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भारतीय मानक मसौदा

इंट्राक्रानियल प्रेशर मॉनिटर्स के लिए विशिष्टता

Draft Indian Standard

Specification for Intracranial Pressure Monitors

ICS: 11.040.01

Neurosurgery Instruments, Implants & Accessories Sectional Committee MHD 07

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FOREWORD

(Formal clause will be added later)

This Indian Standard specifies the general functional requirements of 'Intracranial Pressure Monitors (ICP) '.These are devices with application an invaluable tool for healthcare professionals. ICP monitoring has revolutionized our understanding of brain physiology and has greatly enhanced our ability to diagnose, treat, and manage various neurological conditions.

The human brain, encased within the protective skull, is an intricate and delicate organ that governs our thoughts, emotions, and bodily functions. However, when faced with traumatic injuries, infections, or other neurological conditions, the brain's delicate equilibrium can be disrupted, leading to increased intracranial pressure. Monitoring and managing ICP are of paramount importance in preventing further damage and ensuring the best possible outcomes for patients.

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

The scope of an Intracranial Pressure (ICP) monitor encompasses several key aspects related to its function, application, and importance in medical practice. Here is a detailed overview

Overall, ICP monitoring is a critical tool in managing conditions affecting intracranial pressure, providing essential information that supports timely and effective treatment decisions

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) : 2024	Medical electrical equipment Part 1 General requirements for basic safety and essential performance (Third Revision)
IS/ISO 81060-2 : 2018	This document covers ambulatory blood pressure monitoring
IS 17750 (Part 5) : 2021 / ISO 14708-5:2020	Implants for surgery Active Implantable Medical Devices Part 5: Circulatory Support Devices
IS/ISO 10993-3 : 2014	Biological evaluation of medical devices Part 3 Tests for Geno toxicity, Carcinogenicity and Reproductive toxicity (First Revision)
IS/ISO 10993-4 : 2017	Biological evaluation of medical devices Part 4 Selection of tests for interactions with blood
IS/ISO 10993-5 : 2009	Biological evaluation of medical devices Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-6 : 2016	Biological evaluation of medical devices Part 6 Tests for local effects after implantation
IS/ISO 10993-11 : 2017	Biological evaluation of medical devices Part 11 Tests for systemic toxicity
IS/ISO 11737-1 : 2018	Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products
IS/ISO 11737-2 : 2019	Sterilization of health care products Microbiological methods Part 2 Tests of sterility performed in the definition validation and maintenance of a sterilization process

3 TERMS AND DEFINITIONS: -

3.1 Intracranial Pressure (ICP): The pressure exerted inside the skull and on the brain tissue. It is typically measured in millimeters of mercury (mmHg) or centimeters of water (cmH2O).

3.2 ICP Waveform: The graphical representation of the fluctuation in intracranial pressure over time. It typically shows the pulsatile components, such as the arterial and venous pressure waves, and can provide insights into cerebral perfusion dynamics.

3.3 ICP Monitoring Device: The hardware and equipment used to measure, record, and display intracranial pressure. It includes invasive catheters or sensors, transducers, amplifiers, data acquisition systems, and display units.

3.4 Calibration: The process of adjusting or verifying the accuracy of an ICP monitoring device by comparing its measurements against a known reference or standard. Calibration is typically performed periodically to maintain measurement accuracy.

3.5 Zero Reference Level: The baseline or reference point against which intracranial pressure measurements are referenced. It is typically set at a specific position relative to the patient, such as the level of the external auditory canal or the tragus.

3.6 Intracranial Hypertension: A condition characterized by abnormally high intracranial pressure. It may indicate underlying pathology or medical conditions and requires appropriate management to prevent further complications.

4 GENERAL REQUIREMENT

The general requirements of an ICP (Intracranial Pressure) monitor can vary based on factors such as the intended use, specific clinical setting, and regulatory guidelines.

