

IEC standards - IEC 60601

Safety Class II

presented by:

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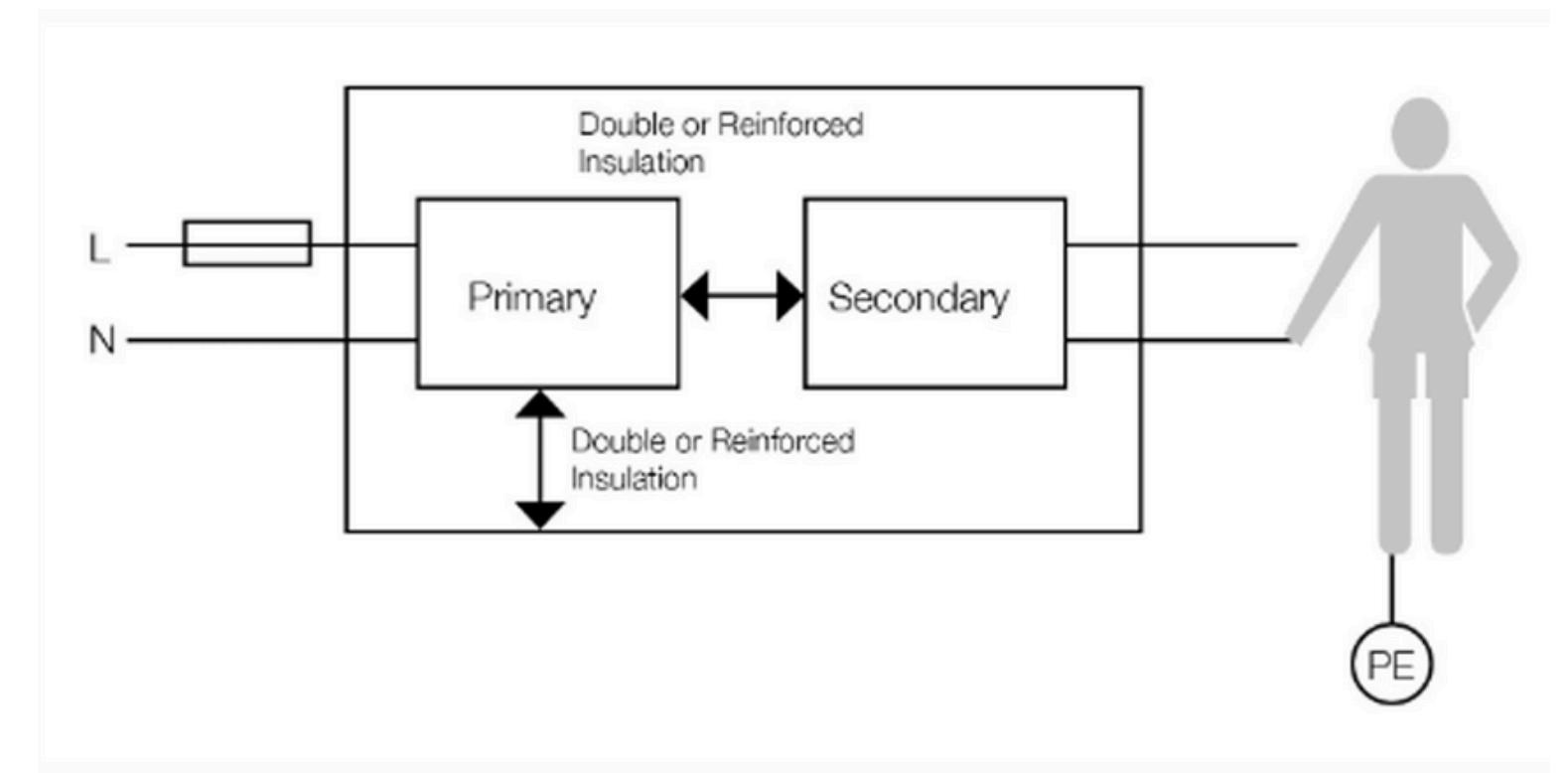


Definition of Class II Equipment

“Electrical equipment in which protection against electric shock does not rely on basic insulation only; additional precautions such as double or reinforced insulation are provided, with no provision for protective earthing.”

Key idea:

Safety is achieved through insulation integrity, not earthing.



