

IEC 60601-1: Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance

1. Purpose

IEC 60601-1 establishes general safety and essential performance requirements for **all medical electrical (ME) equipment**. Objectives:

- Protect patients, operators, and caregivers from **electrical, mechanical, thermal, and radiation hazards**.
 - Ensure devices maintain **essential performance** under **normal and fault conditions**.
 - Provide a structured **risk management framework** for design, testing, and maintenance.
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2. Scope

Covers all **medical electrical equipment and systems**, including:

- Devices in hospitals, clinics, and home healthcare.
- Equipment contacting patients directly (applied parts) or indirectly.
- Hazards: electrical, mechanical, thermal, fire, radiation, and environmental.

Forms the foundation for **collateral (IEC 60601-1-x)** and **particular (IEC 60601-2-x)** standards.

3. Classification of Medical Electrical Equipment

3.1 Applied Part Types (B, BF, CF) with Leakage, Insulation, and Redundancy

Type	Description	Patient Leakage Current	Operator Leakage Current	Enclosure / Earth Leakage	Insulation / Isolation	Redundancy	Typical Devices
B	General applied part; no cardiac contact	AC \leq 1000 μ A / DC \leq 500 μ A	\leq 300 μ A	\leq 500 μ A	Basic insulation; may rely on protective earth	Not required	Thermometers, body ECG leads, stethoscopes
BF	Functional applied part; may contact heart or sensitive areas	AC \leq 500 μ A / DC \leq 100 μ A	\leq 300 μ A	\leq 500 μ A	Reinforced insulation; floating from earth	Optional depending on device	ECG electrodes, anesthesia equipment, ultrasound probes
CF	Cardiac applied part; direct contact with heart or intravascular	AC \leq 100 μ A / DC \leq 10 μ A	\leq 100 μ A	\leq 500 μ A	Double/reinforced insulation; fully floating	Mandatory (dual insulation, fault detection)	Pacemaker leads, defibrillator paddles, cardiac catheters

Notes:

- **Leakage Current:** Measured under **normal** and **single fault conditions**.
 - **DC Limits:** Lower than AC to protect heart and sensitive tissues.
 - **Floating Design:** BF and CF are isolated from earth to reduce shock risk.
 - **Redundancy (CF):** Dual barriers, secondary fault detection, or emergency shutdown ensures cardiac safety.
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3.2 Equipment Categories

Category	Description
Class I	Equipment with protective earth
Class II	Double or reinforced insulation; no reliance on earth
Class III	Powered by safety extra-low voltage (SELV)

3.3 Mode of Operation (C, I, S) – Values

Mode	Description	Typical Duration / Value	Thermal Test Notes
Continuous (C)	Operates continuously	≥ 60 minutes	Device must operate safely without overheating under continuous operation.
Intermittent (I)	Operates at intervals	Example: 30 min ON / 30 min OFF	Thermal tests simulate normal operating cycles; ensure safe temperature rise during ON periods.
Short-term (S)	Brief operation	$\leq 5\text{--}10$ minutes (manufacturer specified)	Thermal tests verify short-use operation does not cause hazard.

4. Essential Safety Requirements

4.1 Electrical Safety (Values Included)

- **Patient Leakage Currents (μA):** B: AC ≤ 1000 / DC ≤ 500 , BF: AC ≤ 500 / DC ≤ 100 , CF: AC ≤ 100 / DC ≤ 10
- **Operator Leakage Currents (μA):** B/BF ≤ 300 , CF ≤ 100
- **Enclosure / Earth Leakage (μA):** ≤ 500 for all types
- **Grounding / Floating:**
 - Class I: protective earth connection

- BF/CF: floating design
- **SELV & Battery Devices:** Leakage $\leq 50 \mu\text{A}$ for critical devices; reinforced insulation required
- **Testing:** Must verify under **normal** and **single fault conditions**

4.2 Mechanical Safety

- Stability against tipping
- No sharp edges or pinch points
- Resistance to mechanical stress during normal use, transport, or handling

4.3 Thermal Safety

- Max surface temperature:
 - Accessible parts: $\sim 41\text{--}43^\circ\text{C}$
 - Applied parts contacting patient: $\sim 41^\circ\text{C}$
- Internal components withstand over-temperature conditions without hazard

4.4 Fire Safety

- Flame-retardant materials
- Testing under short-circuit or overload

4.5 Radiation Safety

- Limits exposure from lasers, X-rays, or UV devices
- Shielding and warning labeling mandatory

4.6 Environmental Considerations

- Operation under varying temperature, humidity, vibration, and altitude
- Protection against electromagnetic interference (EMC)

4.7 Essential Performance

- Critical functions must operate safely under **normal and fault conditions**
 - Examples: Ventilator continues minimal ventilation in single fault; ECG monitoring remains functional with alarm active
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5. Risk Management

- Integrates **ISO 14971** principles
 - Assessment covers: electrical, mechanical, thermal, radiation hazards; use errors; foreseeable misuse
 - Protective measures and mitigations must be tested and validated
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6. Documentation and Marking

- Instruction manuals: clear operation, maintenance
 - Warning signs: electrical hazards, laser/radiation, high temperatures
 - Technical documentation: test results, risk assessment, design verification, software validation
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7. Testing and Verification

Test Type	Examples
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Electrical	Dielectric strength, leakage currents (patient, earth, enclosure)
Mechanical	Drop, tip, vibration, stability tests
Thermal	Surface and internal temperature rise
Functional	Verify essential performance during and after fault conditions

8. Related Collateral Standards (IEC 60601-1-x)

Standard	Focus Area
60601-1-2	Electromagnetic compatibility (EMC)
60601-1-3	Radiation protection in diagnostic devices
60601-1-6	Usability / Human factors engineering
60601-1-8	Alarm systems
60601-1-11	Home healthcare devices
60601-1-12	Transportable equipment (ambulances, field hospitals)

9. Particular Standards (IEC 60601-2-x)

Standard	Device Type
60601-2-2	High-frequency surgical equipment
60601-2-27	Electrocardiographs (ECG)
60601-2-33	Magnetic Resonance Imaging (MRI)
60601-2-40	Cardiac implantable devices
60601-2-52	Sleep apnea devices

 **This version now includes:**

- AC and DC leakage currents
- Applied part types B, BF, CF
- Insulation, floating design, and redundancy requirements
- Mode of operation numeric values
- Complete safety requirements, risk management, testing, documentation, collateral, and particular standards