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)	17 th	31st 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	Member Secretary
Dr. G. D. Puri (In Personal Capacity) Former	Mr. Satyam Rathore, Scientist-B, MHD, BIS,
Dean (Academic), Postgraduate Institute of	New Delhi
Medical Education and Research Chandigarh	

Members Present

S.No.	Name	Organization	
1.	Dr. G.D. Puri	In Individual Capacity	
2.	Prof. Lokesh Kashyap	All India Institute of Medical Sciences, New Delhi	
3.	Shri Akhil Kohli	Allied Medical Services Private Limited, New Delhi	
4.	Mr. Sudhakar Mairpady	Becton Dickinson India Private Limited, Gurugram	
5.	Shri Aseem Sahu	Central Drugs Standard Control Organization, New Delhi	
6.	Shri Ajai Basil	Central Drugs Standard Control Organization, New Delhi	
7.	Mr. Roopesh Veettil	Draeger India Pvt. Ltd, Mumbai	
8.	Dr. Madhu Gupta	Employees State Insurance Corporation (ESIC), New	
		Delhi	
9.	Mr. Syed Mustafiz	Kalam Institute of Health Technology, Vishakhapatnam	
10.	Ms. Sushmita Roy	Kalam Institute of Health Technology, Vishakhapatnam	
11.	Mr. Amit Kumar	Medtronic India Private Limited, Gurugram	
12.	Ms. Monika Joshi	Medtronic India Private Limited, Gurugram	
13.	Ms. Sumukhi Sabbarwal	Medtronic India Private Limited, Gurugram	

14.	Prof. L N Yaddanapudi	Post Graduate Institute of Medical Education And
	_	Research, Chandigarh
15.	Prof. Sandhya	Post Graduate Institute of Medical Education And
	Yaddanapudi	Research, Chandigarh
16.	Dr. Aakriti Gupta	Post Graduate Institute of Medical Education And
		Research, Chandigarh
17.	Dr. Manish Gupta	Sir Ganga Ram Hospital, New Delhi
18.	Mr. Dorai Subramaniam	Wipro G.E. Healthcare Private Limited, New Delhi
19.	Mr. Sanjeev Kumar Gupta	Mandev Tubes
20.	Mr. Jaideep Singh	Mandev Tubes
21.	Mr. Aditya Munot	Mandev Tubes
22.	Mr. Harendra Singh	Mandev Tubes

BIS Directorate General:

23	Ms. Uroosa Warsi	Scientist-B, MHD, Bureau of Indian Standards, New Delhi
24	Ms. Harshada Kadam	Scientist-B, MHD, Bureau of Indian Standards, New Delhi

ITEM 0 GENERAL

0.1 WELCOME ADDRESSES BY MEMBER SECRETARY

Satyam Rathore, Scientist-B, welcomed the members to 17th meeting of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11. 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 present in the 17th meeting of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11 at PGIMER Chandigarh. 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 formally confirmed the minutes of the last meeting (16th) of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11 held on held on 23rd June 2023 in hybrid mode.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The committee formally noted the scope of the committee.

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 for the fresh nominations.

- 2.3 The Committee noted the contents of Item 2.3 of the Agenda
- 2.3.1 Follow-up mail was sent to the members for their fresh nominations. If no reply will be received within a period of 15 days. The organisation will be removed from the committee composition.
- 2.4 The Committee noted the contents of Item 2.4 of the Agenda
- 2.5 The committee accepted the co-option request received from Mandev Tubes and approved the nomination as principal member (Mr. Aditya Ramesh Munot, Director, Mandev Tubes Pvt. Ltd.) and alternate member (Mr. Sanjiv Kumar Gupta, Executive Director, Mandev Tubes Pvt. Ltd.)

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

3.1 The Committee finalized the document mentioned in the Item 3.1 of the Agenda

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

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

ITEM 5 DRAFT UNDER PREPARATION

5.1 The Committee noted the contents of Item 5.1 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 decided to take up the new subject for formulation of Indian Standard on 'Medical Gas Pipeline System Part A: Design, Installation, Validation and Verification'. The committee also suggested to incorporate the Fire Safety and Electrical Safety clauses in the document.

