

**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>
Anesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 11 )	22 <sup>nd</sup>	28 <sup>th</sup> October 2024 Monday 02:30 PM
<i>via Webex platform</i>		
<b>Meeting Link:</b> <a href="https://bismanak.webex.com/bismanak/j.php?MTID=m5840ab3cd06b9aa6af9c6cd778c9467d">https://bismanak.webex.com/bismanak/j.php?MTID=m5840ab3cd06b9aa6af9c6cd778c9467d</a>		
<b>Meeting Number:</b> 2519 631 5352		
<b>Password:</b> Mhd@11		
<b>Chairperson</b>	Dr. G. D. Puri, Executive Director, AIIMS Jodhpur	
<b>Member Secretary</b>	Mr. Satyam Rathore, Scientist-B, MHD, BIS, New Delhi	

**ITEM 0      GENERAL**

**0.1      Welcome Address by Member Secretary**

**0.2      Opening Remarks by The Chairperson**

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

1.1      The minutes of the 21<sup>th</sup> meeting of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 11) held on 30<sup>th</sup> July 2024 approved by the Chairperson was circulated to all members through BIS portal as well as email vide letter no: MHD 11/A 2.21 dated 11<sup>th</sup> September 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 Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 11) is as follows:

- To formulate Indian Standards for instruments and equipment used for anaesthetizing and ventilating a patient, including diagnostic instruments such as sphygmomanometers, suction apparatus, and anaesthetic face mask.
- To coordinate with the work of ISO/ TC 121 “Anaesthetic and Respiratory Equipment” Committee, Subcommittee and Working Groups.

*The Committee may please note.*

2.2 The present composition of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 11) 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 The following co-option request has been received to become a committee member of MHD 11:

Sl. No.	Name	Organisation	Speciality	Nomination
1.	Dr. (Prof.) Nitin Hayaran	Lady Hardinge Medical College, New Delhi	Anaesthesia and Critical care	<i>Fresh nomination</i>

*The committee may approve the nomination.*

2.5 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.*

### ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

3.1 The following draft Indian Standards / Amendments have been sent for wide circulation:

Sl. No.	Document No.	Title	Last date for comments	Comments received (Yes/No)
1.	<b>MHD/11/25365</b> (Modified/Technically Equivalent To: ISO 80601-2-67:2020)	Medical electrical equipment Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment	<b>28 August 2024</b> <i>(last date over)</i>	<b>No</b>
2.	<b>MHD/11/25366</b> (Identical To: ISO 19223:2019)	Lung ventilators and related equipment Vocabulary and semantics	<b>24 August 2024</b> <i>(last date over)</i>	<b>No</b>
3.	<b>MHD/11/25371</b> (Identical To: ISO 26825:2020)	Anaesthetic and respiratory equipment User-applied labels for syringes containing drugs used during anaesthesia Colours design and performance	<b>09 August 2024</b> <i>(last date over)</i>	<b>No</b>
4.	<b>MHD/11/25372</b> (Identical To: ISO 80601-2-55:2018)	Medical electrical equipment Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	<b>14 August 2024</b> <i>(last date over)</i>	<b>No</b>
5.	<b>MHD/11/25373</b> (Identical To: ISO 9360-1:2000)	Anaesthetic and respiratory equipment Heat and moisture exchangers HMEs for humidifying respired gases in humans Part 1: HMEs for use with minimum tidal volumes of 250 ml	<b>10 August 2024</b> <i>(last date over)</i>	<b>No</b>
6.	<b>MHD/11/25374</b> (Modified/Technically Equivalent To: ISO 9360-2:2001)	Anaesthetic and respiratory equipment Heat and moisture exchangers HMEs for humidifying respired gases in humans Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml	<b>10 August 2024</b> <i>(last date over)</i>	<b>No</b>

