

IS 13450 (Part 2/Sec 25): 2018 – Electrocardiographs (ECGs) Safety and Performance Standards

The IS 13450 (Part 2/Sec 25): 2018 standard, aligned with IEC 60601-2-25: 2011, supersedes IS 8048: 1985 and focuses on the safety and performance of electrocardiographs (ECGs). It defines specific requirements for defibrillation protection, mechanical safety, and control accuracy. The standard provides guidelines for testing conditions, user instructions, and device identification to ensure safe and accurate ECG operations in medical settings.

Key aspects of the standard include precise requirements for ECG recording capabilities, patient identification, and electromagnetic compatibility. Emphasis is placed on the accuracy of ECG measurements, including noise levels and frequency response, ensuring reliable diagnostics. The standard also outlines procedures for testing ECG analysis algorithms and the calibration of ECG devices to maintain performance consistency.

For manufacturers and users, compliance with IS 13450 is crucial to ensure the safe and effective operation of ECG equipment. The standard stresses the importance of protection against defibrillation to prevent damage to devices and maintains diagnostic accuracy.

Key Insights:

- Ensures safety and accuracy for ECG equipment used in medical diagnostics.
- Provides protection against defibrillation and outlines performance testing procedures.
- Focuses on measurement accuracy, calibration, and reliability of ECG analysis algorithms.
- Mandatory compliance for manufacturers to ensure safe and effective ECG operation.

This standard is vital for the proper functioning of ECGs, ensuring their reliability and safety in healthcare settings.