

BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

MINUTES

Sectional Committee	Meeting No:	Date, Day & Time
Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 11)	21 st	30 th July 2024 Tuesday 10:30 AM
Chairperson Dr. G. D. Puri, Executive Director, All India Institute of Medical Science, Jodhpur	Member Secretary Mr. Satyam Rathore, Scientist-B, MHD, BIS, New Delhi	

The list of attendees is given at [ANNEXURE-A](#).

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY MEMBER SECRETARY

Mr. Satyam Rathore, Scientist-B, welcomed the members to 21st meeting of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee. He appreciated the members present for sparing their valuable time to participate in this meeting. He emphasized on personal involvement and contribution to all the members, experts and interested stakeholders in formulating Indian Standards and solicited the co-operation of all the members to deliberate on each agenda item to reach at a fruitful decision.

0.2 OPENING REMARKS BY THE CHAIRPERSON

Dr. G. D. Puri, Chairperson, welcomed the members to the 21st meeting of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee. He brought out the importance of standardization in the progress of nation. He requested the members for active deliberations for making the meeting successful. He expressed the need for conducting hybrid meeting at different places in future also to improve participation.

He requested Member Secretary to take up the agenda items for discussion.

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

The committee confirmed the minutes of the last meeting (20th) of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11 held on 30th April 2024 in hybrid mode.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

- 2.1 The committee noted the scope of the committee
- 2.2 The committee deliberated on the composition of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11 and requested member secretary to send mail to the organization where members are superannuated or left to obtain the fresh nominations.
- 2.3 The committee noted the contents of Item 2.3 of the Agenda
- 2.4 The committee noted the contents of Item 2.4 of the Agenda
- 2.5 The committee noted the contents of Item 2.5 of the Agenda
- 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 noted the contents of Item 3.1 of the Agenda
- 3.2 The committee finalized the following draft standards:

Sl. No.	Document No.	Title	Designated Members for Comments, if any
1.	MHD/11/25362	Medical electrical equipment Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment	Nil
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	Nil
3.	MHD/11/25364	Medical electrical equipment Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	Nil
4.	MHD/11/25383	Breathing system filters for anaesthetic and respiratory use Part 2: Non-filtration aspects	<ul style="list-style-type: none">• Dr. Manish Gupta• Dr. Bhuwan Chand Pandey
5.	MHD/11/25381	Breathing system filters for anaesthetic and respiratory use Part 1: Salt test method to assess filtration performance	<ul style="list-style-type: none">• Prof. Pradeep Bhatia• Dr. Bharat Paliwal

6.	MHD/11/25371	Anaesthetic and respiratory equipment User-applied labels for syringes containing drugs used during anaesthesia Colours design and performance	<ul style="list-style-type: none"> • Prof. LN Yaddanapudi • Prof. Sandhya Yaddanapudi • Dr. Aakriti Gupta
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	<ul style="list-style-type: none"> • Dr. G. D. Puri
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	<ul style="list-style-type: none"> • Dr. G. D. Puri
9.	MHD/11/25372	Medical electrical equipment Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	Nil
10.	MHD/11/25375	Anaesthetic and respiratory equipment General requirements for airways and related equipment	Nil

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 The committee noted the contents of Item 4.1 of the Agenda

4.2 The committee noted the contents of Item 4.2 of the Agenda

ITEM 5 DRAFT UNDER PREPARATION

5.1 The following indigenous subject drafts are under preparation:

Sl. No.	Project Title	Committee Decision
1.	Medical grade copper tubes	The committee decided to circulate the P-Draft for a period of 30 days
2.	Code of Practice: "MGPS Piping Installation Work on Project Site"	The experts were requested to prepare the Preliminary draft
3.	Oxygen Purity meter	The experts were requested to prepare the Preliminary draft

4.	Hospital Bed Head Panel and OT Pendants	The committee decided to circulate the P-Draft for a period of 30 days
5.	Respiratory NIV Mask with Tube Inclusion Port	The committee nominated “Dr. Rakesh Garg” as a drafting expert for standard titled “NIV Mask with Tube Inclusion Port”

5.2 The committee noted the contents of Item 5.2 of the Agenda

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 The committee noted the contents of Item 6.1 of the Agenda

ITEM 7 NEW SUBJECTS

7.1 The committee noted the contents of Item 7.1 of the Agenda

7.2 The committee requested the proposer for providing more technical justification on the proposed NWIP “Pressure Regulator for sphygmomanometer testing kits to be used for calibration and testing of sphygmomanometers and automatic blood pressure measuring devices”.

