भारतीय मानक **IS XYZ : 2024**

Indian Standard

Safety Standards and essential performance requirements of bed head panels , Gas Outlets and OT pendants.

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PRE STANDARDISATION DRAFT

Safety and essential performance requirements of bed head panels, gas outlets(OT Pendent)

FOREWORD

This Indian Standard specifies the Safety and essential performance requirements of Bed Head Panels and gas outlet (OT Pendants). The healthcare industry relies on the seamless integration of technology and design to ensure patient safety and optimize medical outcomes.

1. SCOPE

This Indian Standard provides the basic safety and essential performance requirements of Bed head panels and OT pendants which includes electrical safety ,required Test methods ,design and constructional aspects and cleaning and maintenance of Bed head panels and OT pendants..

This document does not covers the requirements of plugs , electrical sockets.

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 indicated below:

- IS/ISO 9170-1 : 2008 ‘Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum’.All the tests and various parts are covered under this ISO standard regarding the terminal units and gas supply

- IS/ISO 13485 :Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes

- IS/ISO 14971 : Medical Devices - Symbols to be Used with Medical Device labels, Labelling and Information to be Supplied Part 1 General requirements(Second Revision).

-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 13871 : 2021 : Powder Coating Of materials

3. TERMINOLOGY

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

3.1 Bed Head Panels : Integrated device of electrical and medical gas supply with mounting attachments.of two types vertical and horizontal , both are used in the same areas.i.e General wards/ICUs.

3.2 OT Pendant : An OT pendant, also known as an operating theater pendant or surgical pendant, is a medical equipment fixture mounted to the movable hydraulic shaft attached to the ceiling commonly used in operating rooms and surgical suites. It's essentially an overhead arm or boom that suspends medical equipment.

3.3 Equipotential surface : An equipotential surface is a design approach that guarantees all conductive parts in a bed head panel are at the same electrical potential, creating a safe zone around the patient.

3.4 Gas Outlets : Gas convenience outlets allow for the ease and flexibility of installing gas appliances. The outlet allows a quick disconnect so an appliance can be 'unplugged', similar to an electric appliance, in order to move it or store it for later use.

3.5 Medical gas :Medical gas is single or mixed gases supplied centrally by medical piping systems for the treatment, diagnosis, or prevention of patients' diseases, or for driving surgical tools and instruments, etc.

3.6 Pressure regulator integrated with cylinder valve :The pressure regulator is attached to the valve outlet connector in order to reduce the gas flow to a working level. The Compressed Gas Association has intentionally made certain types of regulators incompatible with certain valve outlet connections to avoid accidental mixing of gases that react with each other.

3.7 Mountable equipment : The medical equipment which can be mounted/attached to the bed head panels,OT pendants which can be attached directly or by use of support.

3.8 Multiple Socket Outlet MSO : one or more socket-outlets intended to be connected to, or integral with, flexible cables, cords or Medical Electrical Equipment providing Supply Mains or equivalent voltage

3.9 Flammable mixture : mixture of a flammable anaesthetic vapour with air in such a concentration that ignition can occur under specified conditions

3.4 Safety Guard : part of equipment specifically used to provide protection by means of a physical barrier

3.5 Venting :The process which allows a gas to be removed from the escaping point safely to the atmosphere

3.3 Accompanying Document: Document accompanying Medical Electrical equipment, an equipment or an accessory and containing information for the Responsible organisation particularly regarding Basic Safety and Essential requirements.

4. REQUIREMENTS (General,Functional,Performance)

4.1 Medical Gas handling and safety requirements:

Terminal units shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using risk management procedures in accordance with ISO 14971 and which are connected with their intended application, in normal condition and in single fault condition.

