

BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 11)	17th	31 st August 2023 Thursday 10:30 AM
Hybrid Meeting (Physical + Virtual via WebEx Platform) Meeting Link: https://bismanak.webex.com/bismanak/j.php?MTID=m031d267d4a78935e566aa07e8330715a Meeting ID: 2525 071 7701 Password: Mhd@11		
Chairperson Dr. G. D. Puri (In Personal Capacity) Former Dean (Academic), Postgraduate Institute of Medical Education and Research Chandigarh	Member Secretary Mr. Satyam Rathore, Scientist-B, MHD, BIS, New Delhi	

ITEM 0 GENERAL

0.1 WELCOME ADDRESSES 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 16th meeting of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 11) held on 23rd June 2023 approved by the Chairperson was circulated to all members through the BIS portal as well as email vide letter no: MHD/11/A-2.16 dated 12/07/2023.

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 Sectional Committee (MHD 11) is as follows:

- a) To formulate Indian Standards for instruments and equipment used for anaesthetising and ventilating a patient, including diagnostic instruments such as sphygmomanometers, suction apparatus, and anaesthetic face mask.
- b) 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 details of members who have not participated in the last two meetings are given below:

Sl. No.	Organisation	Member Name
1	Allied Medical Services Private Limited, New Delhi	Shri Akhil Kohli, Principal Member
2	Benson Medical Equipment India Private Limited, Gurugram	Shri Sandeep Nanda, Principal Member
3	Directorate General of Armed Forces Medical Services, New Delhi	Col. Amit Sharma, Principal Member
4	Directorate General of Health Services, New Delhi	Dr. Rakesh Kumar, Principal Member
5	Indian Society of Anaesthesiologists, Kolkata	Dr Harsoor, Principal Member Dr K. Venkata Giri, Alternate Member
6	Maulana Azad Medical College, New Delhi	Dr. U.C. Verma, Principal Member Dr. J.S. Dali, Alternate Member
7	Shriram Institute for Industrial Research, Delhi	Dr. M. L. Aggarwal, Principal Member Dr. Ajeet Aggarwal, Alternate Member
8	University College of Medical Sciences and Guru Teg Bahadur Hospital, New Delhi	Dr. Ashok Kumar Saxena, Principal Member
9	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Dr. Rangu Gandhi, Principal Member Dr. Abhishek Verma, Principal Member

2.3.1 Follow-up may be made with the above members for ensuring their participation.

The Committee may please note.

2.4 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:

S. No.	Document Number	Title	Last date of comments	Comments received, if any
1.	MHD 11 (18949)	Specification for Mouth Props and Airways London Hospital Pattern First Revision	27-06-2023	No comments received
2.	MHD 11 (18974)	Specification for Valve Non-Rebreathing Part I Rubens Pattern First Revision	27-06-2023	No comments received
3.	MHD 11 (18975)	Specification for Valve Non-Rebreathing Part 2 Ambu-Hesses Pattern First Revision	27-06-2023	No comments received
4.	MHD 11 (19247)	Specification for Drawover Portable Type Anaesthetic Apparatus (Second Revision)	10-07-2023	No comments received
5.	MHD 11 (22279)	Medical Gas Pipeline Systems Part 1: Pipeline Systems for Compressed Medical Gases and Vacuum (First Revision)	05-07-2023	No comments received
6.	MHD 11 (22626)	Suction Catheters for Use in the Respiratory Tract	18-07-2023	No comments received
7.	MHD 11 (22613)	Anaesthetic and Respiratory Equipment-Breathing Sets and Connectors	18-07-2023	No comments received
8.	MHD 11 (22610)	Lung Ventilators Part 4 Particular Requirements for User-powered Resuscitators (First Revision)	18-07-2023	No comments received
9.	MHD 11 (22615)	Anaesthetic and Respiratory Equipment- Oropharyngeal Airways(First Revision)	18-07-2023	No comments received
10.	MHD 11 (22611)	Anaesthetic and Respiratory Equipment-Tracheobronchial tubes (First Revision)	18-07-2023	No comments received

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

The Committee may kindly deliberate.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 There are currently no documents for wide circulation approval.

The Committee may kindly approve.

ITEM 5 DRAFT UNDER PREPARATION

5.1 There are currently no indigenous subject drafts under preparation.

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 'Medical Gas Pipeline Systems' has been received from Mandev Tubes is attached in **Annexure B**.

