IS/IEC 80601-2-49: 2018 Medical Electrical Equipment
Part 2 Particular Requirements for Basic
Safety and Essential Performance
Section 49 Multifunction patient monitors

IS/IEC 80601-2-49: 2018 is the Indian standard for Medical Electrical Equipment, specifically focusing on Particular Requirements for Basic Safety and Essential Performance of Multifunction Patient Monitors. This standard provides detailed guidelines to ensure the safety, performance, and reliability of multifunction patient monitors used in healthcare settings.

Multifunction Patient Monitor is defined as modular or pre-configured **ME Equipment or Medical Electrical Systems** whose primary intended function is monitoring of a single Patient, has more than one **Physiological Monitoring Unit**, either displays that information or distributes the information for remote display, and either includes an Alarm System or is a component of a Distributed Alarm System **(Cl 201.3.201).**
This standard applies to multifunction patient monitors used for continuous monitoring and assessment of patient physiological parameters, such as heart rate, blood pressure, oxygen saturation (SpO2), temperature, and other vital signs. Major changes are in Clause 208 because many of the former requirements are now addressed by IEC 60601-1-8. **Essential Performance Requirements** for Multifunction Patient Monitors are addressed in subclauses listed in **Table 201.101**.
Consumers (such as healthcare professionals, hospital administrators, and medical device buyers) expect several key quality parameters as mentioned below in multifunction patient monitor equipment to ensure reliable performance, ease of use, and patient safety.
Data Display: The monitor's display should clearly show critical patient data, with options to prioritize or highlight important parameters. This is addressed as per **201.15.101 and 206.101 c)** of the standard.
Alarm system: The system must have effective alarm mechanisms that promptly alert healthcare staff when patient conditions reach predefined critical thresholds. Adjustable alarm limits for different parameters to notify healthcare staff when a parameter goes outside the preset range **(addressed in 201.12.3, 206.101 and 208).**
Data Communication and Data logging: The ME system must be capable of safely transmitting patient data to other healthcare systems or networks for further analysis or record-keeping. The ability to store patient data for later analysis, trend monitoring, and medical record keeping is important (**201.11.8)**.
Protection against Electrical Hazards: Ensures that the monitors are designed and constructed to prevent any electrical hazards, such as electric shock, short circuits, or fire risks, to the patient or healthcare providers (**201.8)**.
Protection against Mechanical Hazards: The equipment must be designed to prevent physical injuries, including sharp edges, excessive heat, or breakage that could result in harm (**201.9)**.
Protection against unwanted and excessive radiation, temperature and other Hazards: The monitor must be capable of functioning safely in various environmental conditions, such as temperature, humidity and electromagnetic interference (**201.10, 201.11 and 201.17)**.
Risk Management: A risk management process must be implemented to identify and mitigate potential hazards associated with the use of the device (201.4.5).
Marking and Labelling: The equipment must include clear and comprehensive labelling that provides important information such as operating instructions, safety warnings, technical specifications, and the manufacturer's details. (201.7.2, 201.7.9.2.9)

IS/IEC 80601-2-49:2018 sets the standards for the safety and performance of multifunction patient monitors, ensuring they are reliable, accurate, and safe for patient use. It addresses a broad range of safety concerns, including electrical, mechanical, and environmental hazards, while also focusing on the essential performance aspects like accuracy, alarms, and user interface. Compliance with this standard helps ensure that patient monitors are both effective and safe in clinical environments.