4.2 Gas outlet Material Requirements:

Materials in contact with the gases, during normal use shall be resistant to corrosion and compatible with oxygen, the other gases and their mixtures in the temperature range specified and the finalized product shall be powder coated with minimum thickness of 4-5 micrometers to ensure durability comply with IS 13871 : 2021 : Powder Coating Of materials

4.3 Protection against electric shock

Circuit Protection:

Overcurrent Protection Devices: OT pendant shall have Fuses and circuit breakers, used to protect circuits from overcurrent conditions, which can cause overheating and potential shock hazards. complying with IEC 60947-1 and 60947-2

For bed head panels the supply mains board shall Fuses and circuit breakers, used to protect circuits from overcurrent conditions, which can cause overheating and potential shock hazards. complying with IEC 60947-1 and 60947-2

OT Pendants shall have Surge Protectors: Protect sensitive electronic equipment from voltage spikes,- which can lead to electrical shock; these should comply with IEC 62305.

4.4Separation of supplies

- Each electrical compartment within a medical supply unit shall be separated from the gas and liquid compartments by a barrier, except where flexible hoses are used for medical gas supply. If electrical cables are installed together with flexible hoses or pipes for medical gas supply, the cables shall be insulated and sheathed, or installed in a flexible conduit complying with IEC 61386-1:2008+A1:2017.

-Terminal units connected to a compressed medical gas distribution system used for oxidising gases or connection points for liquids, shall be located at least 0.2 m from any electrical component which can spark in normal condition or in single fault condition . This does not apply to components where the value of the root mean square (RMS) voltage with no load and the RMS value of the short circuit current do not exceed 10 VA (e.g. intercommunication, voice, data, TV components). The distance shall be measured on the surface of the unit from the centre line of the terminal unit to the nearest exposed part of the electrical accessory/component. Where oxygen, oxygen 93, or nitrous oxide medical gas pipelines or terminal units are contained within a medical supply unit, the specific chamber housing these components shall be vented to atmosphere.complying HTM_02-01_Part_A

4.5 Venting for gas leakage

Where these terminal units are supplied by copper pipelines, these are not subject to a single fault condition and shall be considered a normal condition.
Where these terminal units are supplied by hoses, the assembly of the completed enclosure shall be supported by a manufacturer's leakage test to demonstrate an appropriate evacuation of oxidising gases under single fault condition.

4.6 Method(s) of sterilization

Equipment or its parts intended to be sterilized shall be classified according to the method(s) of sterilization as indicated in the instructions for use by methods validated and described by the Manufacturer

4.7 Suitability for use in different conditions

The Equipment shall possess the physical and chemical properties to be used in oxygen rich environment (93 %) and at different temperatures **(ICU And General Ward Temp Range as per geographic ranges)**

4.8Terminal units for different pressures

Terminal units for the same gas at different nominal distribution pressures (e.g. medical air and air for driving surgical tools) shall have gas-specific connection points for each pressure range.compliance with the **ISO 9170-1:2017** requirements

4.9 Gas-specific connection point

Each terminal unit shall include a gas-specific connection point that shall accept the appropriate gas specific probe only. This connection point shall be included in a socket. .compliance with the **ISO 9170-1:2017** requirements

4.10 Connection of terminal units to the pipeline

Except for connection to a disposal system for nitrogen or air for driving surgical tools, the base block of a terminal unit shall be designed and manufactured for either permanent (e.g. by brazing or welding) or gas-specific (e.g. by means of an NIST, DISS or SIS body) connection to a pipeline distribution system. The connection shall comply with ISO 7396.

4.11 Disconnection force and torque

The force and the torque required to release the locking mechanism of Terminal gas units shall be

a) a push or pull of not more than 110 N and not less than 20 N, and/or
b) a torque of not more than 1 Nm and not less than 0,1 Nm.

The test should be followed by the standard **ISO 9170-1:2017**

4.12 Leakage

The leakage from a terminal unit with or without the probe inserted shall not exceed 0,296 ml/min (which is equivalent to 0,03 kPal/min) complying with **ISO 9170-1:2017** followed by test for leakage

4.13 Nuts and screws

All the nuts and screws used for fixation of all the parts of bed head panels must be non retractable such that they can withstand vibrations caused due to regular attachments or detachments of the plugs,equipment,and gas pipes.

