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STANDARDS & GUIDANCE BRIEF · INTERNATIONAL · INTERNATIONAL STANDARD

IEC 60601-1

Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

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ISSUED BY	International Electrotechnical Commission (IEC/SC 62A)	PREPARED BY	Conner Davidson
EDITION	Edition 3.2 (2005 + Amendment 1:2012 + Amendment 2:2020)	STATUS CHECKED	October 24, 2026
INDUSTRIES	Medical Devices	ONLINE	qesisbest.com/standard-iec-60601-1.html

CURRENT EDITION Edition 3.2 is current. A fourth edition is being drafted in hazard-based fragments; as of July 2026 it was at committee-draft stage, with publication targeted for around 2031. **Next:** Watch the fourth-edition fragments; nothing in them applies until published and recognized.

What It Covers

Basic safety and essential performance of medical electrical equipment and systems: electrical, mechanical, thermal, radiation and fire hazards, programmable electrical systems, and the risk management that ties them together. Collateral standards (60601-1-x) and particular standards (60601-2-x) add to it.

Who It Applies To

Makers of powered medical devices, from patient monitors to infusion pumps. Testing is normally done by an accredited laboratory, often under the IECEE CB Scheme.

Key Requirements

- Essential performance identified through ISO 14971 risk management, and protected.
- Means of protection for patients and operators, with insulation, creepage, and leakage current limits.
- Programmable electrical medical systems (clause 14) developed under a documented life cycle.
- Collateral standards for EMC (60601-1-2), usability (60601-1-6), alarms (60601-1-8) and home use (60601-1-11).

What an Auditor Asks to See

- The test report and the risk management file it relies on, with matching revisions.
- The list of essential performance and how each item is verified.
- Assessment of any design change made after testing.

Where Systems Fall Short

- Essential performance never defined, so nothing can be shown to protect it.
- A test report for a revision of the device that is no longer built.

How QES helps. Linking the test report, the risk file, and design changes so each change is assessed against what was tested. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. Eisner Safety — IEC 60601-1 4th edition status (July 2026) — eisnersafety.com/2026/07/28/iec-60601-1-4th-edition-in-one-place; Intertek — Overview of IEC 60601-1 — www.intertek.com/medical/regulatory-requirements/iec-60601-1.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.