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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीयमानकमसौदा

फोर्मलडीहाईडडोसीमीटर

Draft Indian Standard

Formaldehyde Dosimeter

[ICS 07.140]

Anatomy and Forensic Sciences Equipment Sectional Committee, MHD 23	Last date of Comment **28 Aug 2024**

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards after the finalization of the draft by the Anatomy and Forensic Sciences Equipment Sectional Committee and approval by the Medical Equipment and Hospital Planning Division Council.

This standard describes the specifications for Formaldehyde Dosimeter, a device designed to measure the aerosolized formaldehyde levels in ambient air, to be used in Health care and education: Anatomy Dissection Halls, Histopathology, Forensic Science Labs., Forensic Medicine and Operation theatres, pharmaceutical industry and Food preservative and Furniture Industries, where Formaldehyde is used for different purposes viz: preservative, disinfectant, sterilization etc.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 ‘Rules for Rounding Off Numerical Values (Second Revision)’. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

1. SCOPE

This Indian Standard specifies basic requirements for Formaldehyde Dosimeter is to be used in Anatomy Dissection Halls, Histopathology, Forensic Science Labs., Forensic Medicine and Operation theatres and Furniture Industries, where Formaldehyde is used for different purposes. These areas are likely to gather large volumes of Formaldehyde, exposing the individuals working there. Dosimeter will accurately measure and display the ambient air formaldehyde levels for taking appropriate action to prevent health hazards.

2. REFERENCES

The standards listed below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below.

IS Number	***Title***
IS 13450 (Part 1)	Medical electrical equipment: Part 1 general requirements for basic safety and essential performance (Second Revision)
IS/ISO 14971	Medical devices - Application of risk management to medical devices (First Revision)

The technical committee has reviewed the provisions of the following International Standard referred in this draft standard proposed to be adopted and has decided that it is acceptable for use in conjunction with this standard:

International Standard/ Other Publication	***Title***
IEC 61010-2-101	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

3. REQUIREMENTS

3.1 General Requirements

The equipment shall comply with the requirements of IS 13450 (Part 1) and IEC 61010-2-101.

3.2 Safety Requirements

The device should comply with all safety requirements as described in IS/IEC 61010-1.
(The electrical requirements for laboratory test and measurement equipment)

3.3 Quality Control and Risk Management

The device shall comply with IS/ISO 14971. (IS/ISO 14971 is a standard which first establishes a framework for risk analysis, evaluation, control, and review, and also specifies a procedure for review and monitoring during production and post-production)

3.4 Functional Specifications

3.4.1 The device should be able to detect HCHO (formaldehyde) as low as 0.01ppm.
3.4.2 Its response time should be in between 30s to 90s.
3.4.3 It should have Stable Electrochemical type sensor for REAL TIME HCHO detection in the air.
3.4.4 Should be capable giving Audible/Visible LED warning for high HCHO concentration.
3.4.5 Should have storage of recordings by default, 150000 and 200000 data records.
3.4.6 Water Protection level should be IP65.
3.4.7 LE D with backlighting design technology to display:
a) HCHO levels
b) Temperature
c) Relative humidity
d) Date and Time

4 MATERIAL AND CONSTRUCTION- Specifications

4.1 Body of the device should be made of Acrylonitrile butadiene styrene.
4.2 It should have Plug and Play Portable device
4.3 Provision for Manual calibration.
4.4 Input keys for entering data like temperature and humidity
4.5 Working temperature: - 40 ~ 70 °C and Working humidity:0 ~ 95% RH not gel
4.6 Lithium Battery: 3.6V DC, 1500mAh (standard), with 12 hours' backup and recharge time of less than 5 hours.
4.7 Power supply: suitable for 230 Volts, 1 phase, AC supply.
4.8 Training at the time of installation is essential

5 TERMS AND DEFINITIONS

5.1 Formaldehyde (HCHO) is a small molecule of a colourless, flammable, strong smelling (pickle-like odour) chemical which easily becomes a gas at room temperature, hence part of a larger group of chemicals known as volatile organic compounds (VOCs). Common names for formaldehyde include formalin, formic aldehyde, paraform, formol, formalin (methanol-free), FYDE, formalith, methanal, methyl aldehyde, methylene glycol, methylene oxide, tetraoxymethalene, oxomethane, and oxymethylene. 37-40 % solution of formaldehyde in water is called Formalin which is used as disinfectant and preservative for biological. specimens.

6 OPERATING PARAMETERS

6.1 Temperature of operation: -20°C~ 50°C
6.2 To ensure an <95%RH non-condensing
6.3 Explosion proof
6.4 Repeatability ≤ ± 2%

7 OPERATING MANUAL

Each device shall be accompanied by an operating manual which shall contain the following information:

a) Instructions and plan for installation
b) Operation of the apparatus
c) Routine maintenance and service

8. MARKING AND PACKING

8.1 The device shall be legibly and indelibly marked at a suitable place with unique device identification number
8.2 The manufacturer's name
8.3 Initials or recognized trade-mark
8.4 Serial number
8.5 The country of manufacture.
8.6 The device may be packed as agreed to between the purchaser and the supplier.
8.7 The device shall be securely packed, in any manner, acceptable to the purchaser, so as to minimize the risk of damage in handling, transport and storage

9 BIS Certification Marking

9.1 The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed there under, and the product(s) may be marked with the Standard Mark.