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DEPARTMENT OF BIOMEDICAL ENGINEERING

VI Semester

24BM501 BIOMEDICAL DEVICE DESIGN

5.3 Biomedical Device Safety Standards

➢ Introduction

Standards are documented, consensus-based technical requirements that provide rules, guidelines or characteristics for products and processes. Compliance with **recognised (harmonised) standards** is the practical way for a manufacturer to demonstrate that a device meets the regulatory "essential principles of safety and performance". Standards are produced by bodies such as the **IEC (International Electrotechnical Commission)**, **ISO**, **CENELEC/ BIS / ASTM / AAMI** and are accepted by FDA (Recognized Consensus Standards), the EU (harmonised standards) and CDSCO (BIS / ISO / IEC standards).

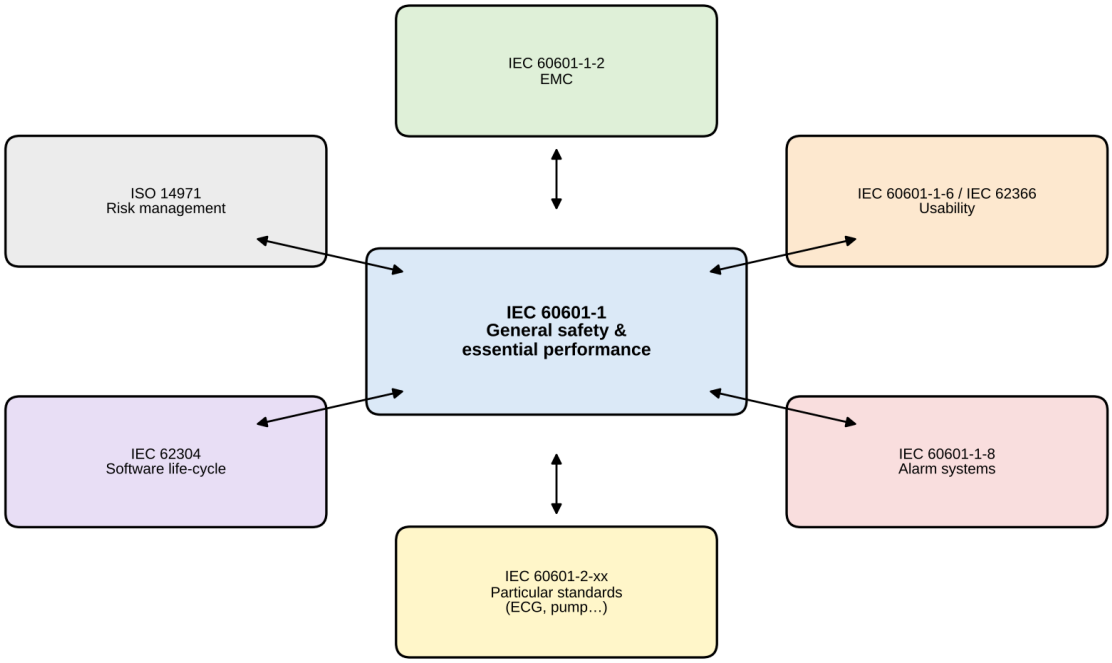


Fig. 5.12 Family of key safety standards around IEC 60601-1

➢ Electrical Safety Fundamentals

The human body is an electrical conductor. The physiological effect of a current depends on its magnitude, frequency, path and duration. In hospitals the patient is often connected directly to

equipment through electrodes or catheters, which bypass the protective skin resistance (about 1–100 kΩ dry, only a few hundred ohms when wet or punctured). Two types of shock are distinguished:

Type	Description	Current levels and effect
Macroshock	Current flows through the intact skin, over a large area of the body	1 mA – perception; 10–20 mA – "let-go" limit, muscle tetany; 75–400 mA – ventricular fibrillation; > 1 A – burns, cardiac arrest
Microshock	Current enters directly into the heart through a catheter, pacing wire or electrode	About **100 µA** can cause ventricular fibrillation – hence the extremely small leakage limits for cardiac devices

➢ IEC 60601-1 – General Requirements for Basic Safety and Essential Performance

IEC 60601-1 is the cornerstone standard for **medical electrical (ME) equipment and ME systems**. The third edition (with amendments) requires a **risk-management process (ISO 14971)** and specifies protection against electrical hazards, mechanical hazards, excessive temperature, fire, radiation, and unsafe outputs. "**Essential performance**" is the performance necessary to avoid unacceptable risk, e.g. the accuracy of the infusion rate or the correct delivery of a defibrillation shock.