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 India's Participation Status in ISO Technical Committees/Subcommittees.

The Committee has liaison with ISO/TC 121 and the updated membership status of India (BIS) in ISO/TC 121 & its Sub-Committees is given below:

S. No.	Committee/ Sub Committee	Title	BIS Membership status
1	ISO/ TC 121	Anaesthetic and Respiratory Equipment	Participating
2	ISO/ TC 121/ SC1	Breathing attachments and anaesthetic machine	Participating
3	ISO/ TC 121/ SC2	Airways and related equipment	Participating
4	ISO/ TC 121/ SC3	Lung ventilators and related Equipment used for patient care	Participating
5	ISO/ TC 121/ SC4	Vocabulary and semantics	Participating
6	ISO/ TC 121/ SC6	Medical gas supply systems	Participating
7	ISO/ TC 121/ SC8	Suction devices	Participating

The committee may please note.

9.2 The nominations were received for participation in international activities associated with ISO/TC 121 subcommittees and its working groups are provided in [Annexure C](#).

The committee may please deliberate and decide.

9.3 The 67th meeting of ISO/TC 121/SC 2 “Airways and related equipment” and ISO/TC 121/SC6 “Medical gas supply systems” is scheduled to be held from 13-17th Nov, 2023 in Ireland (North Wood)

The Committee may please note

9.4 The list of important ISO Standards published by ISO/TC 121 and its Sub Committees is given in [Annexure D](#). The Committee may please examine and identify the ISO Standard(s) which may be adopted as Indian Standard(s), keeping in view India’s National interest.

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 Review of Indian Standards (pre-2000 Standards)

10.2.1 All the Indian Standards published before the year 2000 need to be reviewed for revision/withdrawal/archived in the light of technological developments that have happened so far in relation to these standards.

10.2.2 The list of such Indian Standards is given below.

S. No.	Designation	Title
1	IS 6190: 1971	Specification for anaesthetic face masks
2	IS 8312: 1977	Forceps, Introducing, Endotracheal Tube, Magill's Pattern

The Committee may kindly review.

10.3 Review of Indian Standards (as per 5-year cycle)

10.3.1 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.

10.3.2 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.

10.3.3 The list of such Indian Standards which are due for review in Oct 23 -Dec 23 Quarter is given below.

S. No.	Designation	Title	Revision of the base ISO standard
1	IS/ISO 10524-4: 2008	Pressure regulators for use with medical gases: Part 4 low - Pressure regulators	The base ISO standard “ISO 10524-4: 2008 - Pressure regulators for use with medical gases — Part 4: Low-pressure regulators” has been reviewed by ISO and the version remains the same
2	IS/IEC 80601-2-30: 2018	Medical electrical equipment: Part 2 - 30 particular requirements for basic safety and essential performance of automated non - Invasive sphygmomanometers	The base IEC standard “IEC 80601-2-30: 2018- Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers” has been reviewed by ISO and the version remains the same

The Committee may kindly deliberate and decide further course of action.

ITEM 11 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

11.1 There are currently no issues related to previous meeting.

The Committee may kindly note.

ITEM 12 DATE AND PLACE OF NEXT MEETING

12.1 As per the approved Annual Meeting Calendar for 2023-24, the next meeting of MHD 11 is scheduled on **2nd Nov 2023, Thursday**.

The Committee may kindly note.