7.3 The committee decided to prepare the working draft within a period of 30 days with the inputs /Suggestions from the relevant stakeholders.

ITEM 8 TECHNICAL ISSUES

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

ITEM 9. INTERNATIONAL ACTIVITIES

- 9.1 The Committee noted the contents of Item 9.1 of the Agenda.
- 9.2 The committee noted the nominations received for participation in international activities associated with ISO/TC 121 subcommittees and its working groups, provided in *Annexure A*.
- 9.3 As regards the nomination of Mr Satyam Rathore who is the member secretary of Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11 in various working groups, the Committee noted the following:
 - a) Mr Satyam who is a M.Tech from IIT Bombay in Biomedical Engineering has done his project in Medical Electrical Equipment in BETiC (Biomedical Engineering and Technology Incubation Centre) Lab at IIT Bombay., which is working for the prototyping and manufacturing of Medical Devices and Equipment.
 - b) the project has received the patent of the product also. Further, he also has professional experience in medical device industry where he worked as a Medico engineering analyst at Cipla Research and Development and worked on the development of respiratory devices and also worked in a medical device start-up company which deals in the therapeutic and surgical devices.
 - c) During the course of his work in other organization, he has been dealing with ISO/ IEC standards as well with regard to the understanding and development of Medical Devices.

The committee approved the nominations of experts mentioned in Annexure A

9.4 The Committee noted the contents of Item 9.3 of the Agenda. The mail seeking nomination from members to be a part of the Indian delegation for ISO/TC 121/SC 2 "Airways and related equipment" and ISO/TC 121/SC6 "Medical gas supply systems", scheduled to be held from 13-17th Nov, 2023 in Ireland (North Wood) was sent to the committee member dated 5th Sept 2023, The following nomination has been received:

S. No.	Member Name	Designation	Organization	Details of the meetings to be attended (on which date the
	- 100			meeting is to be attended)
1	Shri. Aseem Sahu	DDCI CDSCO and Memebr of MHD 11	Central Drugs Standard Control Organization (CDSCO)	Meetings of 'ISO/TC 121/SC 2' and 'ISO/TC 121/SC 6' and it's Working Groups, scheduled from 13 th Nov, 2023 to 17 th Nov, 2023.

In addition to the above, it was discussed that the following members also be a part of the Indian delegation.

S.No.	Member Name	Designation	Organization	Details of the meetings to be attended (on which date the meeting is to be attended)
1.	Dr. Goverdhan Dutt Puri	Chairperson of MHD 11 and Former Dean (Academic), PGIMER, Chandigarh	In individual capacity	Meetings of 'ISO/TC 121/SC 2' and 'ISO/TC 121/SC 6' and it's Working Groups, scheduled from 13 th Nov, 2023 to 17 th Nov, 2023.
2.	Mr. A. R. Unnikrishnan	Scientist-F and Head MHD	Bureau of Indian Standards	Meetings of 'ISO/TC 121/SC 2' and 'ISO/TC 121/SC 6' and it's Working Groups, scheduled from 13 th Nov, 2023 to 17 th Nov, 2023.
3.	Mr. Satyam Rathore	Scientist-B and Member Secretary of MHD 11	Bureau of Indian Standards	Meetings of 'ISO/TC 121/SC 2' and 'ISO/TC 121/SC 6' and it's Working Groups, scheduled from 13 th Nov, 2023 to 17 th Nov, 2023.

9.4 The committee decided to adopt and wide circulate for the one month to the list of ISO standards mentioned in Item 9.4 of the agenda.

ITEM 10. PROGRAMME OF WORK

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

10.2 Review of Indian Standards (pre-2000 Standards)

- 10.2.1 The Committee noted the contents of Item 10.2.1 of the Agenda
- 10.2.2 The list of such Indian Standards is given below.