ITEM 8 TECHNICAL ISSUES

8.1 The committee noted the contents of Item 8.1 of the Agenda

ITEM 9 INTERNATIONAL ACTIVITIES

9.1 Participating (P) Membership in ISO/IEC

9.1.1 The committee noted the contents of Item 9.1.1 of the Agenda

9.1.2 The committee noted the contents of Item 9.1.2 of the Agenda

9.2 Participation of Working Group Experts in ISO Technical Committees

9.2.1 The committee noted the contents of Item 9.2.1 of the Agenda

9.2.2 The committee noted the contents of Item 9.2.2 of the Agenda

9.2.3 The following members are occupying coveted position in various Working Groups of ISO and are the designated experts of the associated projects:

Sl. No.	Name	Working Group Number/ Title	Associated Projects/Designated Experts
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 	<ul style="list-style-type: none"> • ISO/CD 7396-1 Medical gas pipeline systems — Part 1: Pipeline systems for

		Oxygen therapy devices • ISO/TC 121/SC6/WG 4 Medical gas pipeline systems	compressed medical gases and vacuum
2.	Dr. Narayana Yaddanapudi	• ISO/TC 121/SC3/ WG13 Biocompatibility of respiratory gas pathways • ISO/TC 121/SC 4/WG1 Respiratory equipment vocabulary	• ISO/DIS 19223-2 Lung ventilators and related equipment — Vocabulary and semantics — Part 2: High frequency and jet ventilation
3.	Ms. Sandhya Yaddanapudi	• ISO/TC 121/SC 2/WG 13 Airway tubes and Connectors • ISO/TC 121/SC 2/WG 17 Laryngoscopes	• ISO 7376:2020/DAmD 1 (Ed 3) : Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation — Amendment 1: Clarification about optical output and illumination requirements
4.	Dr. Aakriti Gupta	• ISO/TC 121/SC4/WG 3 Respiratory care equipment	• ISO/CD 19223-3.2 Lung ventilators and related equipment — Vocabulary and semantics — Part 3: Respiratory care
5.	Mr. Roopesh Veetil	• ISO/TC121/SC1/WG 9 Anaesthetic system	-
6.	Mr. Prashant A Purohit	• ISO/TC 121/SC3/WG 13 Biocompatibility of respiratory gas pathways • ISO/TC 121/SC6/WG 6 Medical Supply Units	-

9.3 Identification of Working Group Experts in ISO Technical Committees

9.3.1 The committee noted the contents of Item 9.3.1 of the Agenda

9.3.2 The committee approved the following proposed nomination of experts in the WGs and they will be designated experts in the associated projects:

Sl. No.	Name	Working Group Number/ Title	Associated Projects
1.	Dr. Bhuwan Chand Panday, Sir Ganga Ram Hospital, New Delhi	ISO/TC 121/SC 1/JWG 1 Joint ISO/TC 121/SC 1-IEC/SC 62D WG: Anaesthesia workstations	<ul style="list-style-type: none"> ISO 80601-2-13 Anaesthesia workstations
		ISO/TC 121/SC 3/JWG 10 Joint ISO/TC 121/SC 3-IEC/SC 62D WG: Oximeters	-

2.	Dr. Bharat Paliwal, All India Institute of Medical Science, Jodhpur	ISO/TC 121/SC 2/WG 16 General requirements for airway devices and related equipment	<ul style="list-style-type: none"> • ISO/DIS 18190.2 (Ed 2) Anaesthetic and respiratory equipment — General requirements for airway devices and related equipment
3.	Dr. Rakesh Garg Indian Society of Anaesthesiologists, Kolkata	ISO/TC 121/SC 4/WG 2 High frequency and jet ventilation	<ul style="list-style-type: none"> • ISO/DIS 19223-2 Lung ventilators and related equipment — Vocabulary and semantics — Part 2: High frequency and jet ventilation
4.	Mr. Satyam Rathore, Scientist – B, BIS	ISO/TC 121/SC 6/WG 8 Pressure regulators	<ul style="list-style-type: none"> • ISO/CD 10524-3 Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (VIPRs)
		ISO/TC 121/SC6/WG 4 Medical gas pipeline systems	<ul style="list-style-type: none"> • ISO/CD 7396-1 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum
		ISO/TC 121/SC 2/WG 14 Heat and moisture control	<ul style="list-style-type: none"> • ISO/CD 9360-1 Anaesthetic and respiratory equipment – Heat and moisture exchangers and breathing system filters (HMEF) for humidifying respired gases in humans — Part 1: Common requirements • ISO/CD 9360-2 Anaesthetic and respiratory equipment – Heat and moisture exchangers and breathing system filters (HMEF) for humidifying respired gases in humans — Part 2: Measurement of moisture loss • ISO/CD 9360-3 Anaesthetic and respiratory equipment – Heat

			and moisture exchangers and breathing system filters (HMEF) for humidifying respired gases in humans — Part 3: Measurement of filtration performance
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9.4 Harmonization of Indian Standards with International Standards

