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*भारतीय मानक मसौदा*

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*Draft Indian Standard*

# E.N.T Workstation

**[ICS 11.040.99]**

Ear, Nose, Throat and Head & Neck Surgery Instruments, Sectional Committee (MHD 04)

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FOREWORD

*(Formal clause will be added later)*

This Indian Standard specifies the general functional requirements of 'ENT workstation', It is used by ENT Doctors to diagnose and treat ENT conditions. These standards cover ENT workstation functional requirements, safety, mobility and accessibility.

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.

*Indian Standard*

# E.N.T Workstation

## 1 SCOPE

This standard specifies the minimum requirements and functionality of ENT workstations used in outpatient medical facilities. It applies to mobile ENT workstations intended for diagnosis and treatment of conditions related to the ear, nose, and throat.

The standard does not encompass specific medical procedures or clinical practices.

## 2 REFERENCES

The standards given 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 these standards.

| ***IS No./ Other Publication*** | ***Title*** |
|---|---|
| IS 13450 (Part 1): 2018 /IEC 60601-1 2012 | Medical Electrical Equipment: (Part 1) General Requirements for Basic Safety and Essential Performance *(second revision)* |
| IS 13450 (Part 1/Sec 2): 2018 / IEC 60601-1-2: 2014 | Medical Electrical Equipment: (Part 1) General Requirements for the Basic Safety and Essential Performance Section 2 Collateral standard: Electromagnetic disturbances — Requirements and tests *(first revision)* |
| IS 62366 : (Part 1) : 2015/IEC 62366-1:2015 | Medical devices — Part 1: Application of usability engineering to medical devices |
| IS/ISO 14971:2019 | Medical devices — Application of risk management to medical devices |
| IS 15223 : (Part 1) : 2016/ ISO 15223-1: 2021 | Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — (Part 1): General requirements |

## 3 TERMS AND DEFINITIONS: -

For the purpose of this standard, the following terms and definitions shall apply.

**3.1 Safety Features:** The built-in components and design elements incorporated into the ENT workstation to minimize the risk of accidents, injuries, and equipment damage.

**3.2 Hose rinsing system** - prevents blockages in the suction system for uninterrupted work

**3.3 Diagnostic Otoscope -** It is a hand-held device (non-endoscopic) primarily designed for examination of the external ear canal, ear canal and tympanic membrane (eardrum) by direct viewing through the ear opening under illumination and magnification on pediatric and adult

patients by clinicians and medically qualified personnel. The otoscope is also intended to assess the flexibility of the tympanic membrane through air pressure.

**3.4 Otoscope Speculum –** It is the cone shaped viewing piece of the otoscope. It comes with various sizes

**3.5 Anti-fog device -** It is used to preheat mirrors to body temperature to prevent fogging.

**3.6 Cold light source –** It is a light generating device intended to provide optimal light and colour rendering at the diagnostic site to perform diagnosis. The Light generated by the device is transmitted by a fiber optic light guide cable for rigid or flexible endoscope or head light.

**3.7 Instrument Storage Tray -** A dedicated instrument tray that is easily accessible and allows for organized placement of instruments and tools used during ENT examinations and procedures.

**3.8 Diagnostic Microscope -** It is an optical instrument designed to illuminate, magnify and visualize the anatomical area to support various diagnoses. The device is operated on a sitting or lying patient and it can be securely moved into the working positions for the treatment.

**3.9 Fiber Optic light guide cable –** It is used to transfer light from one place to another via fiber optic bundle.

**3.10 X-ray film illuminator –** It is used to view the X-ray film

**3.11 Endoscopy Camera -** Used to produce video images in the outpatient Diagnostic where it is indicated for use in ear endoscopy, sinus copy nasopharyngoscopy and laryngoscopes, wherever an endoscope is indicated for use. The optical image is transferred from the diagnostics site to the camera head by a variety of rigid scopes, which are attached to the camera head. The system consists of a camera control unit (CCU) and a camera head with an inbuilt or external LED Light.