7.	<b>MHD/11/25375</b> (Modified/Technically Equivalent To: ISO 18190:2016)	Anaesthetic and respiratory equipment General requirements for airways and related equipment	<b>22 August 2024</b> <i>(last date over)</i>	<b>No</b>
8.	<b>MHD/11/25381</b> (Identical To: ISO 23328-1:2003 )	Breathing system filters for anaesthetic and respiratory use Part 1: Salt test method to assess filtration performance	<b>09 August 2024</b> <i>(last date over)</i>	<b>No</b>
9.	<b>MHD/11/25383</b> (Identical To: ISO 23328-2:2002 )	Breathing system filters for anaesthetic and respiratory use Part 2: Non-filtration aspects	<b>09 August 2024</b> <i>(last date over)</i>	<b>No</b>
10.	<b>MHD/11/25389</b> (Identical To: ISO 18562-3:2024 )	Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 3: Tests for emissions of volatile organic substances	<b>25 August 2024</b> <i>(last date over)</i>	<b>No</b>
11.	<b>MHD/11/25390</b> (Modified/Technically Equivalent To: ISO 18562-4:2024 )	Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 4: Tests for leachables in condensate	<b>28 August 2024</b> <i>(last date over)</i>	<b>No</b>
12.	<b>MHD/11/26320</b> IS 3391: 1965	Specification for Stethoscopes (First Revision)	<b>06 October 2024</b> <i>(last date over)</i>	<b>No</b>
13.	<b>MHD/11/26368</b> IS 7885: 1985	Specification for Macintosh Patterns Spray (Second Revision)	<b>04 October 2024</b> <i>(last date over)</i>	<b>No</b>
14.	<b>MHD/11/26369</b> IS 8312: 1977	Specification for Forceps of Magill's Pattern to place Endotracheal Tube (First Revision)	<b>04 October 2024</b> <i>(last date over)</i>	<b>No</b>

No comments have been received and the above documents may be taken up for finalization.

*The Committee may kindly consider.*

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

4.1 There are currently no drafts for wide circulation

*The Committee may kindly note.*

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 note.*

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

5.1 The following indigenous subject drafts are under preparation.

<b>Sl. No.</b>	<b>Project Title</b>	<b>Mode of Execution</b>	<b>Status</b>
1.	Medical grade copper tubes	Panel 4 , WG 1	P-Draft : Doc No. MHD/11/26815 has been circulated for a period of 30 days
2.	Code of Practice: “MGPS Piping Installation Work on Project Site”	Panel 4 , WG 1	P-Draft is Under preparation
3.	Oxygen Purity meter	Panel 4 , WG 2	P-Draft is Under preparation
4.	Hospital Bed Head Panel and OT Pendants	Intern	P-Draft : Doc No. MHD/11/26817 has been circulated for a period of 30 days
5.	Respiratory NIV Mask with Tube Inclusion Port	Panel 3 , WG 1	P-Draft is Under preparation
6.	Voice Prosthesis	Intern	The working draft is attached in <b><i>Annexure B</i></b>

*The Committee may kindly deliberate and decide.*

#### **5.2 Commenting on P-Drafts by Members of Technical Committee**

5.2.1 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.

5.2.2 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.

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

*The Committee may kindly note.*

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

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 deliberate.*

7.2 The following new work item proposals have been received for standard formulation:

<b>Sl. No.</b>	<b>Project Title</b>	<b>Project Details</b>	<b>Proposed By</b>
1.	Pressure Regulator for sphygmomanometer testing kits to be used for calibration and testing of sphygmomanometers and automatic blood pressure measuring devices	<ul style="list-style-type: none"><li>• The details are attached in the <b><i>Annexure C</i></b></li></ul>	<ul style="list-style-type: none"><li>• Mr. Jasveer Singh, CSIR-NPL, New Delhi</li></ul>
2.	TAI Apparatus (Toical Analgesic Inducer)	<ul style="list-style-type: none"><li>• The details are attached in the <b><i>Annexure D</i></b></li></ul>	<ul style="list-style-type: none"><li>• ZTOP IOT Solutions Private Limited and ICMR</li></ul>

