IEC 60601 ECG Electrode Tester

Model KP-ECG100E | YY/T 0196-2005 & ANSI/AAMI EC12 Compliant

Standards: YY/T 0196-2005, ANSI/AAMI EC12, IEC 60601-2-25, IEC 60601-2-27

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Product Overview

The KingPo KP-ECG100E IEC 60601 ECG Electrode Tester is a compact benchtop electrical performance tester specifically designed for evaluating disposable ECG electrodes used with electrocardiographs and ECG monitoring equipment. It performs five key electrical tests in accordance with YY/T 0196-2005 and ANSI/AAMI EC12 standards, supporting routine quality control, batch verification, incoming inspection, and technical documentation for manufacturers and testing laboratories.

The system features one-button automated operation, a 7-inch capacitive touchscreen interface, automatic data calculation, and report generation. Its compact design (480 × 460 × 200 mm, approx. 5 kg) makes it ideal for laboratory and production environments. The tester integrates built-in standard test circuits, reducing manual wiring and ensuring consistent, repeatable measurements for critical electrode parameters such as impedance, offset voltage, noise, defibrillation recovery, and bias current tolerance.

Key Advantages

- **Automated One-Button Testing with Built-in Programs**
  Engineering: Pre-configured standard test programs for all five electrical performance tests with fully automated execution and minimal operator intervention.
  Benefit: Significantly improves testing efficiency, reduces human error, and ensures consistent results across operators and batches, ideal for high-volume quality control.
- **Comprehensive Five-Test Suite for Electrode Performance**
  Engineering: Integrates AC impedance, DC offset voltage, combined offset instability & internal noise, defibrillation overload recovery, and bias current tolerance tests in a single instrument with precise current sources and high-impedance measurement circuits.
  Benefit: Provides complete electrical characterization of disposable ECG electrodes per international standards, enabling thorough quality assurance and regulatory compliance documentation.
- **High-Precision Measurement with Real-Time Data & Reports**
  Engineering: High-accuracy force/current sources, wide measurement ranges (e.g., 0–10 kΩ impedance, ±400 mV offset), automatic peak capture, and built-in report generation with calculated results.
  Benefit: Delivers traceable, auditable data and professional reports instantly, streamlining quality documentation and reducing post-test analysis time.
- **User-Friendly 7-Inch Touchscreen Interface**
  Engineering: Intuitive 7-inch capacitive touchscreen (800 × 480) for parameter setting, real-time result display, and one-touch operation of standard test sequences.
  Benefit: Simplifies operation for laboratory technicians, minimizes training requirements, and allows quick parameter adjustments for different electrode types or custom test needs.
- **Compact Benchtop Design with Built-in Safety**
  Engineering: Space-saving dimensions (480 × 460 × 200 mm, ~5 kg), robust construction, and integrated test circuits that reduce external wiring and potential errors.
  Benefit: Fits easily on standard lab benches, is portable for multi-site use, and enhances safety and reliability by minimizing manual connections during high-voltage defibrillation recovery tests.

Technical Specifications

3.1 General System Parameters

Parameter	Specification	Remark / Notes
Model	KP-ECG100E	IEC 60601 ECG Electrode Tester
Display	7-inch capacitive touchscreen, 800 × 480	Parameter setting and real-time result display
Operation Mode	One-button automated operation	Built-in standard test programs
Report Function	Automatic test data calculation and report	For quality documentation and traceability

	generation	
Power Supply	AC 220 V ±10%, 50/60 Hz	Other voltages available upon request
Dimensions (W × D × H)	480 × 460 × 200 mm	Compact benchtop design
Weight	Approx. 5 kg	Portable for laboratory use
Test Object	Disposable ECG electrodes	For electrical performance evaluation

3.2 Detailed Electrical Test Parameters

Test Parameter	Specification	Measurement Details
AC Impedance	100 µA sine-wave AC current at 10 Hz	Range: 0–10 kΩ
DC Offset Voltage	DC input impedance ≥10 MΩ; 60–90 s measurement	Range: -400 mV to +400 mV
Combined Offset Instability & Internal Noise	Frequency response: 0.01 Hz–1 kHz; input impedance ≥10 MΩ; 60–360 s	Range: -5 mV to +5 mV
Defibrillation Overload Recovery	10 µF capacitor, 200 V test source; observations at 5 s, 15 s, 25 s, 35 s	Range: -400 mV to +400 mV
Bias Current Tolerance	200 nA DC current; measurement time ≥8 h	Range: -400 mV to +400 mV

Testing Principle

The KP-ECG100E evaluates the electrical performance of disposable ECG electrodes through five standardized tests based on YY/T 0196-2005 and ANSI/AAMI EC12. These tests assess the electrode's ability to transmit bioelectric signals accurately and reliably under various conditions:

1. **AC Impedance:** Applies a low-level 100 µA, 10 Hz sine-wave current to measure the electrode's impedance (0–10 kΩ), which affects signal quality and noise susceptibility.
2. **DC Offset Voltage:** Measures the inherent DC voltage generated at the electrode-skin interface (-400 mV to +400 mV) over 60–90 seconds with high input impedance (≥10 MΩ).
3. **Combined Offset Instability and Internal Noise:** Evaluates low-frequency drift and noise (-5 mV to +5 mV) using a wide frequency response (0.01 Hz–1 kHz) over extended periods (60–360 s).
4. **Defibrillation Overload Recovery:** Simulates defibrillator discharge (200 V through 10 µF capacitor) and monitors voltage recovery at multiple time points (5 s, 15 s, 25 s, 35 s) to ensure rapid return to baseline.
5. **Bias Current Tolerance:** Applies a small DC bias current (200 nA) for extended periods (≥8 hours) to assess long-term stability and polarization effects (-400 mV to +400 mV).

All tests use automated sequencing with built-in circuits for consistent application of currents/voltages and precise measurement, ensuring compliance with electrode-specific performance requirements for ECG applications.

Typical Applications

- Disposable ECG electrode manufacturers — Production quality control, batch verification, and outgoing product inspection
- Medical device quality inspection institutions — Incoming inspection of electrode components and conductive materials
- Third-party testing laboratories — Performance verification and technical documentation for regulatory submissions
- R&D teams — Evaluation of new electrode materials, conductive gels, and structural designs
- Hospitals and clinical engineering departments — Verification of electrode performance for ECG monitoring equipment

Compliance & Manufacturer

This equipment is designed for electrical performance testing of disposable ECG electrodes in accordance with YY/T 0196-2005 and ANSI/AAMI EC12. It supports applications related to IEC 60601-2-25 and IEC 60601-2-

27 for ECG equipment. The tester focuses specifically on electrode electrical characteristics and is not a full medical electrical safety tester, ECG simulator, or biological/adhesive performance evaluator.

Factory verification of test circuits, measurement accuracy, and safety functions is performed before delivery. Regular calibration of the instrument is recommended for continued accuracy and traceability. Custom electrode configurations and test report formats can be provided upon request.

Manufactured under ISO 9001, ISO 14001, and ISO 45001 quality management systems by KingPo Technology Development Limited.

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