

11.1.1 All Indian Standards published before the year 2000 need to be reviewed for revision/withdrawal/archiving in the light of technological developments that have happened so far in relation to these standards. This exercise has to be completed in a time bound manner. In this regard, there are 7 documents under printing. There are no other Pre. 2000 standard remaining.

*The Committee may kindly note.*

### 11.2 Review of Standards as per 5-year cycle



11.2.1 As per the policy of BIS, the Indian Standards, which have completed five years since their last publication/reaffirmation, are to be reviewed by the concerned Sectional Committee for their reaffirmation/revision/withdrawal/amendment/archiving in the light of technological developments that have happened so far in relation to these standards.

11.2.2 With a view to improve the quality of standards formulation process and making it more evidence based, BIS envisions to undertake research and prepare a review document in respect of each of the Indian Standards, which are due for revision.

11.2.3 In the year 2024- 2025 there are no standards for review.

*The Committee may kindly note.*

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

12.1 There are no specific issues to be discussed.

*The Committee may kindly note.*

## **ITEM 13 DATE AND PLACE OF NEXT MEETING**

13.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 07 is scheduled on 19<sup>th</sup> December 2024.

<b>Quarter</b>	<b>Q1 Apr-June 2024</b>	<b>Q2 July-Sept 2024</b>	<b>Q3 Oct-Dec 2024</b>	<b>Q4 Jan-Mar 2025</b>
Date	27 June 2024 , Thursday	26 Sep 2024, Thursday	19 Dec 2024, Thursday	3March 2025, Monday

*The Committee may kindly note.*

## **ITEM 14 ANY OTHER BUSINESS**

<b>Sr. No</b>	<b>Organization name</b>	<b>Project</b>	<b>Purposed</b>	<b>Amount</b>
1.	NIT Jalandhar	RTMS	Dr. Jaydeep Kaur NIT Jalandar	10 Lac.

*The Committee may kindly note.*

*Annexure A*  
**Composition of Neurosurgery Instruments, Implants &  
Accessories Sectional Committee**

<b>Sr. No</b>	<b>Organization</b>	<b>Member Name</b>	<b>Role</b>	<b>Attendance</b>
<b>1.</b>	G B Pant Hospital, New Delhi	Dr. Daljit Singh	<b>Chairperson</b>	2/2
<b>2.</b>	Abbott Healthcare India Private Limited, Mumbai	Ms. Lipi Chakhaiyar	Principal Member	1/2
		Ms. Shweta Sharma	Alternate Member	
<b>3.</b>	Association of Indian Medical Device Industry, New Delhi	Mr. Puhazhendi Kaliyappan	Alternate Member	1/2
		Mr. Naveen Khanna	Principal Member	
		Mr. Ankur Bhargava	Alternate Member	
<b>4.</b>	Boston Scientific India Private Limited, Gurugram	Mr. Prashanth Prabhakar	Alternate Member	2/2
		Mr. Dev Chopra	Principal Member	
<b>5.</b>	Central Drugs Standard Control Organization, New Delhi	Mr. Aseem Sahu	Principal Member	1/2
		Ms. Shyamni Sasidharan	Alternate Member	
<b>6.</b>	Defence Bio-Engineering and Electromedical Laboratory, Ministry of Defence, Bengaluru	Dr. Jayant Daniel	Principal Member	1/2
			Alternate Member	
<b>7.</b>	Directorate General of Health Services, New Delhi	Dr. Ajay Choudhary	Principal Member	1/2
		Dr. K. B. Shanker	Alternate Member	
<b>8.</b>	Happy Reliable Surgeries Private Limited, Bangalore	Mr. Hemant Savale	Principal Member	1/2
		Mr. Sanjeev Gautam	Alternate Member	
<b>9.</b>	Indian Institute of Technology Hyderabad, Hyderabad	Dr. Avinash Eranki	Alternate Member	2/2
		Dr. Kousik Sarathy S	Alternate Member	
<b>10.</b>	Johnson and Johnson Pvt Ltd	Ms. Meenakshi Goal	Principal Member	(New)
		Ms. Aishwarya Chaudran	Alternate Member	
		Ms. Bhuwan Singla	Alternate Member	
<b>11.</b>	Karl Storz Endoscopy India Private Limited, New Delhi	Mr. Manish Thakore	Alternate Member	(New)
		Mr. Kapil Rana	Principal Member	

<b>12.</b>	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Santosh Kumar Balivada	Principal Member	2/2
		Ms. Divya Anil Patil	Alternate Member	
		Ms. Purva Suhas Phalke	Alternate Member	
<b>13.</b>	Medtronics India Private Limited , Gurugram	Mr. Himanshu Makhija	Principal Member	New
		Mr. Sandeep Verma	Alternate Member	
<b>14.</b>	Skull Base Surgery Society of India, Chennai	Mr. Harsh Deora	Principal Member	1/2
<b>15.</b>	In Personal Capacity	Mr. Asok Kumar Raghavan Nair	Personal Capacity	1/2