4.1 Measurement Accuracy: The ICP monitor should provide accurate and reliable measurements of intracranial pressure. It should have a defined measurement range, typically from 0 to a certain maximum pressure, such as 50 mmHg.4.2 Data Storage:

4.2 Calibration: The monitor should be calibrated regularly to maintain measurement accuracy. Calibration procedures should be specified and followed according to standards or manufacturer guidelines.

4.3 Electrical Safety: The ICP monitor should comply with electrical safety standards to ensure patient safety. It should have appropriate insulation, grounding, and protection against electrical hazards Size and Portability:

4.4 Mechanical Safety: The device should be designed and constructed to ensure mechanical safety. It should be robust, resistant to impact or accidental drops, and free from any sharp edges or protrusions that could cause injury to the patient or user.

4.5 User Interface: The monitor should have an intuitive user interface, with clear and easy-to-understand controls and display. It should provide real-time, accurate, and easily readable data to the healthcare professional.

4.6 Alarm System: An ICP monitor should include an alarm system to alert healthcare providers when the intracranial pressure exceeds predetermined thresholds or when other critical conditions arise. The alarm system should be audible and visible, with adjustable settings and clear alarm indications.

4.7 Data Recording and Connectivity: The monitor should have the capability to record and store ICP measurements over time. It should also provide connectivity options to transfer data to other systems or devices for further analysis and integration into the patient's medical record.

4.8 Infection Control: The device should be designed to facilitate infection control practices. It should be easy to clean and disinfect, and should incorporate materials and surfaces that are resistant to microbial growth.

4.9 Power Source: The ICP monitor should have a reliable power source, such as battery backup or a secondary power supply, to ensure continuous operation during power outages or when the patient is being transported.

4.10 Documentation and User Manuals: The monitor should come with comprehensive documentation, including user manuals, operating instructions, maintenance procedures, and troubleshooting guidelines.

Reference range of intracranial pressure monitoring

Age group	ICP value in mm of Hg
Adults (Supine)	5 - 15
Juvenile	3 – 7
Infants	1.5 - 6

5 FUNCTIONAL REQUIREMENT

The functional requirements of an ICP monitor typically include the following:

5.1 Accuracy measurement: The ICP monitor should provide accurate and reliable measurements of intracranial pressure. It should have a high level of precision and accuracy to ensure that the readings reflect the true pressure within the skull.

5.2 Continuous monitoring: The ICP monitor should be capable of continuously monitoring intracranial pressure over an extended period. This allows for real-time assessment of pressure changes and trends, providing valuable data for diagnosis, treatment optimization, and complication management.

5.3 Sensitivity and dynamic range: The ICP monitor should have the sensitivity to detect small pressure changes and a wide dynamic range to capture both normal and elevated intracranial pressure levels. This ensures that it can effectively monitor a range of clinical conditions and accommodate different patient needs.

5.4 Reliability and stability: The ICP monitor should be reliable and stable, providing consistent and accurate measurements over time. It should be resistant to interference from external factors, such as electromagnetic fields or patient movements that could affect the accuracy of the readings.
5.5 User-friendly interface: The ICP monitor should have a user-friendly interface that allows healthcare professionals to easily operate and interpret the data. The interface should display the pressure readings clearly and provide intuitive controls for adjusting settings or accessing additional features.
5.6 Alarm system: An alarm system is essential in an ICP monitor to alert healthcare professionals when intracranial pressure exceeds predefined thresholds or when sudden pressure changes occur. The alarms should be clear, distinguishable, and adjustable to suit the specific needs and preferences of the medical staff.
5.7 Data recording and analysis: The ICP monitor should have the capability to record and store data for further analysis and review. It should offer options for data retrieval, export, and integration with other medical records or monitoring systems.
5.8 Compatibility and connectivity: The ICP monitor should be compatible with other medical equipment and systems commonly used in critical care settings. It should have the ability to connect to a central monitoring station or interface with electronic health record systems for seamless data sharing and integration.
5.9 Patient safety features: The ICP monitor should incorporate safety features to minimize the risk of complications or harm to the patient. This may include features such as non-invasive monitoring options appropriate sterilization and infection control measures for invasive monitors, and secure fixation mechanisms to prevent dislodgement.
5.10 Portability and durability: Depending on the clinical setting, the ICP monitor may need to be portable and durable. This allows for flexibility in monitoring patients in different locations and ensures that the device can withstand the demands of a healthcare environment.