Classification of ME equipment

Basis	Classes	Meaning
Protection against electric shock (means of protection)	**Class I**	Basic insulation + protective earth connection of accessible conductive parts (three-pin plug)
	Class II	Double or reinforced insulation; no earth needed (symbol: square within square)
	Internally powered	Battery-operated equipment (also classified if connected to mains)
Degree of protection of applied part	**Type B, BF, CF**	See figure – increasing protection for patient contact
Degree of ingress protection	IP code (IEC 60529)	IP22, IP44, IPX8 etc. for liquids and dust
Mode of operation	Continuous / short-time / intermittent	Determines thermal design

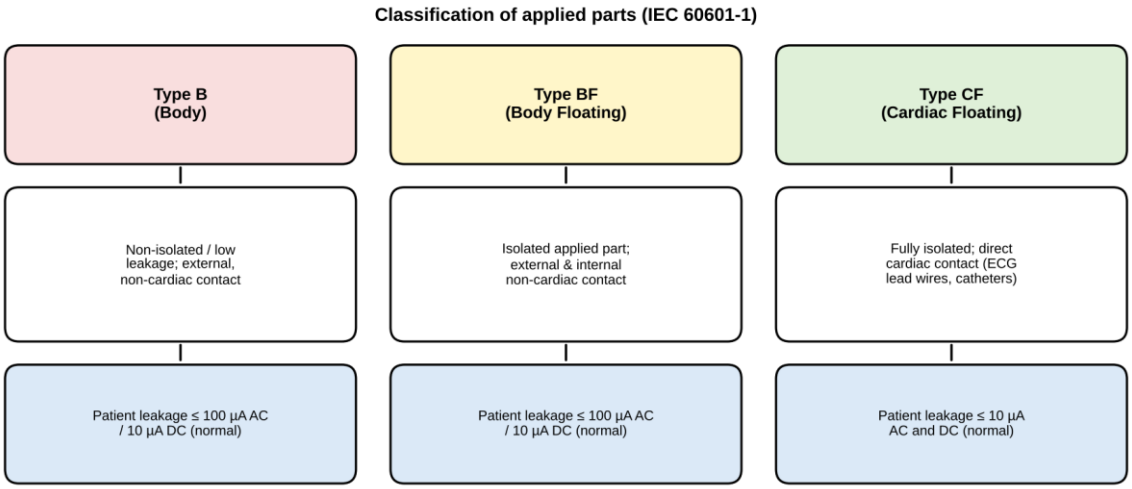


Fig. 5.13 Type B, BF and CF applied parts

Leakage currents

Leakage current is the unwanted current that flows from the equipment to earth, to the enclosure, or through the patient. It is measured in normal condition (NC) and single fault condition (SFC), such as a broken earth wire or an open neutral.