**3.12 Endo-scope Holder –** It is used to hold the various rigid endoscopes

***NOTE* — an illustrative sketch of sub-assemblies of ENT workstation is presented in Fig. 1.**

## 4 GENERAL REQUIREMENT

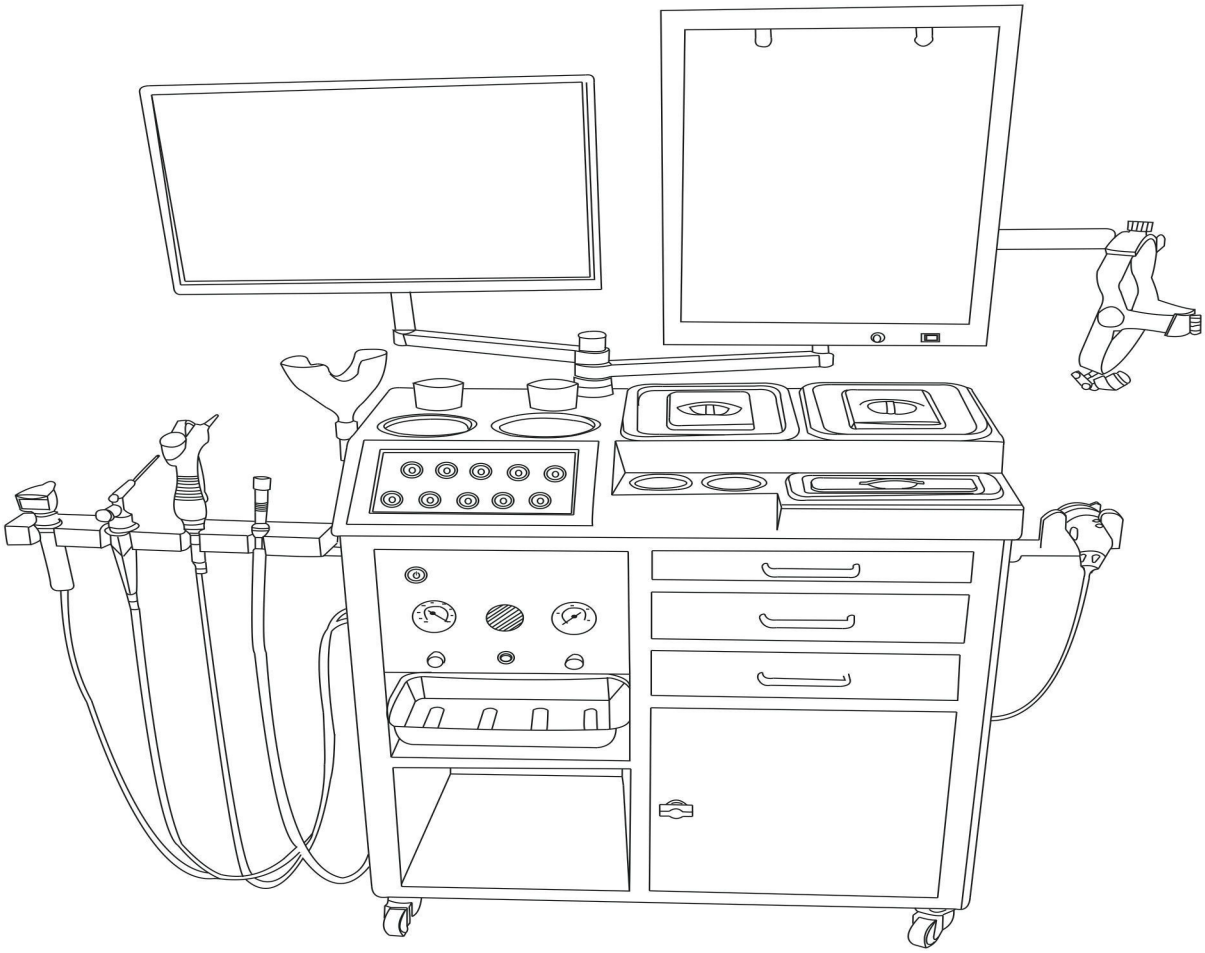

**Figure 1 — Illustrative sketch of ENT workstation**

The following requirements shall be applicable

**4.1** General Requirements for Basic Safety and Essential Performance of the ENT workstation shall be compliant to IS 13450 (Part 1).

**4.2** To avoid cross contamination, the workstation shall have an instrument-handling concept, for the separation of clean and used instruments. It helps the doctors to take clean instruments out of the workstation cabinet/tray on one side then, when the treatment is complete, disposes them on the other side of the cabinet/tray.

**4.3** The workstation shall provide a spacious, clean, and durable work surface for ENT examinations and procedures, facilitating comfortable patient positioning and easy access to the ear, nose, and throat areas.

**4.4** The workstation shall allow for the secure integration and placement of essential ENT equipment.

**4.5** The device shall be user-friendly in shape, size and ensure easy mobility with castors wheels.

**4.6** The workstation shall be equipped with appropriate caster wheels that allow for easy movement while ensuring stability during use and it shall remain stable and secure during examination and comply with the requirements of IS 4034.

**4.7** The workstation materials and surfaces shall be resistant to damage from cleaning agents and disinfectants. Non-porous and smooth surfaces shall be used to facilitate effective cleaning and disinfection.