ITEM 13 ANY OTHER BUSINESS

Annexure A

COMPOSITION OF SECTIONAL COMMITTEE

S.No.	Organization	Member Name
1	In Individual Capacity	Dr. G.D. Puri
2	All India Institute of Medical Sciences, New Delhi	Prof. Lokesh Kashyap
3	All India Institute of Medical Sciences, New Delhi	Prof. Ganga Prasad
4	Allied Medical Services Private Limited, New Delhi	Shri Akhil Kohli
5	Becton Dickinson India Private Limited, Gurugram	Shri Neeraj Sharma
6	Becton Dickinson India Private Limited, Gurugram	Mr. Sudhakar Mairpady
7	Benson Medical Equipment India Private Limited, Gurugram	Shri Sandeep Nanda
8	Central Drugs Standard Control Organization, New Delhi	Dr. Rikta Saha
9	Central Drugs Standard Control Organization, New Delhi	Shri Arvind R. Hiwale
10	Directorate General of Armed Forces Medical Services, New Delhi	Col. Amit Sharma
11	Directorate General of Health Services, New Delhi	Dr. Rakesh Kumar
12	Draeger India Pvt. Ltd, Mumbai	Ms. Jhankana Gyani
13	Draeger India Pvt. Ltd, Mumbai	Mr. Prashant A Purohit
14	Draeger India Pvt. Ltd, Mumbai	Mr. Roopesh Veettil
15	Employees State Insurance Corporation (ESIC), New Delhi	Dr. Madhu Gupta
16	Indian Society of Anaesthesiologists, Kolkata	Dr. Harsoor
17	Indian Society of Anaesthesiologists, Kolkata	Dr K. Venkata Giri
18	Kalam Institute of Health Technology, Vishakhapatnam	Shri Dilip Kumar Chekuri
19	Kalam Institute of Health Technology, Vishakhapatnam	Ms. Sushmita Roy Chowdhury
20	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Syed Mustafiz Ahmed
21	Maulana Azad Medical College, New Delhi	Dr. U.C. Verma
22	Maulana Azad Medical College, New Delhi	Dr. J.S. Dali
23	Medtronic India Private Limited, Gurugram	Ms. Sumukhi Sabbarwal
24	Medtronic India Private Limited, Gurugram	Ms. Monika Joshi
25	Medtronic India Private Limited, Gurugram	Mr. Amit Kumar
26	Ministry of Railways, New Delhi	Dr. Sunil Krishnan
27	Ministry of Railways, New Delhi	Dr. A.K. Sharma
28	Philips India Limited, Gurugram	Shri A V A Rajendra Prasad
29	Philips India Limited, Gurugram	Ms. Radhika Devi
30	Post Graduate Institute of Medical Education and Research, Chandigarh	Prof. LN Yaddanapudi

31	Post Graduate Institute of Medical Education and Research, Chandigarh	Prof. Sandhya Yaddanapudi
32	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr. Aakriti Gupta
33	Shriram Institute for Industrial Research, Delhi	Dr. M. L. Aggarwal
34	Shriram Institute for Industrial Research, Delhi	Dr. Ajeet Aggarwal
35	Sir Ganga Ram Hospital, New Delhi	Dr. Bimla Sharma
36	Sir Ganga Ram Hospital, New Delhi	Dr. Manish Gupta
37	University College of Medical Sciences and Guru Teg Bahadur Hospital, New Delhi	Dr. Ashok Kumar Saxena
38	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Dr. Rangu Gandhi
39	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Dr. Abhishek Verma
40	Wipro G.E. Healthcare Private Limited, New Delhi	Smt. Geetha S.S.
41	Wipro G.E. Healthcare Private Limited, New Delhi	Shri Dorai Subramaniam

Annexure C

**Name of Organization: Post Graduate Institute of Medical Education and Research,
Chandigarh**

Nominated Members:

1.

Name	Designation	Contact Number	Email Id
Dr. Goverdhan Dutt Puri	Former Dean (Academic), Postgraduate Institute of Medical Education and Research Chandigarh	9815199717	gdpuri007@hotmail.com

Nominated for following ISO/ TC 121 Committee, Subcommittees and working groups:

S. No.	Committee/ Subcommittee	Title	Working Group	Title
i	ISO/TC 121/SC3	Respiratory devices and related equipment used for patient care	ISO/TC 121/SC 3/JWG 1 Joint ISO/TC 121/SC 3-IEC/SC 62D WG	Critical care ventilator

2.

Name	Designation	Contact Number	Email Id
Dr. Narayana Yaddanapudi	Professor, Dept. of Anaesthesia, and Intensive Care	7087009522, 9815836656	narayana.yaddanapudi@gmail.com

Nominated for following ISO/ TC 121 Committee, Subcommittees and working groups:

S. No.	Committee/ Subcommittee	Title	Working Group	Title
i	ISO/ TC 121/SC3	Respiratory devices and related equipment used for patient care	ISO/TC 121/SC3/ WG 13	Biocompatibility of respiratory gas pathways
			ISO/TC 121/SC3/WG 15	Infant cardiorespiratory monitors
			ISO/ TC/ SC3/ WG16	User-powered resuscitators
ii	ISO/TC 121/SC4	Vocabulary and semantics	ISO/TC 121/SC 4/WG1	Respiratory equipment vocabulary

3.