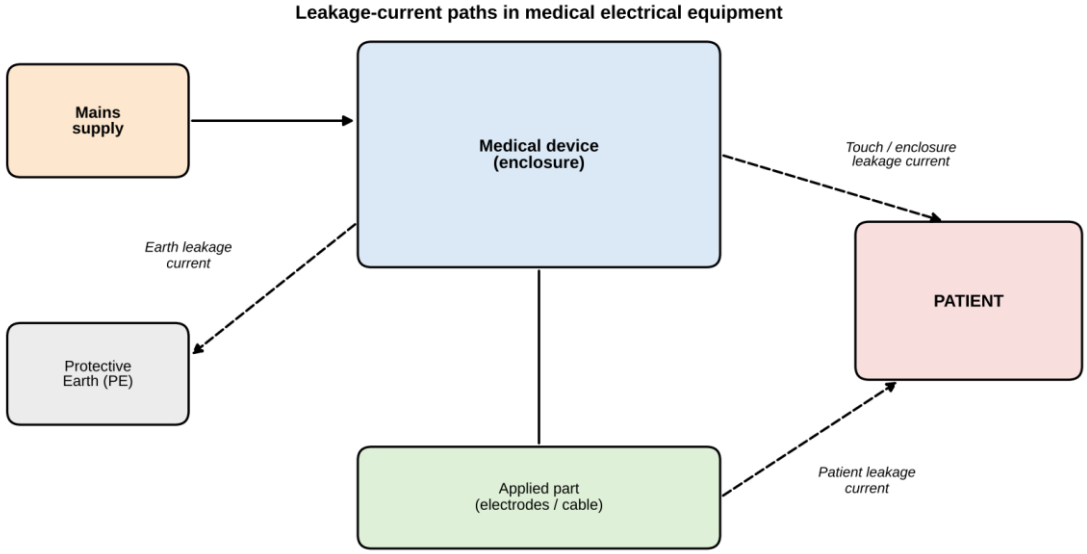


Fig. 5.14 Leakage-current paths in ME equipment

Leakage current	NC	SFC
Earth leakage current	5 mA	10 mA
Touch (enclosure) current	100 µA	500 µA
Patient leakage current – Type B / BF (AC)	100 µA	500 µA
Patient leakage current – Type CF	10 µA	50 µA
Patient auxiliary current – Type CF	10 µA	50 µA

Other requirements of IEC 60601-1

- ✓ **Dielectric strength and creepage / clearance:** insulation must withstand test voltages (e.g. 1.5 kV to 4 kV depending on means of protection); distances prevent flash-over.
- ✓ **Means of Patient Protection (MOPP) and Means of Operator Protection (MOOP):** 2 × MOPP is generally needed for patient-applied parts connected to mains.
- ✓ **Protective earth resistance:** ≤ 0.1 Ω for the test current (25 A or 1.5 × rated current).
- ✓ **Temperature limits** for surfaces touching the skin; **mechanical stability**, strength and moving parts; **fire enclosure** and flammability.
- ✓ **Defibrillation-proof** applied parts withstand 5 kV defibrillator pulses and recover quickly.
- ✓ **Accompanying documents:** instructions for use, technical description, markings and symbols (ISO 15223-1).

➢Collateral and Particular Standards

Standard	Scope
IEC 60601-1-2	Electromagnetic compatibility (EMC): emissions and immunity (ESD ±8 kV contact, radiated RF immunity 3–10 V/m, EFT/burst, surge)
IEC 60601-1-6 / IEC 62366-1	Usability engineering – reduce use errors through formative and summative evaluation
IEC 60601-1-8	Alarm systems – priority (high / medium / low), sounds, delay and visual indicators
IEC 60601-1-11 / 1-12	Equipment for home healthcare and emergency medical services environment
IEC 60601-2-xx (particular)	Product-specific requirements – 2-4 Defibrillators, 2-24 Infusion pumps, 2-25 Electrocardiographs, 2-27 ECG monitoring, 2-47 Ambulatory ECG, 2-49 Multifunction patient monitors etc.
IEC 62304	Medical device **software life-cycle** processes; safety classes A, B, C depending on harm that software failure could cause
IEC 80001-1 / IEC 81001-5-1	Risk management of medical IT-networks; security activities in the product life cycle
IEC 61010-1 / ISO 15189	Safety of laboratory equipment; medical laboratory quality
IS 13450 (BIS)	Indian adoption of IEC 60601-1

➢Biological Safety – ISO 10993

ISO 10993-1 sets out the **biological evaluation** of medical devices within a risk-management process. Tests depend on the **nature of body contact** (surface, external communicating, implant) and **duration** (limited ≤ 24 h, prolonged 24 h–30 d, long-term > 30 d).