*The Committee may kindly deliberate and decide.*

## **ITEM 8 TECHNICAL ISSUES**

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 121 Anaesthetic and respiratory equipment	Participating Member
2.	ISO/TC 121/SC 1 Breathing attachments and anaesthetic machines	Participating Member
3.	ISO/TC 121/SC 2 Airway devices and related equipment	Participating Member
4.	ISO/TC 121/SC 3 Respiratory devices and related equipment used for patient care	Participating Member
5.	ISO/TC 121/SC 4 Vocabulary and semantics	Participating Member
6.	ISO/TC 121/SC 6 Medical gas supply systems	Participating Member
7.	ISO/TC 121/SC 8 Suction devices	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 The following Projects are currently under process in ISO/TC 121:**

<b>S. No.</b>	<b>Reference</b>	<b>Title</b>	<b>Designated Experts</b>
1	ISO 5359:2014	Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases	-
2	ISO 18082:2014 (vers 2)	Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases	-
3	ISO 7376:2020/DAMd 1 (Ed 3)	Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation — Amendment 1: Clarification about optical output and illumination requirements	Prof. Sandhya Yaddanapudi
4	ISO/DIS 7376-2	Anaesthetic and respiratory equipment — Part 2: Video laryngoscopes	Prof. Sandhya Yaddanapudi
5	ISO/CD 5364	Anaesthetic and respiratory equipment — Oropharyngeal airways	-
6	ISO 8836:2019 (Ed 5)	Suction catheters for use in the respiratory tract	-
7	ISO/CD 80601-2-94	Medical electrical equipment — Part 2-94: Particular requirements for basic safety and essential performance of inhalational therapy nebulizer equipment	-
8	ISO/DIS 80601-2-67 (Ed 3)	Medical electrical equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment	-
9	ISO/DIS 80601-2-69 (Ed 3)	Medical electrical equipment — Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment	-
10	ISO/NP 81060-7	Non-invasive sphygmomanometers — Part 7: Part 7: Clinical performance verification of intermittent or repeated intermittent cuffless measurement type	-
11	ISO DIS 19223-3	Lung ventilators and related equipment--Vocabulary and semantics--Part 3: Respiratory care	Dr. Rakesh Garg
12	ISO/DIS 19223-2	Lung ventilators and related equipment — Vocabulary and semantics — Part 2: High frequency and jet ventilation	Dr. Rakesh Garg

*The committee members are requested to send their nomination to be a designated expert in these ISO projects as per their area of expertise.*

## ITEM 10. PROGRAMME OF WORK

10.1 The present Programme of Work of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 11) is available at BIS website [www.bis.gov.in](http://www.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	11
Under Development	17

## 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. The details in this regard are given below:

Total as per PoW	Under Development	Under Print	Remaining	Under Progress (out of the remaining)	Pending
17	6	4	7	7	0

11.1.2 The list of the above Indian Standards at various stages is given at [Annexure D](#).

*The Committee may kindly review.*

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

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.

*The Committee may kindly note.*

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

12.1 There are currently no issues related to previous meeting.

*The Committee may kindly note.*

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

13.1 As per the approved Annual Meeting Calendar for 2023-24, the next meeting of MHD 11 is scheduled on **28<sup>nd</sup> January, 2025**.