Name	Designation	Contact Number	Email Id
Ms. Sandhya Yaddanapudi	Professor, Department of Anesthesia and Intensive Care	7087009523, 9872005576	sandhya.yaddanapudi@gmail.com

Nominated for following ISO/ TC 121 Committee, Subcommittees and working groups:

S. No.	Committee/ Subcommittee	Title	Working Group	Title
i	ISO/TC 121/SC2	Airways and related equipment	ISO/TC 121/SC 2/WG 13	Airway tubes and connectors
			ISO/TC 121/SC 2/WG 17	Laryngoscopes

4.

Name	Designation	Contact Number	Email Id
Dr. Aakriti Gupta	Assistant Professor Dept. of Anaesthesia & Intensive Care	7087007817, 8194800554	aakriti1988.ag@gmail.com

Nominated for following ISO/ TC 121 Committee, Subcommittees and working groups:

S. No.	Committee/ Subcommittee	Title	Working Group	Title
i	ISO/TC 121/SC 4	Vocabulary and semantics	ISO/TC 121/SC4/WG 3	Respiratory care equipment

Name of Organization: Draeger India Pvt. Ltd

Nominated Members:

1.

Name	Designation	Contact Number	Email Id
Mr. Roopesh Veetil	Lead System Designer	9008331175	roopesh.veetil@draeger.com

Nominated for following ISO/ TC 121 Committee, Subcommittees and working groups:

S. No.	Committee/ Subcommittee	Title	Working Group	Title
i	ISO/ TC 121	Anaesthetic And respiratory equipment	ISO/TC 121/WG1	Connectors for respiratory therapy devices and accessories

ii	ISO/ TC 121	Anaesthetic And respiratory equipment	ISO/TC 121/WG3	Cybersecurity for anaesthetic and respiratory equipment
iii	ISO/TC 121/SC 1	Breathing attachments and anaesthetic machines	ISO/TC121/SC1/WG 9	Anaesthetic system

2.

Name	Designation	Contact Number	Email Id
Mr. Prashant A Purohit	Assistant Manager - Quality and Regulatory Affairs	7400489665	prashant.purohit@draeger.com

Nominated for following ISO/ TC 121 Committee, Subcommittees and working groups:

S. No.	Committee/ Subcommittee	Title	Working Group	Title
i	ISO/TC 121/SC 3	Respiratory devices and related equipment used for patient care	ISO/TC 121/SC 3/WG 13	Biocompatibility of respiratory gas pathways
ii	ISO/TC 121/SC 6	Medical gas supply systems	ISO/TC 121/SC 6/WG 6	Medical Supply Units

3.

Name	Designation	Contact Number	Email Id
Mr. Vijay Sharma	Design and Development Engineer	7045646415	vijay.sharma@draeger.com

Nominated for following ISO/ TC 121 Committee, Subcommittees and working groups:

S. No.	Committee/ Subcommittee	Title	Working Group	Title
i	ISO/TC 121/SC 6	Medical gas supply systems	ISO/TC 121/SC 6/WG 8	Pressure regulators
ii	ISO/TC 121/SC 6	Medical gas supply systems	ISO/TC 121/SC 6/WG 4	Medical gas pipeline systems

Annexure D

S. No.	ISO Standard	Title
1	ISO 80601-2 -55:2018	Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
2	ISO 80601-2-90:2021	Medical electrical equipment — Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment
3	ISO 80601-2-87:2021	Medical electrical equipment — Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators
4	ISO 80601-2-72:2023	Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
5	ISO 80601-2-74:2021	Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
6	ISO 80601-2-67:2020	Medical electrical equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment
7	ISO 10079-4:2021	Medical suction equipment — Part 4: General requirements
8	ISO 16571:2014	Systems for evacuation of plume generated by medical devices
9	ISO 19223:2019	Lung ventilators and related equipment — Vocabulary and semantics
10	ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
11	ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
12	ISO 17510:2015	Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
13	ISO 23368:2022	Anaesthetic and respiratory equipment — Low-flow nasal cannulae for oxygen therapy
14	ISO 5359:2014	Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases
15	ISO 5359:2014/Amd 1:2017	Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases — Amendment 1