4.14 Earthing point

The bed head panels must contain earthing points such that it ensures.

-Protecting from electric shock: Earthing points prevent electric shocks by providing a path for fault currents to flow to the earth also

- reducing risk of fire: Earthing points reduce the risk of fire by preventing overheating and potential ignition points.

-Ensuring device safety: Earthing points protect devices from electrical damage by providing a path for leakage current.

4.13 Electrical requirements

If required by regional or national regulations, terminal units shall be fitted with means for connection to an equipotential bonding installation.

4.14 Support

: Supporting base must be attached to the Bed head panes(Horizontal and vertical) which can withstand the load of maximum 10 kg and for OT pendants should be of 20 kg(exceptional should be mentioned during packaging)

5 EXTRA REQUIREMENTS

5.1 Cleaning

The sterilization of medical electrical equipment is guided by international standards, which include :

- ISO 7396-1:2016 - Medical gas systems - Part 1: Pipework and equipment

- ISO 7396-2:2017 - Medical gas systems - Part 2: Anaesthetic gas scavenging systems

- NFPA 99:2020 - Health Care Facilities Code

- ASSE 6000:2018 - Medical Gas Systems

5.2 Lubricants and Disinfectants

If lubricants are used in equipment and operating the equipment,, they shall be compatible with oxygen, the other medical gases and their mixtures in the temperature range specified .

5.3 Maintenance of wires and pipes

To prevent excess length of the wire or pipes on the ground when attached to the bed head panel/OT pendant should be maintained , this is one of the preventive measures for causing chaos during an emergency.

5.4 Aesthetics

The aesthetics of bed head panels are essential for creating a comforting and healing environment in healthcare settings which include Color and finishing.

6 Test methods

6.1 Terminal units of medical gas.

6.1.1 Test for leakage: To ensure there is no leakage from the terminal units when provided with different pressures of the medical gas in comp with ISO 7396-1,

Clause 5.3**.**

6.1.2 Test for endurance of sockets

Tests the socket's ability to withstand:

- Mechanical stress (insertion, withdrawal, and vibration)
- Electrical stress (overvoltage, undervoltage, and short circuits)
- Environmental stress (temperature, humidity, and water exposure)

ISO 7396-1

6.1.3 Test for cross connection : to ensure there is no cross connection between the gas outlets.

- ISO 7396-2:2017 - Clause 6.3.4 - "Check for cross-connection"

- NFPA 99:2020 - Section 5.3.4 - "Cross-Connection Testing"

- ASSE 6000:2018 - Section 4.3.4 - "Cross-Connection Testing"

6.2 Testing the endurance of electrical sockets

To ensure the endurance of the electrical sockets attached to the bed head panels.

- IEC-60884-1: This is the most general one, and it is the basis for other certifications such as China Compulsory Certification (CCC) or UL (Underwriters Laboratories) in the United States

6.4 Chemical Resistance Test:

Method: Expose the panel to various chemicals commonly found in hospital environments (e.g., disinfectants, cleaning agents) for a set period of 10 hours.-.

Criteria: Inspect for any changes in the panel’s surface, such as discoloration, swelling, or corrosion.

6.5 Abrasion Resistance Test:

For ABS: The following tests have to be conducted complying with the following standards

1. Taber Abrasion Test (ASTM D1044)- Uses a Taber abrasion machine to evaluate the resistance of ABS to abrasion.

2. Martindale Abrasion Test (ISO 12947-1) - Uses a Martindale machine to evaluate the

abrasion resistance of ABS fabrics and plastics.