**4.8** The workstation shall provide instructions for the proper cleaning and disinfection of all workstation components, including surfaces, instrument holders, and storage areas.

**4.9** The workstation shall comply with the power consumption of all the components sufficient to handle combined power requirements. Basic power requirement is 200- 230V AC, 50Hz

**4.10** Shall have a power cable of minimum 3.0 meter.

**4.11** Coating and plating on each part shall be durable to resist discoloration, wear and corrosion

**4.12** The Equipment shall comply with the Application to Risk Management of Medical Equipment on helping identify the risks associated with tools, ensuring patient safety according to IS/ISO 14971.

**4.13** All the functions of the ENT treatment unit start up automatically when you pick up the corresponding handles, and can be controlled using one hand.

**4.14** The workstation's electrical wiring shall be properly installed, protected and secured to prevent damage or accidental disconnection. Connections shall be secure and free from loose or exposed wires.

**4.15** The workstation shall have appropriate grounding and bonding to prevent electrical shocks and ensure safety. Grounding conductors shall be properly installed and connected to electrical equipment.

**4.16** The workstation shall incorporate electrical safety devices to protect against electrical hazards. Circuit breakers or fuses, and other protective devices shall be installed and maintained to prevent overloads and short circuits**.**

**4.17** The workstation shall include measures to protect against electrical leakage.

## 5 Functional requirement:

The essential parts of the device shall meet the following requirements, if the below features are attached to the main device:

### 5.1 Suction System

**5.1.1** The device shall have an oil free vacuum pump of minimum 40 l/min.

**5.1.2** The maximum vacuum pressure shall be between -500mmHg (-0.67bar) to - 675 mmHg (-0.9bar).

**5.1.3** The negative pressure shall be adjustable and the adjusted pressure shall be visible in the vacuum gauge in mmHg.

**5.1.4** Controller shall be below the vacuum gauge and easy to adjust the required negative pressure by the user.

**5.1.5** Suction bottle/secretion canister shall be minimum of 2.0 liters (2000cc) and shall have electronic overfill protection with bacterial filter.

**5.1.6** The waste in the suction bottle shall be easy to dispose and clean

**5.1.7** The outlet suction hose on the patient side shall be easy to clean or dispose and shall have a comfortable length to reach the patient easily.

### 5.2 Hose rinsing system

**5.2.1** The suction hose shall easily match/fit the suction hose-rinsing nozzle

**5.2.2** Water storage tank or container should be between 0.5 to 5 liters. And can be combined with other accessories.

### 5.3 Medication spray system

**5.3.1** The positive pressure of the medication sprayer shall not be more than 2.5kg/cm² (2.5 bar)

**5.3.2** The system shall have a pressure controller to adjust the required pressure from 0.2 to its maximum value but not more than 2.5kg/cm² (2.5 bar)

**5.3.3** Shall have a pressure gauge with the reading in kg/cm² or bar

**5.3.4** The pressure gauge and the controller shall be easy to view and adjust by the user.

**5.3.5** The medication spray bottle shall be easy to clean to avoid contamination

**5.3.6** Clear instruction shall be provided by the manufacturer to the user to use the medicines as per the medication supplier instruction, including the expiry date etc.

### 5.4 Ear irrigation system

**5.4.1** The ear irrigation storage container/canister shall be filled with drinking water quality or isotonic saline solution.

**5.4.2** Clear instruction shall be provided by the manufacturer to periodically clean the storage container/canister against any contamination

**5.4.3** The default temperature shall be 37°C only and to be safe from electric shock.

**5.4.4** The temperature indicator shall be available on the unit.

**5.4.5** Depending on the doctors need the temperature can be adjusted from 32°C to 42°C

5.4.6 Shall have an ear irrigation bowl with suction cannula support.

**5.5 Diagnostic Otoscope**

**5.5.1** The colour temperature of the light can be between 3000 K to 4000 K, warm white or halogen colour (not yellow or white)

**5.5.2** The optical parts should be clear of fog and molds and conform to IS 988: 1959.

**5.5.3** Shall have an electrically operated handle.

**5.5.4** Field of view shall be minimum 4.0mm (at 15mm, +/-1mm) distance

**5.5.5** The view shall be magnified with glass of minimum 2.0x

**5.5.6** Shall have a speculum of minimum 4 for different cannula sizes.

**5.6 Cold Light Source**

**5.6.1** The manufacturer should provide clear instruction for the possible injuries due to heat and brightness.

**5.6.2** The brightness of the light shall be controlled

**5.6.3** The colour temperature of the light can be between 3000 K to 6000 K

**5.6.4** The adapter shall support fiber optic light guide cable

**5.6.5** The cooling system shall not product noise more than 50dBa at 1.0 meter

**5.6.6** Fiber Optic light guide cable shall be minimum of **6** fit length

**5.7 Anti-fog device**

**5.7.1** The preheater is heated up to about 45°C for 5 secs and should be auto cut-off to avoid burn of coil and shock.