These functional requirements ensure that an ICP monitor can effectively and accurately measure intracranial pressure, provide continuous monitoring, offer user-friendly operation, and facilitate data analysis and integration for optimal patient care.

6 Shape and Dimensions:

The shape and dimensions of an Intracranial Pressure (ICP) monitor can vary depending on the specific design and manufacturer. However, I can provide you with some general information regarding the typical shape and dimensions of an ICP monitor.

Shape: ICP monitors often have a compact and portable design to facilitate their use in various clinical settings. They are typically rectangular or square, with rounded corners for enhanced safety and ergonomics. The front face of the monitor usually features a display screen for visualizing data and control buttons for user interaction.

Dimensions: The dimensions of an ICP monitor can vary, but they are typically small and lightweight to ensure ease of use and portability. Here are some approximate dimensions you might find for an ICP monitor:

a) Width: Typically ranges from 5 to 8 inches (12.7 to 20.3 cm).
b) Height: Usually ranges from 3 to 6 inches (7.6 to 15.2 cm).
c) Depth: Generally, around 1 to 2 inches (2.5 to 5.1 cm).

7 DEVICE BODY

A single-channel physiological recorder typically consists of the following device components:

7.1 Control Buttons or Knobs: Following IEC 62366-1, these buttons or knobs allow the user to navigate through the recorder's functions and settings.

7.2 Input Port: This is where the physiological sensor or electrode is connected to the recorder. As per IEC 60601-1, Clause 201.14, the input port may have specific connectors or jacks depending on the type of signal being recorded (e.g., ECG leads, EEG electrodes, or EMG sensors).

7.3 Sensor or Electrode: As per IEC 60601-1, this is the component that comes into contact with the body and detects the physiological signal of interest. The type of sensor or electrode used depends on the specific physiological measurement being recorded.

7.4 Amplifier: Manufacturer's Internal Standards and Design controls addresses the design, safety, and performance of amplifiers for their single-channel physiological recorder. The physiological signal detected by the sensor or electrode is usually weak and needs to be amplified for accurate measurement.

7.5 Microprocessor or Controller: It can help identify potential risks associated with software malfunctions or failures and implement measures to mitigate these risks .The microprocessor or controller is responsible for managing the overall operation of the physiological recorder.

7.6 Display: According to ISO 14971, It can be an LCD screen, OLED display, or any other visual interface that shows real-time waveforms, numerical values, or graphical representations.

7.7 Memory: The memory can be used to store a certain duration of data or may allow for external storage options such as SD cards or USB drives.

7.8 Power Source: While ISO 14971, does not specify context related to the power sources, but we can take reference to Clause 4.3 of ISO 14971 as it outlines the general requirements for risk management planning, which includes identifying and analyzing potential hazards related to the device's design, construction, and use, as well as assessing risks associated with the device's intended power sources.

7.9 Connectivity Options: Some recorders may include connectivity options such as USB ports, Bluetooth, or wireless capabilities to allow data transfer to external devices or remote monitoring applications.

8 APPLICATION BASED SOFTWARE

8.1 ECG Analysis Software: This software provides advanced tools for analyzing and interpreting ECG data captured by the single-channel recorder as per Clause 201.5 of IEC 60601-2-25.

8.2 Sleep Analysis Software: It provides detailed reports on sleep patterns and disturbances based on the recorded physiological signals as per IEC 60601-2-47, Clause 201.5.

