

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

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Anesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 11)	21 st	30 th July 2024 Tuesday 11:00 AM
<i>via Webex platform</i>		
Meeting Link: https://bismanak.webex.com/bismanak/j.php?MTID=m78dcaa2ff0d44c38877ce36dc463e771		
Meeting Number: 2513 433 0872		
Password: Mhd@11		
Chairperson	Dr. G. D. Puri	
Member Secretary	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 20th meeting of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 11) held on 30th April 2024 approved by the Chairperson was circulated to all members through BIS portal as well as email vide letter no: MHD 11/A 2.20 dated 31st May, 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 members were absent in the last meeting held on 30th April 2024 and follow-up was made with these members and the status is given below:

Sl. No.	Organisation	Nomination
1.	Allied Medical Services Private Limited, New Delhi	<i>Confirmation received on their interest for participation in MHD 11</i>

The Committee may please note.

2.5 The following members were consecutively absent in last two meetings held on 30th April, 2024 and 20th Feb, 2024:

Sl. No.	Organisation
1.	Employees State Insurance Corporation (ESIC), New Delhi
2.	Medtronic India Private Limited, Gurugram

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

The Committee may please note.

2.6 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.	MHD/11/25362	Medical electrical equipment Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment	25 May 2024	No
2.	MHD/11/25363	Medical electrical equipment Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients	25 May 2024	No
3.	MHD/11/25364	Medical electrical equipment Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	2 June 2024	No
4.	MHD/11/25383	Breathing system filters for anaesthetic and respiratory use Part 2: Non-filtration aspects	9 August 2024	
5.	MHD/11/25381	Breathing system filters for anaesthetic and respiratory use Part 1: Salt test method to assess filtration performance	9 August 2024	
6.	MHD/11/25371	Anaesthetic and respiratory equipment User-applied labels for syringes containing drugs used during anaesthesia Colours design and performance	9 August 2024	
7.	MHD/11/25374	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	10 August 2024	

8.	MHD/11/25373	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	10 August 2024	
9.	MHD/11/25372	Medical electrical equipment Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	14 August 2024	
10.	MHD/11/25375	Anaesthetic and respiratory equipment General requirements for airways and related equipment	22 August 2024	

3.2 The documents where no comments have been received 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.

Sl. No.	Project Title	Status
1.	Medical grade copper tubes	Ready for the P-Draft (Attached in <i>Annexure B</i>)
2.	Code of Practice: "MGPS Piping Installation Work on Project Site"	Under preparation
3.	Oxygen Purity meter	Under preparation
4.	Hospital Bed Head Panel and OT Pendants	Ready for the P-Draft (Attached in <i>Annexure C</i>)
5.	Respiratory NIV Mask with Tube Inclusion Port	Experts needs to be identified

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

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 deliberate.

7.2 A new subject for formulation of Indian Standard on “Pressure Regulator for sphygmomanometer testing kits to be used for calibration and testing of sphygmomanometers and automatic blood pressure measuring devices (*Attached in Annexure D*)” has been received from Mr. Jasveer Singh, CSIR-NPL, New Delhi and was circulated to all members for comments/observations. No comments have been received so far.

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:

Sl. No.	Liaison Committee of ISO	Type of Membership
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 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.

9.2.2 The following members are occupying coveted position in various Working Groups of ISO as 'Expert'.

Sl. No.	Name	Working Group Number/ Title
1.	Dr. Goverdhan Dutt Puri	<ul style="list-style-type: none">• ISO/TC 121/SC3/JWG 1 Critical care ventilator• ISO/TC 121/SC2/WG 11 Oxygen therapy devices• ISO/TC 121/SC6/WG 4 Medical gas pipeline systems
2.	Dr. Narayana Yaddanapudi	<ul style="list-style-type: none">• ISO/TC 121/SC3/ WG13 Biocompatibility of respiratory gas pathways• ISO/TC 121/SC 4/WG1 Respiratory equipment vocabulary
3.	Ms. Sandhya Yaddanapudi	<ul style="list-style-type: none">• ISO/TC 121/SC 2/WG 13 Airway tubes and Connectors• ISO/TC 121/SC 2/WG 17 Laryngoscopes
4.	Dr. Aakriti Gupta	<ul style="list-style-type: none">• ISO/TC 121/SC4/WG 3 Respiratory care equipment
5.	Mr. Roopesh Veetil	<ul style="list-style-type: none">• ISO/TC121/SC1/WG 9 Anaesthetic system
6.	Mr. Prashant A Purohit	<ul style="list-style-type: none">• ISO/TC 121/SC3/WG 13 Biocompatibility of respiratory gas pathways• ISO/TC 121/SC6/WG 6 Medical Supply Units