9.4.1 The committee noted the contents of Item 9.4.1 of the Agenda

9.5 The committee noted the contents of Item 9.5 of the Agenda

9.5.1 The committee noted the contents of Item 9.5.1 of the Agenda

ITEM 10 PROGRAMME OF WORK

10.1 The committee noted the contents of Item 10.1 of the Agenda

10.2 The committee noted the contents of Item 10.2 of the Agenda

ITEM 11 REVIEW OF INDIAN STANDARDS

11.1 Review of Pre-2000 Standards

11.1.1 The committee reviewed the contents of Item 11.1.1 of the Agenda

11.1.2 The committee reviewed the contents of Item 11.1.2 of the Agenda

11.2 Review of Standards as per 5-year cycle

11.2.1 The committee noted the contents of Item 11.2.1 of the Agenda

11.2.2 The committee noted the contents of Item 11.2.2 of the Agenda

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

12.1 The committee noted the contents of Item 12.1 of the Agenda

ITEM 13 DATE AND PLACE OF NEXT MEETING

13.1 The committee noted the contents of Item 13.1 of the Agenda

ITEM 14 ANY OTHER BUSINESS

14.1 The committee deliberated on the withdrawal of IS 11378:2002/ISO 5358:1992 “Anaesthetic machines for use with humans”. The committee observed that ISO also does not refer to any other standard which supersedes ISO 5358:1992. Further another existing ISO standard on the subject [IS 13450 (Part2/Sec13) / ISO 13450-2-13 “Medical Electrical Equipment: Part 2 Particular Requirements for the Basic Safety and Essential Performance: Sec 13 Anaesthetic Workstation”] pertains to complete Anaesthesia Workstation. Accordingly, the committee decided to explore the possibilities of developing a new indigenous standard catering to the requirements of Indian industries so that quality of such type of Anaesthetic machines used in the country can also be ensured.

14.2 The committee deliberated and accepted the New Work Item Proposal “Impulse Oscillometry” as per the subjects received from the Department of Pharmaceuticals (DoP) for formulation of Indian Standard

ANNEXURE – A

LIST OF ATTENDEES

Sl.No.	Member	Organization
1.	Dr. G.D. Puri (Chairperson)	All India Institute of Medical Science, Jodhpur
2.	Prof. Pradeep Bhatia	All India Institute of Medical Science, Jodhpur
3.	Dr. Bharat Paliwal	All India Institute of Medical Science, Jodhpur
4.	Prof. Ganga Prasad	All India Institute of Medical Sciences, New Delhi
5.	Mr. Akhil Kohli	Allied Medical Services Private Limited, New Delhi
6.	Mr. C. S. Prasad	Association of Indian Medical Device Industry, New Delhi
7.	Mr. Sudhakar Mairpady	Becton Dickinson India Private Limited, Gurugram
8.	Mr. Neeraj Sharma	Becton Dickinson India Private Limited, Gurugram
9.	Mr. Gulhane Akshay Dinkar	Central Drugs Standard Control Organization, New Delhi
10.	Mr. Roopesh Veettil	Draeger India Pvt. Ltd, Mumbai
11.	Dr. Rakesh Garg	Indian Society of Anaesthesiologists, Kolkata
12.	Dr. Amit Kumar	Indian Society of Anaesthesiologists, Kolkata
13.	Mr. Aditya Munot	Mandev Tubes Private Limited, Mumbai
14.	Mr. Sanjiv Kumar Gupta	Mandev Tubes Private Limited, Mumbai
15.	Mr. A V A Rajendra Prasad	Philips India Limited, Gurugram
16.	Dr. Aakriti Gupta	Post Graduate Institute of Medical Education and Research, Chandigarh
17.	Dr. Manish Gupta	Sir Ganga Ram Hospital, New Delhi
18.	Dr. Bhuwan Chand Panday	Sir Ganga Ram Hospital, New Delhi
19.	Mr. Dorai. Subramaniam	Wipro G.E. Healthcare Private Limited, New Delhi
20.	Mr. Nandhakumar A	Wipro G.E. Healthcare Private Limited, New Delhi

BIS Directorate General:

1.	Mr. Satyam Rathore (Member Secretary)	Scientist 'B'/Assistant Director, MHD, Bureau of Indian Standards
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