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भारतीय मानक मसौदा

एक चैनल फिजियोलॉजिकल रिकॉर्डर के लिए विशिष्टता

Draft Indian Standard

Specification for Single Channel Physiological Recorder

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 'Single channel physiological recorder'. These are devices with application-based software that enables the users that enhances their functionality and enables specific cases and data analysis.

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 a single-channel physiological recorder is limited to capturing and monitoring a single physiological parameter or signal at a time. Some common examples of single-channel physiological recorders include electrocardiogram (ECG) recorders, electromyography (EMG) recorders, and electroencephalography (EEG) recorders.

The specific scope of a single-channel physiological recorder depends on the type of signal it is designed to measure.

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 2/Sec 25) : 2018/ IEC 60601-2-25 : 2011	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 25 Electrocardiographs
IS 13450 (Part 1/Sec 2) : 2024	Medical electrical equipment : Part 1 General requirements for basic safety and essential performance, Section 2 Electromagnetic disturbances Requirements and tests (Second Revision)
IS/ISO 13485 : 2016	Medical devices — Part 1: Application of usability engineering to medical devices
IS 17932 (Part 1) : 2023/ ISO 10993-1 : 2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process (ISO 10993-1 : 2018, MOD)
IS/ISO 14971 : 2019	Medical devices - Application of risk management to medical devices First Revision
IS 17922 (Part 1) : 2023/ IEC 62366-1: 2015	Medical Devices Part 1: Application of Usability Engineering
IS/ISO 14971 : 2019 ISO 14971:2019	Medical devices - Application of risk management to medical devices First Revision
IEC 62304: 2006(en)	Medical device software — Software life cycle processes
IS/ISO/IEEE 11073-10101 : 2020	Health Informatics Point-of-Care Medical Device Communication Part 10101 Nomenclature
IS 13450 (Part 2/Sec 26) : 2021/ IEC 80601-	Medical electrical equipment Part 2 Particular requirements for basic safety and essential performance Section 26

2-26 : 201	Electroencephalographs
IS 13450 (Part 2/Sec 40) : 2020/ IEC 60601-2-40 : 2016	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 40 Electromyographs and evoked response equipment

3 TERMS AND DEFINITIONS: -

3.1 Single Channel: Refers to the capability of recording a single physiological signal at a time. A single-channel physiological recorder can capture and record one specific parameter such as ECG, EEG, or EMG.

3.2 Physiological Recorder: A device used to acquire, amplify, filter, and record physiological signals from the body. It typically consists of signal acquisition circuitry, signal conditioning components, and storage capabilities.

3.3 Signal Acquisition: The process of capturing and converting a physiological signal from the body into an electrical form that can be processed and recorded by the physiological recorder. This involves the use of sensors or electrodes placed on the body.

3.4 Signal Conditioning: The manipulation and modification of the acquired physiological signal to improve its quality and make it suitable for further processing and analysis. This may include amplification, filtering, noise reduction, and baseline adjustment.

3.5 Sampling Rate: The rate at which the physiological signal is sampled and recorded by the physiological recorder. It is measured in samples per second (Hz) and determines the temporal resolution of the recorded data.

3.6 Digital Conversion: The process of converting the analog physiological signal into a digital format that can be stored, analyzed, and manipulated by digital systems. Analog-to-digital converters (ADCs) are used to perform this conversion.

3.7 Storage Capacity: The amount of memory or storage available in the physiological recorder to store the recorded data. It is measured in bytes or megabytes and determines the maximum duration or amount of data that can be recorded.

3.8 Data Compression: The technique used to reduce the size of recorded data without significant loss of information. It helps optimize storage utilization and may employ algorithms such as lossless or loss compression.

3.9 Data Transfer: The process of transferring the recorded data from the physiological recorder to an external device or system for further analysis, storage, or visualization. This can be achieved through wired connections (e.g., USB) or wireless communication protocols (e.g., Bluetooth, Wi-Fi).

3.10 User Interface: The interface provided by the physiological recorder allows users to interact with the device. It may include buttons, touchscreen displays, or other input/output mechanisms to control recording sessions, adjust settings, and view real-time or recorded data.

3.11 Calibration: The process of adjusting and verifying the accuracy of the physiological recorder and its measurements. Calibration ensures that the recorded data corresponds to the actual physiological values and may involve comparing the recorder's readings to known standards.

3.12 Electrode/Sensor: A device used to detect and acquire the physiological signal from the body. Electrodes are typically used for electrical signals like ECG or EEG, while sensors may be used for other types of signals such as temperature, pulse, or oxygen saturation.