S.	Designation	Title	Committee decision
No.			
1	IS 6190:	Specification for	Standard may be reaffirmed for a period of five
	1971	anaesthetic face masks	years w.e.f due date and revised in due course
2	IS 8312:	Forceps, Introducing,	Standard may be reaffirmed for a period of five
	1977	Endotracheal Tube,	years w.e.f due date and revised in due course
		Magill's Pattern	

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

- 10.3.1 The Committee noted the contents of Item 10.3.1 of the Agenda.
- 10.3.2 The Committee noted the contents of Item 10.3.2 of the Agenda
- 10.3.3 The list of such Indian Standards which are due for review in Oct 23 -Dec 23 Quarter is given below.

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

The Committee decided to reaffirm the above standards for a period of five years as the base ISO version remains the same.

ITEM 11 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

11.1 The Committee noted the contents of Item 11.1 of the Agenda

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**.

ITEM 13 ANY OTHER BUSINESS

13.1 There being no other business. The meeting ended with a thanks to the chair and all the members present.

Annexure A

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

Nominated Members:

1.

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

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

S.	Committee/	Title	Working Group	Title
No.	Subcommittee			
i	ISO/TC	Respiratory devices	ISO/TC 121/SC	Critical care ventilator
	121/SC3	and related	3/JWG 1	
		equipment used for		
		patient care		
ii	ISO/TC	Airways	ISO/TC 121/SC	Oxygen therapy devices
	121/SC2	and related	2/WG 11	
		equipment		
iii	ISO/TC 121/SC	Medical	ISO/TC 121/SC	Medical gas pipeline
	6	gas supply	6/WG 4	systems
		systems		

2.

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

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

S.	Committee/	Title	Working Group	Title
No.	Subcommittee			
i	ISO/TC	Respiratory devices	ISO/TC 121/SC3/ WG	Biocompatibility of
	121/SC3	and related	13	respiratory gas
		equipment used for		pathways
		patient care	ISO/TC 121/SC3/WG	Infant
			15	cardiorespiratory
				monitors

			ISO/TC/SC3/WG16	User-powered
				resuscitators
ii	ISO/TC	Vocabulary and	ISO/TC 121/SC 4/WG1	Respiratory equipment
	121/SC4	semantics		vocabulary

3.

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

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

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

4.

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

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

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

Name of Organization: Draeger India Pvt. Ltd

Nominated Members:

1,

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

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

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

S.	Committee/	Title	Working Group	Title
No.	Subcommittee			
i	ISO/TC 121/SC 3	Respiratory devices and related equipment used for patient care		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	7045646415	vijay.sharma@draeger.com
	Development		
	Engineer		

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

S.	Committee/	Title	Working Group	Title
No.	Subcommittee			
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	ISO/TC 121/SC	Medical gas pipeline
		systems	6/WG 4	systems

Along with these experts the expert nominated from Bureau of Indian Standards is:

Nominated Members:

1.

Name	Designation	Contact Number	Email Id
Satyam Rathore	Scientist-B/	7389102399	satyam.rathore@bis.gov.in
	Assistant Director		

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

S.	Committee/	Title	Working	Title
No.	Subcommittee		Group	
i	ISO/TC 121/ SC 3	Respiratory Devices and Related Equipment Used for Patient Care	ISO/TC 121/SC 3/JWG 1	Critical care ventilators
ii	ISO/TC 121/ SC 3	Respiratory Devices and Related Equipment Used for Patient Care	ISO/TC 121/SC 3/JWG6	Medical Electrical Equipment and Medical Electrical Systems used in Home Care Applications (IEC lead)
iii	ISO/TC 121/ SC 3	Respiratory Devices and Related Equipment Used for Patient Care	ISO/TC 121/SC 3/JWG11	Medical Electrical Equipment and Medical Electrical Systems used in emergency medical services (IEC lead)
iv	ISO/TC 121/ SC 3	Respiratory Devices and Related Equipment Used for Patient Care	ISO/TC 121/JWG12	Medical Electrical Equipment and Medical Electrical Systems for home respiratory care devices
v	ISO/TC 121/ SC 3	Respiratory Devices and Related Equipment Used for Patient Care	ISO/TC 121/ SC3/JWG14	Electromedical diagnostic and patient monitoring equipment (IEC lead)