8.3 Stress Test Analysis Software: Software designed for stress testing applications includes features for analyzing ECG recordings during stress tests as per Clause 201 of IEC 60601-2-51. In this clause, subsection 201.11.1 is particularly relevant.

8.4 Remote Monitoring Software:. It includes features like secure data transmission, data visualization, trend analysis, and customizable alerts for abnormal values or events.

8.5 Sports Performance Analysis Software: Software designed for sports and fitness applications provides tools to analyse physiological data captured during exercise or training sessions.

8.6 Data Management and Reporting Software: This software enables efficient data management, storage, and retrieval of recorded physiological data. It may include features for patient data organization, report generation, data export in various formats.

9 ACCESSORIES

It's important to note that the specific accessories and their usage may vary between different ICP monitoring systems and healthcare facilities. Always refer to the manufacturer's instructions and follow the guidelines provided by healthcare professionals when using an ICP monitor and its accessories.

8.1 Catheter: This is the main component of the ICP monitor system. It is a thin, flexible tube that is inserted into the brain to measure the intracranial pressure. The catheter is available in different lengths and diameters to suit the patient's needs.

8.2 Connector: The connector is used to connect the catheter to the monitoring system. It ensures a secure and leak-proof connection between the catheter and the monitoring device.

8.3 Pressure Transducer: The pressure transducer converts the pressure measurements from the catheter into electronic signals that can be processed and displayed on the monitoring system. It is a key component for accurate pressure monitoring.

8.4 Monitoring System: The monitoring system is the main unit that receives the pressure signals from the transducer and displays the intracranial pressure readings. It may include a display screen, control buttons, alarms, and data storage capabilities.

8.5 Transducer Cable: The transducer cable is used to transmit the pressure signals from the transducer to the monitoring system. It is a specialized cable designed to carry the sensitive pressure signals without interference.

8.6 Mounting Bracket/Stand: These accessories are used to securely mount the monitoring system, keeping it stable and easily accessible for healthcare professionals. They may include brackets, clamps, or stands that can be attached to beds, walls, or other surfaces.

8.7 Sterile Dressing: After the catheter insertion, a sterile dressing is applied to the site to maintain cleanliness and prevent infection. The dressing helps to protect the insertion site and keep it secure.

8.8 Calibration Kit: Periodic calibration of the ICP monitor is essential to ensure accurate pressure readings. A calibration kit may include calibration tools and solutions to calibrate the pressure transducer and maintain the system's accuracy.

10 TEST

Here are some key tests conducted during the testing phase:

10.1.1 Usability Testing:

a) Engage healthcare professionals or potential end-users to conduct usability testing
b) Gather feedback on the overall user experience, ergonomics, and ease of use
c) Evaluate the intuitiveness and efficiency of the user interface
d) Identify any areas for improvement or potential user interface enhancements

10.2 Durability and Reliability Testing:

a) Subject the prototype to rigorous durability testing to ensure it can withstand real-world conditions and usage
b) Perform mechanical stress tests to assess the robustness of the enclosure and mounting mechanisms
c) Conduct environmental testing to evaluate the performance of the ICP monitor under various temperature, humidity, and vibration conditions
d) Verify the reliability and stability of pressure measurements over extended periods of operation

10.3 Electrical Safety Testing:

a) Verify compliance with electrical safety standards and regulations
b) Perform insulation resistance tests to ensure electrical components are adequately insulated
c) Conduct grounding and leakage current tests to assess safety against electrical hazards
d) Test the ICP monitor for electromagnetic compatibility (EMC) to ensure it does not interfere with or be affected by other medical equipment

10.4 Iterative Design Improvements:

a) Analyses the results of the functional, usability, durability, and safety tests
b) Identify any design flaws, performance gaps, or user feedback for improvement
c) Make necessary design iterations and modifications to address the identified issues
d) Repeat the prototyping and testing process as required validation of the changes Setup and Configuration

10.5 Regulatory Compliance:

a) Ensure that the prototype meets the applicable regulatory requirements for medical devices.
b) Prepare the necessary documentation, including design controls, risk analysis, and testing reports, to support regulatory submissions.