3. Wet Abrasion Test (ASTM D2486) - Evaluates the resistance of ABS to abrasion when exposed to water.

4. Dry Abrasion Test (ASTM D1242) - Evaluates the resistance of ABS to abrasion under dry conditions.

5. Falling Sand Abrasion Test (ASTM D968) - Evaluates the resistance of ABS to abrasion caused by falling sand.

6. Grit Abrasion Test (ASTM D613)- Evaluates the resistance of ABS to abrasion caused by grit and sandpaper.

7. Abrasion Resistance by Rotary Drum (ISO 4649) - Evaluates the resistance of ABS to abrasion using a rotary drum machine.

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6.6 Test for durability of markings and colour coding

Rub the markings and colour coding by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol and then for 15 s with a cloth rag soaked with isopropanol. Carry out this test at ambient temperature. Verify that the markings required are still legible.

7 Marking

7.1 Terminal units, probes and their gas-specific components shall be durably and legibly marked with the symbol of the relevant gas in accordance with Table

The test for the durability of markings is given in

NOTE In addition to the symbol, the name of the gas can be used.

7.2 The height of the lettering shall be at least 2,5 mm.

7..3 Terminal units and probes shall be marked with the manufacturer's name or identification mark and, if applicable, with additional means to ensure traceability such as type, batch or serial number or year of manufacture.

Table — Symbols and colour coding for medical gases

Medical gas or mixture	**Symbol**	**Colour coding**[a, b]
Oxygen	O_2	White
Oxygen 93	$O_2$93	White-Emerald green
Nitrous oxide	N_2O	Blue
Medical air	Air[c]	Black-White

[a] According to ISO 32, except vacuum.

[b] An example of yellow is given by NCS 0060Y in SS 01 92 02.

[c] National languages may be used for air and vacuum.

8.1 Technical description

Terminal units shall be accompanied by a technical description; instructions for use, storage and transportation; and an address to which the operator can refer.

8.2 Instructions

8.2.1 The manufacturer shall provide instructions for installation and a reference to the testing procedures for terminal units given in ISO 7396-1.

8.2.2 Instructions for use shall include information necessary for the operation of the terminal unit in accordance with its specification and shall include a description of the procedure for connection and disconnection of probes. Instructions for use shall give detailed instructions for cleaning, inspection and preventive maintenance to be performed by the operator or by authorized persons, and shall recommend the frequency of such activities. A list of recommended spare parts shall be provided.

8.2.3 Particular attention shall be given to the following safety-related items:

the danger of fire or explosion due to the use of lubricants not recommended by the manufacturer.

8.3 BIS Certification Marking: The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

8.4Packaging of Bed Head Panels After Manufacturing

Proper packaging of bed head panels is crucial to ensure they arrive at their destination undamaged and ready for installation. The packaging process includes the following steps:

8.4.1. Protective Wrapping:

- Each bed head panel is wrapped in protective materials such as bubble wrap or foam sheets to prevent scratches and surface damage.

8.4.2. Edge Protection:

- Reinforced edge protectors are applied to the corners and edges of the panels to safeguard against impacts during handling and transportation.

8.4.3. Sealed Plastic Cover:

- The wrapped and protected panels are then placed in a sealed plastic cover to shield them from dust, moisture, and contaminants.

8.4.4. Custom-Fit Packaging:

- Panels are placed in custom-fit corrugated cardboard boxes or crates, ensuring a snug fit to minimize movement and potential damage.

8.4.5. Shock Absorbers:

- Foam inserts or other shock-absorbing materials are used inside the boxes to cushion the panels against shocks and vibrations.

8.4.6. Labeling:

- Each package is clearly labeled with handling instructions, such as "Fragile," "Handle with Care," and "This Side Up," along with the product details and destination information.

8.4.7. Palletization:

- For larger shipments, boxes are securely strapped to pallets to facilitate safe handling with forklifts and to prevent shifting during transit.

8.4.8. Inspection and Quality Check:

- A final inspection ensures that each package meets quality and safety standards before shipment.

These packaging measures ensure that bed head panels are well-protected during transportation, preserving their quality and readiness for installation upon arrival.