Concept of Double Insulation and Reinforced Insulation

<p>Basic insulation:</p> <ul style="list-style-type: none">• Primary barrier between live conductors and accessible parts.• Prevents electric shock in normal operating conditions.	<p>Supplementary insulation:</p> <ul style="list-style-type: none">• Independent second barrier added in case the basic insulation fails.• Maintains safety under single-fault condition.
<p>Double Insulation</p> <ul style="list-style-type: none">• Combination of basic + supplementary insulation.• Provides two Means of Protection (MOP) against electric shock.• Common in plastic-housed portable devices (e.g., monitors, pumps).	<p>Reinforced Insulation</p> <ul style="list-style-type: none">• A single insulation system designed and tested to provide the same protection as double insulation.• Saves space while offering two MOP in one layer (used in transformers, cables, PCB layouts).

Safety Outcome

Even if one barrier breaks down, current cannot reach the patient or metal enclosure. Ensures continuous protection in both normal and fault conditions.

Construction Features of Class II Equipment

1 No Protective-Earth Conductor

- Class II equipment does not rely on an earth connection for safety.
- The design ensures protection through insulation barriers instead.

2 Double / Reinforced Insulation

- All accessible conductive parts are completely isolated from live circuits.
- Even under a single-fault condition, the user or patient cannot touch a live surface.

3 Creepage & Clearance

- Both must comply with IEC 60601-1 Tables 7–12, ensuring adequate spacing to prevent arcing or tracking.

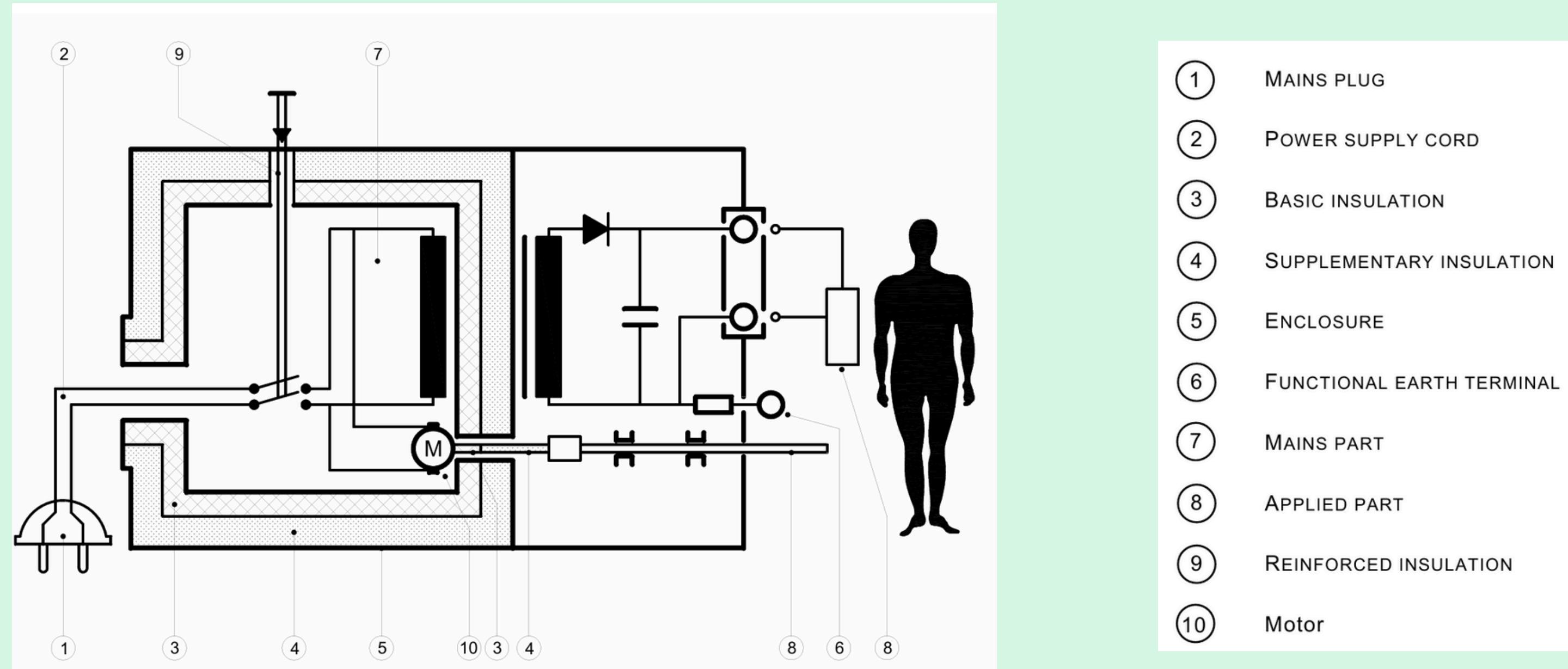
4 Design Integrity

- Layouts and materials selected to maintain insulation over device lifetime, resisting heat, humidity, and mechanical stress.