4 GENERAL REQUIREMENT

The general requirements of a single-channel physiological recorder can vary depending on the specific physiological signal being recorded and the intended use of the device.

4.1 Sampling Rate: The recorder should be able to sample the physiological signal at a sufficiently high rate to capture relevant details and ensure an accurate representation of the signal. As per Clause 201.14 of ISO 60601-2-47, the sampling rate should be chosen based on the frequency range and characteristics of the physiological signal being recorded.

4.2 Data Storage: The recorder should have sufficient memory or storage capacity to store the recorded data. The storage medium can be an internal memory, removable storage, or both.

4.3 Power Source: The recorder should have a reliable power source that can sustain continuous operation for the desired recording duration as per Clause 7of IEC 60601-1. This can be achieved through built-in rechargeable batteries or an external power supply. The power source should provide adequate voltage and current to ensure proper functionality.

4.4 User Interface: By the reference of IEC 62366-1, Clause 7, the recorder should have a user-friendly interface that allows for easy operation and control. This may include buttons, knobs, or a touchscreen display for adjusting settings, starting/stopping recordings and reviewing recorded data.

4.5 Size and Portability: Depending on the intended use, the recorder should be compact and portable, allowing for easy mobility and use in various environments. This is particularly important for applications that require ambulatory or remote monitoring.

4.6 Compliance and Safety: The recorder should meet relevant industry standards and safety regulations to ensure accuracy, reliability, and user safety. Compliance with standards such as ISO 13485 . regulations may be necessary, especially if the device is intended for medical or clinical use.

5 FUNCTIONAL REQUIREMENT

5.1 Time Synchronization For precise analysis and correlation with other physiological signals, the recorder should have the capability to synchronize its internal clock with a common time reference, such as network time or GPS.

5.2 Storage Capacity: In the ISO/IEEE 11073-10101, it is explained that the recorder should have sufficient storage capacity to store the recorded data for a desired duration. The capacity requirement will depend on factors such as the sampling rate, bit depth, and duration of the recording sessions.

5.3 Data Security: To ensure the security and integrity of the recorded data, the recorder may incorporate measures such as encryption, access control mechanisms, and secure data transfer protocols to protect sensitive physiological information.

5.4 Calibration and Configuration: The recorder should provide options for calibration and configuration to adjust recording parameters according to specific requirements or user preferences. Calibrations with standards such as IEC 60601-2-40 produces and form settings for signal gain, filtering, and other parameters (take this standard as a reference as it is related to ECG, EEG, or EMG machines.

5.5 Data Transfer: The recorder should provide means for transferring the recorded data to an external device. Or system for further analysis or storage. This could be accomplished through wired connections or wireless communication protocols as per IEEE 11073-10101; it could have relevant information regarding data communication for physiological signal recorders.

6 DEVICE BODY

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

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

6.2 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).

6.3 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.

6.4 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.

6.5 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.

6.6 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.

6.7 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.

6.8 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.

6.9 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.

7 APPLICATION BASED SOFTWARE

7.1 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.

7.2 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.

7.3 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.

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

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

7.6 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.

8 ACCESSORIES

Single-channel physiological recorders can be complemented by various accessories to enhance their functionality and usability. Here are some common accessories used with single-channel physiological recorders:

8.1 Electrodes: Electrodes are essential accessories for recording physiological signals, such as ECG or EEG. They are placed on the patient's skin to ensure proper signal transmission from the body to the recorder.

8.2 Lead Wires: Lead wires are used to connect the electrodes to the single-channel physiological recorder. These wires transmit the electrical signals from the electrodes to the recorder for processing and analysis. They come in different lengths and connector types to ensure compatibility with the recorder's input ports.

8.3 Adhesive Patches or Straps: Adhesive patches or straps are used to secure the electrodes in place during recording. These accessories ensure that the electrodes remain in contact with the skin, providing a stable signal transmission and minimizing movement artifacts.

8.4 Battery Packs or Power Adapters: Single-channel physiological recorders may require batteries for portable operation. Battery packs or power adapters provide a reliable power source to ensure continuous recording without interruptions.

8.5 Storage and Carrying Cases: Storage and carrying cases are useful accessories to protect the single-channel physiological recorder and its components during transportation or storage. They provide a safe and organized way to store the device, cables, electrodes, and other accessories when not in use.

8.6 Data Transfer Cables or Wireless Connectivity: Depending on the recorder's capabilities, data transfer cables or wireless connectivity options may be available. These accessories allow for the seamless transfer of recorded physiological data from the recorder to a computer or other devices for further analysis or storage.