9.2.3 The nomination of above members as 'Expert' to ISO Working Groups has been considered by BIS based on the recommendations of the Sectional Committee taking into account that he/she would actively participate in the projects concerned. By accepting an appointment as an Expert, the respective members are committing to actively participate in the Working Group to which he/she is appointed and to fulfill the obligations associated with participation. The Working Group Experts are also required to inform the National Mirror Committee (i.e the concerned BIS Technical Committee that has the liaison with the ISO

Technical Committee) of their contribution and progress of the work. The level of contribution of the nominated Working Group Experts may be reviewed and decision may be taken regarding continuation/ termination of nomination.

The Committee may kindly consider.

9.3 Identification of Working Group Experts in ISO Technical Committees

9.3.1 India (BIS) is not participating in the following Working Groups of ISO as no Experts have been nominated by BIS in these WGs:

Sl. No.	Working Group Number/ Title
1.	ISO/TC 121/SC 1/JWG 1 Joint ISO/TC 121/SC 1-IEC/SC 62D WG: Anaesthesia workstations
2.	ISO/TC 121/SC 1/JWG 6 Joint ISO/TC 121/SC 1- IEC/SC 62D WG : Respiratory gas monitors
3.	ISO/TC 121/SC 2/AHG 1 Face masks
4.	ISO/TC 121/SC 2/WG 6 Respiratory therapy tubing and connectors
5.	ISO/TC 121/SC 2/WG 14 Heat and moisture control
6.	ISO/TC 121/SC 2/WG 16 General requirements for airway devices and related equipment
7.	ISO/TC 121/SC 3/JWG 2 Joint ISO/TC 121/SC 3-IEC/SC 62A WG : Alarm systems
8.	ISO/TC 121/SC 3/JWG 5 Joint ISO/TC 121/SC 1 and SC 3-IEC/SC 62A WG : Physiologic closed-loop controllers
9.	ISO/TC 121/SC 3/JWG 7 Joint ISO/TC 121/SC 3-IEC/SC 62D WG : Non-invasive blood pressure monitoring equipment
10.	ISO/TC 121/SC 3/JWG 8 Joint ISO/TC 121/SC 3-IEC/SC 62D WG: Clinical Thermometers
11.	ISO/TC 121/SC 3/JWG 10 Joint ISO/TC 121/SC 3-IEC/SC 62D WG : Oximeters
12.	ISO/TC 121/SC 4/WG 2 High frequency and jet ventilation
13.	ISO/TC 121/SC 6/WG 5 Transportable liquid oxygen systems for medical use
14.	ISO/TC 121/SC 6/WG 7 Plume evacuation systems
15.	ISO/TC 121/SC 6/WG 8 Pressure regulators

9.3.2 The Organizations / Members may propose for nomination of experts in the above WGs considering the following:

- a. The knowledge and expertise of the expert in the subject area.
- b. The willingness of the member to fulfill the responsibilities and expectations and commitment to devote ample time for international standardization activities.

The Committee may kindly consider.