**5.8 Headlight/Headband**

**5.8.1** Adjustable knob shall be provided in the headband to fix in users head comfortably

**5.8.2** Light spots can be adjusted, and shall have up/down movement to adjust the light spot.

**5.8.3** Shall support LED light with 3000 K to 6000 K colour temperature

**5.9 X-ray film illuminator**

**5.9.1** Shall have a minimum of two film lock clip

**5.9.2** It shall be based on LED with cool white light.

**5.9.3** Shall be electrically operated.

**5.10** Endoscopy Camera

**5.10.1** The resolution shall be same or more than 720x576 pixels

**5.10.2** Shall have a sensor support with around 1/3" format

**5.10.3** The camera head shall be lightweight and easy to hold

**5.10.4** The cable of the camera shall be organized easily.

**5.10.5** Endoscopy camera holder shall be provided to keep the camera head safely and easily accessible to doctors

**5.10.6** The video output format shall be minimum one or more USB, RCA, BNC, DVI, HDMI and/or display port**.**

**5.11 Endoscopy Monitor**

**5.11.1** The monitor size shall be 19" diagonal or higher.

**5.11.2** The monitor shall support color**.**

**5.11.3** It shall support the aspect ratio of 4:3 and/or 16:9

**5.11.4** Shall support video input format of minimum one or more RCA, BNC, DVI, HDMI and/or display port.

**5.11.5** The monitor shall have a swivel movement to easy adjustment.

**5.11.6** The monitor shall be mounted at a minimum 3 ft. viewing distance from the doctor**.**

**5.12 Endoscope Holder**

**5.12.1** Shall support a minimum of two rigid endoscopy holders.

**5.13 Instrument Storage Tray**

**5.13.1** More than two instrument trays/cabinet shall be provided

**5.13.2** The tray shall not get rusted.

**5.13.3** Shall support a maximum load of 5.0 kg.

**5.13.4** To avoid contamination clean and used instruments shall be organized separately on two or more trays on different sides.

**5.14 Storage Drawer**

**5.14.1** The drawer shall have the maximum load of 4.5 kg.

**5.14.2** It shall have a rails system from smooth movement with locking system.

**5.15 Writing Pad**

**5.15.1** The workstation shall support a writing surface to write and keep prescription with pen.

**5.15.2** The writing pad shall support a load of 5.0 Kg.

**5.15.3** It shall have a pullout rail; at the same time, the user shall not be exposed to any grease of mechanical or electromechanical rails on the writing surface.

## 6 ACCESSORIES

**6.1 Diagnostic Microscope –**

**6.1.1** The handle shall be on the head to pull down the microscope. Once the examination over the head with its armrest should go to its default height.

**6.1.2** When it is pulled down the light should turn on automatically, and off when the handle is released.

**6.1.3** It shall support minimum 3-step magnification**.**

## 7 TEST

**7.1** IS 13450 (Part 1): 2018 / IEC 60601-1 2012.

The device shall conform to the requirement of Medical Electrical Equipment: Part 1 General Requirements for Basic Safety and Essential Performance (Second Revision)

**7.2** IS 13450 (Part 1/Sec 2): 2018 / IEC 60601-1-2: 2014. The device shall conform to the requirement of Medical Electrical Equipment: Part 1 Medical Electrical Equipment: Part 1 General Requirements for the Safe Section 2 Collateral standard: Electromagnetic disturbances — Requirements and tests (First Revision) shall apply.

## 8 MARKING

**8.1** Each portable ENT Workstation shall be marked with the following:

a) Manufacturer's name/ trademark,

b) Name and address of the manufacturer,

c) Name and address of the marketer,

d) Month and year of manufacture,

e) Unique Device Identification (UDI) / serial number

**8.2 BIS CERTIFICATION MARKING**

The product(s) that meet the requirements of this standard can be certified through the conformity assessment schemes under the Bureau of Indian Standards Act, 2016, and the associated Rules and Regulations. Once certified, the product(s) can be marked with the Standard Mark as an indication of compliance.

The marketing of ENT workstation must be accurate and truthful. It must not make any false or misleading claims about the safety or effectiveness of the workstation.

## 9 PACKING

The device and its accessories must be securely packed within a case or box to ensure that they remain intact and protected during storage and transportation.

**9.1** The case for the device should be constructed from a suitable material and designed in a manner that, when the device and accessories are well protected. This ensures that the contents remain secure and protected during storage and transportation.