Collaborate with regulatory experts to navigate the process and ensure compliance with relevant standards and regulations

11 MARKING

11.1 When it comes to mandatory markings on ICP monitors, specific requirements may vary depending on regulatory standards and local guidelines. However, here are some common markings that are typically required or recommended:

a) Manufacturer’s name/ trademark,
a) Manufacturer's Name and/or Logo: The ICP monitor should display the name or logo of the manufacturer for identification purposes.
b) Model and Serial Number: Each monitor should have a model and serial number assigned by the manufacturer. These markings help with product traceability and maintenance tracking.
c) Date of Manufacture: It is common for medical devices to display the date of manufacture, which helps determine the age and potential warranty coverage of the monitor.
d) Regulatory Compliance Marks: Depending on the region or country, ICP monitors may need to display regulatory compliance marks or symbols, such as CE marking for compliance with European Union directives or FDA approval markings for devices sold in the United States.

e) Power Supply Requirements: The monitor may include markings indicating the required power supply specifications, such as voltage range and frequency. This ensures proper electrical compatibility.
f) Safety Information: Essential safety information, including warnings, precautions, and usage instructions, should be clearly displayed on the monitor. This helps users operate the device safely and minimizes the risk of misuse.
g) User Interface Labels: The monitor should have clear labels for its various controls, buttons, and ports. These labels assist users in operating the device effectively and navigating its functions.
h) Alarm Indicators: If the ICP monitor has built-in alarm capabilities, it should have visible markings or symbols to indicate the presence and status of alarms. This allows healthcare providers to identify alarm conditions promptly.

12 BIS CERTIFICATION

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 there under, and the product(s) may be marked with the Standard Mark.

13 PACKING

The packaging of ICP monitors typically involves several considerations to ensure the safe transportation and storage of the equipment. While I do not have information on the specific packaging designs of all ICP monitors on the market, I can provide you with some general guidelines followed in medical device packaging. Here are some common practices:

13.1.1 Protection: The primary purpose of the packaging is to protect the ICP monitor from physical damage during shipping and handling. The packaging should be designed to absorb shocks, vibrations, and other impacts that may occur during transportation.

13.1.2 Sterility: If the ICP monitor is a sterile product, the packaging should maintain its sterility until it reaches the end-user. It may include a sterile barrier, such as a sealed pouch or container, to prevent contamination.

13.1.3 Cushioning: The packaging should include appropriate cushioning materials like foam inserts, bubble wrap, or air-filled pouches to provide additional protection against impact and minimize the risk of damage to the monitor.

13.1.4 Sealing: Proper sealing of the packaging is crucial to protect the ICP monitor from dust, moisture, and other environmental factors. Sealing methods can include adhesive closures, heat-sealing, or zip-lock mechanisms, depending on the packaging design.

13.1.5 Labelling: The packaging should have clear and accurate labelling that includes essential information such as product name, model number, serial number, manufacturer details, handling instructions, and any necessary safety or warning labels.

13.1.6 Instructions for Use: In addition to external labelling, the packaging may include an instruction manual or user guide to provide instructions on how to handle and use the ICP monitor effectively.

13.1.7 Compliance: The packaging should comply with relevant industry standards and regulations, such as those set forth by the FDA (U.S. Food and Drug Administration) or other regulatory bodies in different countries.

13.2 Drop Test after Packing:

The drop test height refers to the distance from which the ICP monitor is dropped onto a hard surface. The height can vary depending on the specific requirements or standards applicable to the device. Common drop test heights for electronic devices can range from 76 cm (30 inches) to 122 cm (48 inches), but it's important to refer to the relevant standards or manufacturer's guidelines for the specific test height.