5 Enclosure Material

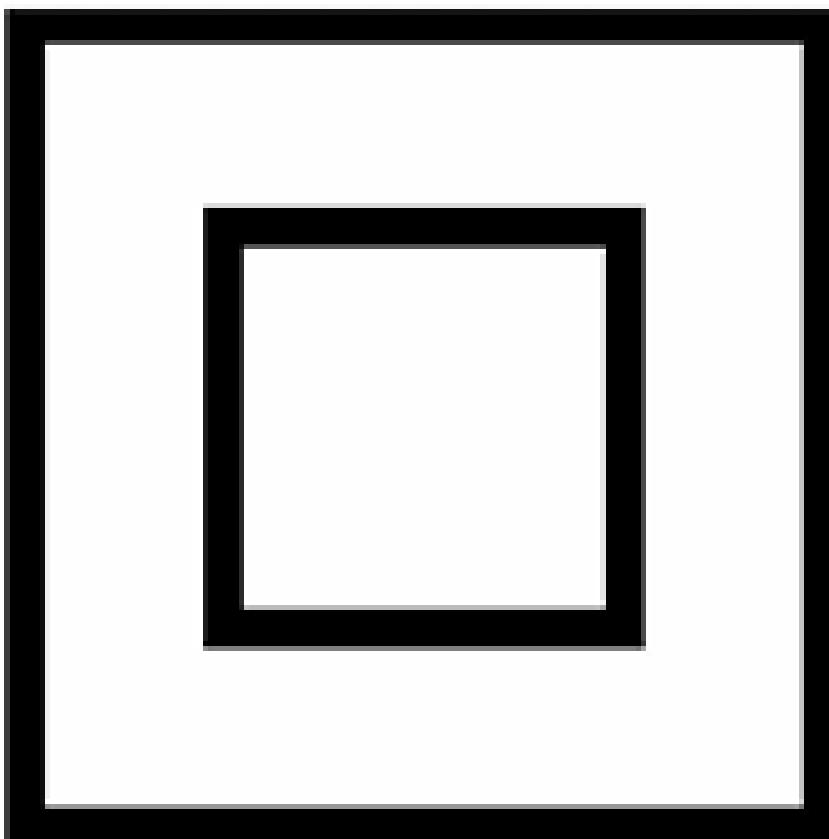
- Plastic or composite housings are preferred, lightweight, durable, and inherently insulating.
- If metal chassis is used, it must be fully encapsulated or double-insulated to prevent accidental contact.

Internal Design Elements of Class II Devices



- Every conductive path from the mains to the patient or operator passes through two independent insulation barriers.
- The functional earth exists only for electromagnetic compatibility, not protection.
- Even in a single-fault condition, no current can reach the patient.

Marking and Identification



The symbol for class II equipment is 2 concentric squares indicating double insulation as shown in the image.

- Must appear on:
 - Equipment enclosure
 - Rating plate and accompanying documents
- Warns users that no earth connection should be made

Testing Requirements for Class II Equipment

Test	Purpose	Typical Standard / Limit
Dielectric Strength Test	Ensures insulation can safely withstand high voltages between live parts and accessible surfaces.	4–5 kV AC for 1 minute
Insulation Resistance Test	Checks insulation material quality and verifies no moisture or contamination.	$\geq 50 \text{ M}\Omega$ at 500 V DC
Leakage Current Test	Confirms that touch and patient currents remain within safe levels during operation.	$\leq 0.1 \text{ mA}$ (touch); $\leq 0.01 \text{ mA}$ (patient)
Creepage & Clearance Verification	Measures spacing between conductive parts to prevent arcing and tracking.	$\geq 8 \text{ mm}$ (mains to accessible parts)
Single Fault Condition Test	Simulates failure of one insulation barrier to confirm continued protection.	No electric shock hazard allowed