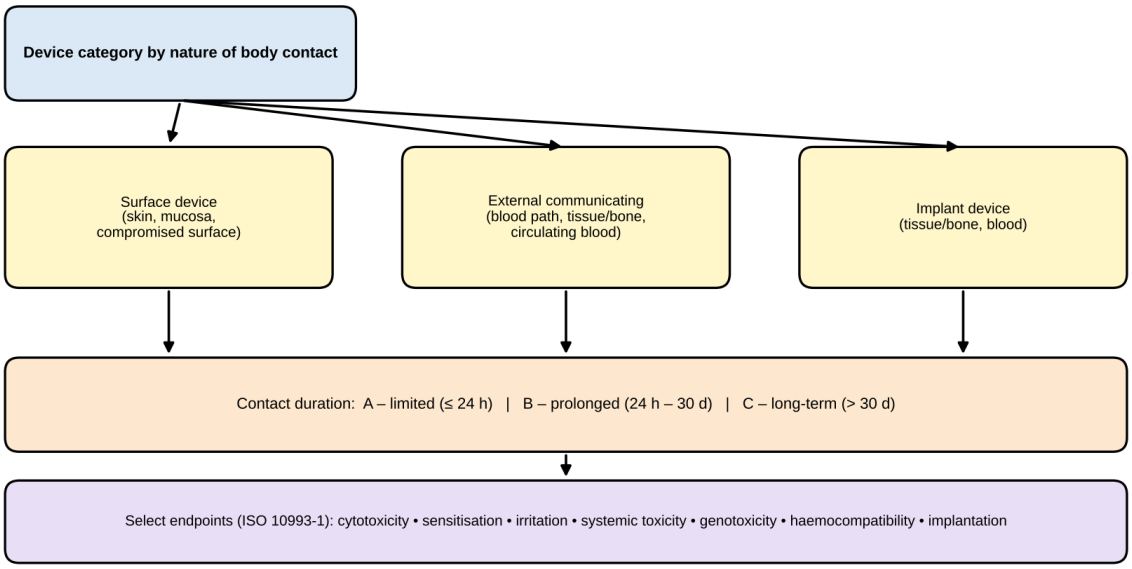


Fig. 5.15 Selection of biological-evaluation endpoints (ISO 10993-1)

Part	Test / topic
ISO 10993-5	In-vitro cytotoxicity
ISO 10993-10	Skin sensitisation and irritation
ISO 10993-11	Systemic toxicity
ISO 10993-4	Interaction with blood (haemolysis, thrombosis)
ISO 10993-3	Genotoxicity, carcinogenicity, reproductive toxicity
ISO 10993-6	Implantation effects
ISO 10993-18 / -17	Chemical characterisation and toxicological risk of extractables

➢Sterilisation, Packaging, Labelling and Others

- ✓ **Sterilisation:** ISO 11135 (ethylene oxide), ISO 11137 (radiation), ISO 17665 (moist heat); sterility assurance level (SAL) of 10^{-6}.
- ✓ **Packaging:** ISO 11607 for terminally sterilised devices; shelf-life and transport testing (ASTM D4169).
- ✓ **Symbols and labelling:** ISO 15223-1 (symbols), ISO 20417 (information supplied by the manufacturer), UDI barcode.
- ✓ **Radiation safety:** IEC 60601-1-3, AERB (Atomic Energy Regulatory Board) approval for X-ray and radiotherapy equipment in India.
- ✓ **Clinical investigation:** ISO 14155 (good clinical practice for devices).

➢Safety Testing and Compliance Process

1. Identify applicable standards (general, collateral, particular) and perform a gap analysis.
2. Carry out **risk analysis** and define essential performance.

3. Design for safety (insulation, earthing, isolation, protection circuits).
4. Pre-compliance testing in the company laboratory.
5. Formal type testing in an **accredited laboratory** (ISO/IEC 17025, NABL) – electrical safety analyser, hipot, EMC chamber.
6. Prepare the test reports and technical file; obtain certification (CB scheme, BIS, CE).
7. **Production-line tests** (earth continuity, leakage, insulation) on every unit, and periodic safety checks in the hospital by the biomedical engineer.