8.7 Calibration Tools: Calibration tools are used to ensure the accuracy and precision of the single-channel physiological recorder. They allow for periodic calibration of the device to maintain reliable and consistent measurements as per ISO/IEC 17025, the standard may not have a specific clause that directly addresses the calibration of a particular type of medical device but we can refer.

9 TEST

9.1 Functional Testing: This involves testing the basic functions of the recorder, such as power on/off, starting/stopping recording, adjusting settings (e.g., gain, filtering), and displaying real-time physiological data as per IEC 60601-1, Clause 15, also all the references mentioned ie. ECG, EEG ,EMG Machine (by the reference from IEC 60601-2-25, IEC 60601-2-26, IEC 60601-2-40.

9.1.1 Setup and Configuration (includes connecting the appropriate sensor or electrode to the recording device and ensuring that it is correctly positioned on the subject's body to capture the desired physiological signal).

9.1.2 Calibration and Baseline (perform any necessary calibrations to ensure that the recorded signal aligns accurately).

9.2 Signal Quality Testing: Clause 9.2 of IEC 60601-1 addresses "Measurement of output (signals) and signal quality," and it outlines the requirements for verifying the accuracy and fidelity of recorded physiological signals in medical electrical equipment, including single-channel physiological recorders like ECG machines.

9.2.1 Setup and Configuration

9.2.2 Baseline Signal Recording (record a baseline signal under normal physiological conditions)

9.2.3 Signal Calibration

9.2.4 Signal Accuracy Test

9.3 Calibration Testing: Clause 9.3 of IEC 60601-1 addresses "Calibration of Measuring Functions." This clause outlines the requirements for verifying and calibrating the measuring functions of medical electrical equipment, including single-channel physiological recorders like ECG machines.

9.4 Accuracy and Precision Testing: As per Clause 201.14 of IEC 60601-2-27, this test evaluates the recorder's accuracy and precision in measuring physiological parameters. Accuracy and precision testing help determine the device's measurement error and its ability to provide consistent and reliable measurements.

9.5 Performance Testing: As per IEC 60601-1, Clause 11, Performance testing involves evaluating the recorder's performance under different operating conditions. This may include assessing factors such as sampling rate, resolution, dynamic range, response time, data storage capacity, and battery life.

9.6 Compatibility Testing: Compatibility testing verifies the recorder's compatibility with other devices or systems it needs to interface with as per IEC 60601-1, the clause that pertains to Compatibility Testing is clause 9.6.

9.6.1 Identify Interface Requirements (Determine all the devices or systems the recorder needs to interface with which include sensors, electrodes, communication networks, data storage devices, or other medical devices.

9.6.2 Create Test Setup

9.6.3 Define Test Cases

9.6.4 Execute Test Cases

9.6.5 Record Test Results

9.7 Usability Testing: Usability testing assesses the recorder's user-friendliness and ease of use. It involves evaluating the device's interface, controls, menu navigation, and overall user experience (Reference IEC 62366-1, Clause 7. Usability testing helps identify any issues or improvements related to the device's user interface design and user interaction.

10 MARKING

10.1 Each portable smart physiological recorder 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, and

e) Unique Device Identification / serial number

11 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.

12 PACKING

The packaging of a single-channel physiological recorder typically includes materials and design elements that protect the device during transportation, storage, and display. Here are some common aspects of the packaging for a single-channel physiological recorder:

12.1 Outer Box or Carton: The device is typically packaged in an outer box or carton, which provides structural integrity and protects the recorder from physical damage. The box is usually made of sturdy cardboard or other durable materials.

12.2 Inner Protective Cushioning: Inside the outer box, there is often protective cushioning material, such as foam inserts or molded plastic trays, to securely hold and protect the recorder.

12.3 Accessories Compartment: The packaging may have a designated compartment or section to hold the accompanying accessories, such as electrodes, lead wires, batteries, user manuals, and calibration tools. This ensures that all the necessary components are organized and readily available to the user.

12.4 Instruction Manual and Documentation: The packaging includes an instruction manual and other relevant documentation, such as warranty information, safety instructions, and regulatory compliance certificates. These documents provide guidance on using the device and offer essential information for the user as per ISO13485.

12.5 Branding and Labelling: The packaging often features the brand logo, product name, and model number for easy identification. Additional labeling may include product specifications, serial numbers, and barcode/QR codes for inventory management and traceability purposes.

12.6 Protective Wrapping: The single-channel physiological recorder is typically wrapped in a protective material, such as plastic shrink-wrap or a static-free bag, to guard against dust, moisture, and electrostatic discharge.