*The Committee may kindly note.*

**ITEM 14 ANY OTHER BUSINESS**

Annexure A

**MHD 11-Anesthetic, Resuscitation and Allied Equipment**

**Last 3 meetings Attendance Report**

<b>S. No.</b>	<b>Organization</b>	<b>Member Name</b>	<b>21<sup>th</sup></b>	<b>20<sup>th</sup></b>	<b>19<sup>th</sup></b>
1.	In Individual Capacity	Dr. G.D. Puri (Chairperson)	P	P	P
2.	All India Institute of Medical Science, Jodhpur	Prof. Pradeep Bhatia	P	P	-
		Dr. Bharat Paliwal	P	P	-
3.	All India Institute of Medical Sciences, New Delhi	Prof. Ganga Prasad	P	P	P
4.	Allied Medical Services Private Limited, New Delhi	Mr. Akhil Kohli	P	A	P
5.	Association of Indian Medical Device Industry, New Delhi	Mr. C. S. Prasad	P	P	P
6.	Becton Dickinson India Private Limited, Gurugram	Mr. Sudhakar Mairpady	P	P	A
		Mr. Neeraj Sharma	P	A	P
7.	Central Drugs Standard Control Organization, New Delhi	Mr. Aseem Sahu	-	A	P
		Mr. Ajai Basil	-	P	P
		Mr. Gulhane Akshay Dinkar	P	P	P
8.	Draeger India Pvt. Ltd, Mumbai	Ms. Jhankana Gyani	-	A	A
		Mr. Prashant A Purohit	-	P	A
		Mr. Roopesh Veettil	P	A	P
9.	Indian Society of Anaesthesiologists, Kolkata	Dr. Rakesh Garg	P	P	A
		Dr. Rajiv Gupta	-	A	P
		Dr. Amit Kumar	P	P	A
10.	Mandev Tubes Private Limited, Mumbai	Mr. Aditya Munot	P	P	P
		Mr. Sanjiv Kumar Gupta	P	P	P
		Mr. Surendra Kamalakar Parab	-	P	A
11.	Philips India Limited, Gurugram	Shri A V A Rajendra Prasad	P	P	P
		Ms. Radhika Devi	-	A	A

12.	Post Graduate Institute of Medical Education And Research, Chandigarh	Prof. LN Yaddanapudi	-	P	A
		Prof. Sandhya Yaddanapudi	-	A	A
		Dr. Aakriti Gupta	P	P	P
13.	Sir Ganga Ram Hospital, New Delhi	Dr. Manish Gupta	P	P	P
		Dr. Bhuwan Chand Panday	P	P	P
14.	Wipro G.E. Healthcare Private Limited, New Delhi	Shri Dorai. Subramaniam	P	P	P
		Mr. Nandhakumar A	P	P	P

*Annexure D*

<b>S. No.</b>	<b>Designation</b>	<b>Title</b>	<b>Current Status</b>
1	IS 3390 : 1988	Specification for sphygmomanometers, mercurial (Second Revision)	Draft is ready for wide circulation
2	IS 3391 : 1965	Specification for stethoscopes	In Wide circulation
3	IS 3392 : 1965	Specification for anaesthetic airways	In Wide circulation
4	IS 3393 : 1965	Specification for mouth props and airways (London Hospital Pattern)	Published
5	IS 4154 : 1967	Specification for endotracheal connections	In Print
6	IS 5622 : 1970	Soda-Lime Canisters for Use with Gas Anaesthetic Apparatus ( Waters' to-and-Fro)	Draft is ready for wide circulation
7	IS 5680 : 1969	Specification for rubber tubing for medical use	In Wide circulation
8	IS 6190 : 1971	Specification for anaesthetic face masks	Draft is ready for wide circulation
9	IS 6194 : 1971	Specification for intermittent positive pressure respirator, bag type, manually operated	Draft is ready for wide circulation
10	IS 6207 : 1971	Specification for trolleys for oxygen cylinders	Draft is ready for wide circulation
11	IS 6581 : 1972	Specification for endotracheal tubes (Rubber)	In Print
12	IS 6807 : 1972	Reinforced (Flexo-metallic) Magill's Endotracheal Tube	In Print
13	IS 7176 : 1985	Specification for anaesthetic apparatus, drawover portable type (First Revision)	Published
14	IS 7625 : 1975	Gag, Mouth, Doyen's Pattern	Draft is ready for wide circulation
15	IS 7652 : 1988	Specification for sphygmomanometer, aneroid type (First Revision)	Draft is ready for wide circulation
16	IS 7885 : 1985	Spray, Macintosh's Pattern	In Wide circulation
17	IS 8254 (Part 1) : 1976	Valve, Non-Rebreathing - Part I : Ruben's Pattern	Published
18	IS 8254 (Part 2) : 1976	Value, Non-rebreathing - Part II : Ambu-hesse's Pattern	In print
19	IS 8312 : 1977	Forceps, Introducing, Endotracheal Tube, Magill's Pattern	In Wide circulation

20	IS 8432 : 1977	Specification for tubes, tracheostomy (Rubber Or Plastics)	Published
21	IS 9462 : 1980	Specification for humidifier, nebulizing, ventury type	In Wide circulation