9.4 Harmonization of Indian Standards with International Standards

9.4.1 ISO comprising of global experts on various subjects regularly bring out International Standards. The Sectional Committees on a regular basis needs to review the ISO Standards published against the existing National Standards, current trade practices, consumer expectations, global trends, etc and decide for review of the published National Standards. In the process, Sectional Committees after a close scrutiny of the ISO Standards, may decide on adoption/adaptation of the ISO Standards keeping in view the technical relevance of the subject to the national conditions. Harmonization is not undertaken in case the ISO Standards are not relevant to Indian conditions or would put the Indian industry at disadvantage. The Sectional Committees while reviewing such ISO Standards also explore the possibility of adopting such ISO Standards on which no Indian Standards exist.

The Committee may kindly note.

9.5 The meetings of ISO/TC 121/SC6 and WGs, are scheduled to be held from 18-22 November 2024, in Wien (Austria).

9.5.1 The mail seeking nomination from members to be a part of the Indian delegation for ISO/TC 121/SC6 and WGs meetings, are scheduled to be held from 18-22 November 2024, in Wien (Austria) was sent to the committee members dated 22nd July 2024.

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.

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	19
Under Development	10

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
21	2	8	12	8	3

11.1.2 The list of the above Indian Standards at various stages is given at *Annexure C*.

The Committee may kindly review.

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.

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 2024-25, the next meeting of MHD 11 is scheduled on 22nd October, 2024.

The Committee may kindly note.

ITEM 14 ANY OTHER BUSINESS

14.1 Following draft Standard may be considered for Withdrawn:

S. No.	Designation	Title	Comments received from CMD BIS
1	IS 11378: 2002	Anaesthetic machines for use with humans (First Revision)	<ul style="list-style-type: none">• The IS 11378:2002 is the identical adoption of ISO 5358:1992.• The base ISO 5358:1992 has been withdrawn by ISO.• Due to the withdrawal of ISO 5358:1992 the IS 11378:2002 needs to be withdrawn

The Committee may deliberate and decide.

[Annexure A](#)

MHD 11-Anesthetic, Resuscitation and Allied Equipment

Last 3 meetings Attendance Report

S. No.	Organization	Member Name	20 th	19 th	18 th
1.	In Individual Capacity	Dr. G.D. Puri	P	P	P
2.	All India Institute of Medical Science, Jodhpur	Prof. Pradeep Bhatia	P	-	-
		Dr. Bharat Paliwal	P	-	-
3.	All India Institute of Medical Sciences, New Delhi	Prof. Ganga Prasad	A	A	A
		Prof. Lokesh Kashyap	P	P	P
4.	Allied Medical Services Private Limited, New Delhi	Mr. Akhil Kohli	A	P	P
5.	Association of Indian Medical Device Industry, New Delhi	Mr. C. S. Prasad	P	P	A
6.	Becton Dickinson India Private Limited, Gurugram	Mr. Sudhakar Mairpady	P	A	P
		Ms. Nitilesh Kumarii	A	P	A
7.	Central Drugs Standard Control Organization, New Delhi	Mr. Aseem Sahu	A	P	P
		Mr. Ajai Basil	P	P	P
		Mr. Gulhane Akshay Dinkar	P	P	P
8.	Draeger India Pvt. Ltd, Mumbai	Ms. Jhankana Gyani	A	A	A
		Mr. Prashant A Purohit	P	A	P
		Mr. Roopesh Veettil	A	P	P
9.	Indian Society of Anaesthesiologists, Kolkata	Dr. Rakesh Garg	P	A	P
		Dr. Rajiv Gupta	A	P	A
		Dr. Amit Kumar	P	A	P
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	P
11.	Philips India Limited, Gurugram	Shri A V A Rajendra Prasad	P	P	P
		Ms. Radhika Devi	A	A	A
12.	Post Graduate Institute of Medical Education And Research, Chandigarh	Prof. LN Yaddanapudi	P	A	P
		Prof. Sandhya Yaddanapudi	A	A	P
		Dr. Aakriti Gupta	P	P	P
13.	Sir Ganga Ram Hospital, New Delhi	Dr. Manish Gupta	P	P	P
		Dr. Bhuvan Chand Panday	P	P	A

14.	Wipro G.E. Healthcare Private Limited, New Delhi	Shri Dorai. Subramaniam	P	P	P
		Mr. Nandhakumar A	P	P	P